Evaluation of Abuse Potential of Synthetic Opioids Using \textit{In Vivo} Pharmacological Studies

Diversion Control Division (DCD)

RFQ: 15DDHQ19Q00000012
I. **Schedule of Services – Section 1**

Unit cost estimates for different pharmacological tests. Advance payments for costs incurred to conduct assays as specified in Table 1 or 2 are not authorized. Vendor will bill DEA on a monthly basis based on actual expenses (i.e., consumables, assay costs). Expense report will include total number of assays completed and the unit cost of each type of assay (e.g., 4 drug discrimination assays x specified unit cost = $). Drug costs will vary depending on amount needed. Any drug amount exceeding 1 g or a cost of $500 will need approval by DEA prior to ordering.

Table 1. Assay costs for Base Year

<table>
<thead>
<tr>
<th>Assay</th>
<th>Unit Cost² ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td></td>
</tr>
<tr>
<td>Drug Discrimination of test drug</td>
<td></td>
</tr>
<tr>
<td>Locomotor Activity</td>
<td></td>
</tr>
<tr>
<td>Drug Cost – Not to Exceed</td>
<td>$500.00</td>
</tr>
<tr>
<td>Incidentals</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL COST ($)</strong></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Assay costs for Option Year I

<table>
<thead>
<tr>
<th>Assay</th>
<th>Unit Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td></td>
</tr>
<tr>
<td>Drug Discrimination of test drug</td>
<td></td>
</tr>
<tr>
<td>Locomotor Activity</td>
<td></td>
</tr>
<tr>
<td>Drug Cost Not to Exceed</td>
<td>$500.00</td>
</tr>
<tr>
<td>Incidentals</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL COST ($)</strong></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Assay costs for Option Year II

<table>
<thead>
<tr>
<th>Assay</th>
<th>Unit Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td></td>
</tr>
<tr>
<td>Drug Discrimination of test drug</td>
<td></td>
</tr>
<tr>
<td>Locomotor Activity</td>
<td></td>
</tr>
</tbody>
</table>

---

1 All studies should include statistically appropriate number of animals per group (at least 8 animals).
2 This can include lab consumables, overhead cost (if applicable), etc.). Please itemize.
### Table 1. Assay costs for Option Year III

<table>
<thead>
<tr>
<th>Assay</th>
<th>Unit Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td></td>
</tr>
<tr>
<td>Drug Discrimination of test drug</td>
<td></td>
</tr>
<tr>
<td>Locomotor Activity</td>
<td></td>
</tr>
</tbody>
</table>

**Drug Cost Not to Exceed** $500.00  
**Incidentals**  
**TOTAL COST ($)**

### Table 1. Assay costs for Option Year IV

<table>
<thead>
<tr>
<th>Assay</th>
<th>Unit Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td></td>
</tr>
<tr>
<td>Drug Discrimination of test drug</td>
<td></td>
</tr>
<tr>
<td>Locomotor Activity</td>
<td></td>
</tr>
</tbody>
</table>

**Drug Cost Not to Exceed** $500.00  
**Incidentals**  
**TOTAL COST ($)**
Statement of Work

Evaluation of Abuse Potential of Synthetic Opioids Using In Vivo Pharmacological Studies

II. Background

The Drug Enforcement Administration’s (DEA) Diversion Control Division (DC), Drug and Chemical Evaluation Section (DPE) is responsible for evaluating drugs and chemicals to determine whether these substances have abuse potential. These evaluations are used by DEA to support its domestic scheduling activities. In order for DEA to determine the abuse potential of drugs and chemicals, pharmacological, medical, epidemiological, and other scientific data for these drugs, when necessary, are needed to initiate the administrative procedure to place these substances under regulatory control according to the guidelines of the Controlled Substances Act (CSA).

Recently, numerous synthetic opioids have emerged within the United States and poses significant risk to the public safety. Numerous synthetic opioids have been identified in samples submitted to federal, state and local forensic laboratories. There have been reports of overdoses, including fatalities, associated with the abuse of these substances. In response to the associated public health threat with the abuse of synthetic opioids, the Administrator of the DEA has placed several synthetic opioids in Schedule I of the CSA under a temporary scheduling order to avoid an imminent hazard to the public safety. Preliminary studies (in vitro) have shown that these substances share pharmacological similarities with other known drugs of abuse. However, detailed information on their biological and pharmacological activities is limited.

III. Brief description of work

For this project, unless otherwise specified by the DEA representative, the vendor shall purchase the reference drugs and all test substances\(^3\) approved by the DEA for testing. The DEA will provide the test substances otherwise not commercially available to the potential vendor for the requested testing. Most of these substances are Schedule I substances. Therefore, the vendor should already have a Schedule I researcher registration with DEA. The vendor shall conduct appropriate preclinical studies on these substances in comparison to appropriate controls and reference standard substances. The reference training drugs shall include, but not be limited to morphine, fentanyl and other drugs as directed by the DEA representative. Each substance shall be assessed for its abuse potential by using appropriate studies in rodents. The vendor will provide the DEA with investigational study results and a description of the methodology used to conduct the investigation in the form of a study report based on the timeline specified in this statement of work (SOW), if not earlier. If a report on all requested studies cannot be provided by the specified timelines, a letter stating the anticipated date of completion of investigations and anticipated delivery of a study report will be required prior to that date. Final study conditions, including but not limited to the number of rodent, or the strain of rodent used, shall be subject to

---

\(^3\) The vendor shall provide adequate information on the purity of the test substance before conducting pharmacological testing. Also, should the drug cost exceed $500, the vendor shall contact DEA representative for approval.
approval of the DEA representative. The vendor shall be able to conduct all studies though not all assays might be requested

IV. Specific requirements

Task 1. Drug source, storage and recordkeeping.

I. Drug Source: Unless otherwise specified by the DEA representative (if it is determined that the test substance is not commercially available), the vendor shall purchase the reference and test drugs. The cost of the drug should not exceed $500. If there is a deviation, DEA representative should be notified immediately. Actual cost of drug can be billed as an invoice. The vendor shall conduct a preclinical evaluation of these test substances (as specified in tasks listed below) in comparison to appropriate controls and the appropriate reference standard. Pharmacological evaluation of each test substance shall be done using appropriate in vivo assays as approved by DEA.

II. Record Keeping: The vendor shall maintain electronic and paper copies of a chronological log of the test substance receipt and evaluation using Microsoft Excel spreadsheet software. When each substance is received, the following shall be recorded:

a) test substance's name;

b) source of the test substance (if it is a purchased or a standard substance);

c) purity of the test substance (all test and reference drug should be ≥ 98%);

d) date testing of the test substance was authorized;

e) date the test substance was received (if provided by the DEA);

f) amount of test substance received (if provided by the DEA);

g) pharmacological studies authorized by DEA for the test substance (e.g. locomotor activity and drug discrimination);

h) date when the study began for each authorized study;

i) amount of test substance used for each authorized study;

j) date when the study was completed for each authorized study;

k) date when the report was sent to the DEA.

This cumulative Receipt and Evaluation log shall be kept up to date and forwarded to the DEA representative upon request.

III. Drug Storage and Schedule I Researcher Registration Requirement: Some of the test substances maybe in Schedule I of the Controlled Substances Act (CSA). Under these circumstances, it is required that the test substances be stored under Schedule I requirements as specified by the CSA and that the vendor evaluating the test substances shall be registered with the DEA as a Schedule I researcher. Some reference drugs are in Schedule II of the CSA. Therefore appropriate DEA license and storage requirement shall be maintained. In cases where test substances are not Schedule I, drug storage

---

4 The vendor shall provide adequate information on the purity of the test substance before conducting pharmacological testing.
requirements shall be maintained under Good Laboratory Practices (GLP) or GLP-like conditions.

Task 2. Protocols of \textit{in vivo} pharmacological studies (locomotor, analgesia, drug discrimination, and other optional studies) in laboratory rodent animals

General protocols that are used for \textit{in vivo} analgesia, drug discrimination, and other optional studies shall be provided by the vendor to the DEA. The protocols shall contain a description of the methodology used to conduct the investigation, a description of the apparatuses that will be used for conducting the studies, maintenance of the animals to be used in the tests, procedures for analysis of the data including proposed statistical methods, and proposed presentations of the data and study results. Specifically, the study protocol should conform to the following standards:

I. A study protocol shall be provided for each individual \textit{in vivo} pharmacological study. For example, one protocol should be provided for analgesia and one protocol for drug discrimination, etc.

II. The study protocols must be specifically written to meet the protocol preferences as listed in this SOW under Tasks 3, 4, 5, and 6.

III. The study protocol should closely follow the format of the materials and methods section that would be submitted for a peer-reviewed journal article. Details including the animal strain, number of animal, animal care, experimental design, data analysis including statistical methods and generation of results (e.g. ED$_{50}$ and 95\% confidence limit values, repeated measures ANOVA as appropriate) shall be included.

IV. The study protocol shall include examples of how data will be presented. For example, representative dose-response curves, tables, and statistical analyses should be included. This information can be taken from previously published studies. However, this information should be included in a section as part of the study protocol and shall not be submitted as a separate file, but the data should be cited (i.e. submitting the example paper with the study protocol would not be considered acceptable).

V. Signature lines shall be included on each study protocol. Upon approval of the protocol by DEA and the vendor, the protocol will be signed by each representative. The original signed document will remain with DEA. A copy of the signed protocol will be provided to the vendor. The signed protocols will serve as an official record.

Following receipt of the standard protocols by the DEA representative, a phone conversation may be scheduled to discuss the study protocols and SOPs. Any significant deviations or modifications from the protocol by the vendor must be authorized by DEA. The vendor must provide a modified protocol (e.g., change in time points, change in vehicle used, modification needed based on a specific test substance, etc.), the amended or modified protocol must be submitted in writing to the DEA representative for review and approval. The DEA representative must approve work with each new assay modifications.
**NOTE:** The DEA representative must approve work with each new test method prior to its initiation. Only those test substance specified by the DEA shall be evaluated in the new study under development. For the most part, standard substances (known drugs of abuse such as morphine and fentanyl) shall be used. Special reports and data summaries shall adhere to a format determined by the DEA.

**Task 3. Evaluation of test substances in *in vivo* analgesic effects**

I. **Objective:** The goal of this *in vivo* pharmacological study is to understand whether administration of test substances can result in an analgesic effect. Using the general protocol and SOPs agreed to by the vendor and DEA in Task 2, the vendor shall, as specified by the DEA representative, evaluate standard (reference) and/or test substances using the agreed upon *in vivo* analgesia assays. Locomotor activity or other dose-finding assays can be conducted to achieve appropriate doses prior to the analgesia studies.

II. **Experimental Design:** Analgesia assays shall be conducted in mice or rats. If alternative rodent animal species or alternate species are selected, the vendor will provide to the DEA a comprehensive rationale for selecting a different animal species. The DEA and the vendor shall agree on the strain of rodent to be used for each of the studies. The vendor shall follow the DEA-approved *in vivo* analgesia protocol for conducting these studies. Briefly, analgesia study will be conducted using the warm-water tail withdrawal assay (this is the preferred method for the opioid drug class; however, other anti-nociceptive assays can be considered if a protocol and justification is made). Selection of the appropriate tests shall be agreed upon by both the DEA and vendor. Rodents will be injected via appropriate route (e.g., subcutaneous for opioid substance) with either vehicle or reference substances or test substance. To determine the receptor mediated effect, the analgesic effect of these compounds shall be evaluated in the presence of appropriate dose(s) of standard receptor antagonist(s) (e.g., naltrexone). Experimental groups for evaluating each test substance shall consist of appropriate number of doses and statistically appropriate number of animals per group (at least 8 animals). Data from the proposed experiments shall be summarized in terms of *ED₅₀* (median effective dose; a dose producing the analgesic effect by 50%). Dose response curves from the studies shall also be included. Reference drugs shall be included in the proposed study. *ED₅₀* values may be presented as mean ± SEM. A 95% confidence interval or an equivalent data reporting measurement should be calculated from the dose-response curves. A statistical analysis of data collected from all tests for comparing different treatment groups with vehicle control should be performed and the resulting data should be presented.

III. **Potential Experimental Issues and Reporting:** In the event that any experimental issues arise (e.g., inability to dissolve test compound, unexpected results, animal lethality, deviation or departure from the agreed protocol, statistics issue due to experimental constrains ), the vendor shall immediately notify the DEA representative, in writing (email) with the issue and if it was resolved. Based on the issue noted by the vendor, the DEA representative may schedule a phone conversation or respond by email. All
experimental issues that arise and the resolutions shall be documented in writing even if the issue and resolutions are discussed in a phone conversation.

Study Report: Following completion of the in vivo analgesia study for each test substance, the results in the form described in Task 7 (e.g. ED$_{50}$ and 95% confidence limit values, dose response curves) shall be provided to the DEA representative for review and acceptance. The DEA representative may contact vendor if there are any notable issues with the results.

Task 4. Evaluation of test substances in in vivo drug discrimination assay

I. Objective: The goal of this in vivo pharmacological study is to understand whether the test substances can be substituted for the discriminative-stimulus effects produced by a known drug of abuse. Using the general protocol and SOPs agreed to by the vendor and DEA in Task 2, the vendor shall, as specified by the DEA representative, evaluate standard (reference) and/or test substances using the in vivo drug discrimination assay.

II. Experimental Design: Drug discrimination studies shall be conducted in rats. If alternative rodent animal species or alternate species are selected, the vendor will provide to the DEA a comprehensive rationale for selecting a different animal species. The DEA and the vendor shall agree on the strain of rodent to be used for each of the studies. The vendor shall maintain groups of animals (rats) trained to discriminate the stimulus effects of a given reference drug (from its vehicle during each year of the agreement. It is expected that drug discrimination training for the animals commence within a week after the protocol is approved. The reference training drugs shall include, but not be limited to, morphine and fentanyl or as directed by the DEA representative. The training and reference drugs should be tested periodically to establish a dose-effect reference standard in the rats. The vendor shall have the equipment available for drug discrimination testing procedures such that the experiments can be conducted in a relatively expedient manner for this assay. Additionally, it is encouraged to have multiple and/or automated apparatus for evaluating the discriminative stimulus effects in order to increase efficiency of completing the experiments.

III. Potential Experimental Issues and Reporting: In the event that any experimental issues arise (e.g. inability to dissolve test compound, unexpected results, animal lethality, deviation or departure from the agreed protocol, statistics issue due to experimental constrains ), the vendor shall immediately notify the DEA representative, in writing (email) with the issue and if the issue was resolved. Based on the issue noted by the vendor, the DEA representative may schedule a phone conversation or respond by email. All experimental issues that arise and the resolutions shall be documented in writing even if the issue and resolutions are discussed in a phone conversation.

IV. Study Report: Following completion of the in vivo drug discrimination study for each test substance, the results in the form described in Task 7 (e.g. ED$_{50}$ and 95% confidence limit values, dose response curves) shall be provided to the DEA representative for review and acceptance. The DEA representative may contact vendor if there are any notable issues with the results.
Task 5. Final study report for each substance tested

Following completion of the experiments in Task 3, 4, and 5 a final study report containing the complete methodology, data analysis, and study results for each test substance shall be provided in electronic format to the DEA.

i) Study Reports: A final study report containing the complete methodology, data analysis, and study results for each compound/assay shall be provided to the DEA. The DEA representative will provide an example of a Final Study Report for the vendor to use in preparation of the report. Where feasible, data shall be presented in tables and figures and the results shall be described in a textual format. Raw data should also be included in an appendix to the report. The vendor shall first submit a draft report in using Microsoft word to the DEA Representative. Upon review by the DEA Representative, revisions may need to be made. Once revisions are completed or the draft is cleared by the DEA Representative, final copies of the report shall be provided to the DEA Representative in electronic MS word version as well as a portable document file (PDF) format. Each report shall be due no later than thirty (30) calendar days after the study completion date. The format shall be as follows:

ii.) Front cover to contain: Date, title (to include compound name), researcher (name/address/phone number, email), contract number, DEA representative (name).

iii.) Main body to contain: (1) A brief (one or two paragraph) summary of the findings (2) detailed methods, and (3) results organized as text, tables, and/or figures, as agreed upon with DEA representative.

Task 6. Reporting Requirements

All reports required herein shall be submitted in electronic format to the DEA representative as detailed in the following subsections. The preparation and submission of regularly recurring Technical Progress Reports will be required for this agreement. These reports shall require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined by the DEA Representative.

a. Monthly reports: On or before the 5th working day following the end of each period of performance year, the vendor shall submit one electronic copy in PDF format of a report on activities during the month. In the report, vendor shall include (1) all study reports completed during the month (2) a table, or set of tables, of all compounds tested in the contract, with the main results so far, and (3) entries for the compounds next in line for testing as specified above.

b. Study Reports: See task 7 for details on these reports.
c. **Annual Progress Reports:** On or before the 5th working day following the end of each period of performance year, the vendor shall submit a report on activities during the year. One electronic copy in Microsoft Word or PDF format shall be sent to the DEA representative. In the report, vendor shall include: *section 1* – a summary of the overall results generated on all substances during the past 12 months; *section 2* – a brief summary of any problems encountered while conducting the established experimental assays and, if applicable, a description of how those problems were resolved, as well as a brief summary of progress in any experimental assay development; *section 3* – the log of all substances purchased; *section 4* – any other information required. The summary of overall findings (section 1) should not be an all-inclusive summary of data generated on standard substances but, rather a summary of highlights.

**Task 7. Level of Effort**

The DEA Representatives reserve the right to visit the laboratory where testing is being conducted.

a) **Meetings between DEA and vendor:**

i. Monthly conference calls: After submission of the monthly report, the vendor and the DEA representative shall have a teleconference meeting once a month. Other DEA and contract staff may participate if necessary. These meetings may be waived at the discretion of the DEA representative. Specific items for discussion shall be subject to the approval of the DEA representative.

ii. In-person meetings: At approximately 12-month intervals, DEA representatives may set-up a meeting with the vendor for the purpose of reviewing past, current, and/or proposed work under this agreement. These meetings may be waived at the discretion of the DEA representative. Specific items for discussion shall be subject to the approval of the DEA representative.

iii. Pre-Meeting Materials: Three weeks before each meeting, the vendor shall prepare "pre-meeting packets" summarizing all data on test compounds to be presented and describing relevant assay methods. This packet shall also include summaries of: (1) proposals for optimizing existing assays; (2) progress in ongoing assay development; (3) proposals for new assay development; (4) problems encountered in implementing tasks required in the agreement; and (5) proposed solutions to problems encountered. The vendor shall deliver this information to the DEA representative at least 3 weeks in advance of the meeting for approval, and after approval has been obtained, to each consultant at least 2 weeks prior to the meeting.

iv. Post-Meeting Materials: After the meeting, the vendor shall prepare a post-Meeting report, summarizing the recommendations and comments of the
attending consultants and DEA staff. The report shall include recommendations for optimizing specific assays and suggestions for incorporating new assays into the DEA testing program. The Post-Meeting Report shall be sent to the DEA representative within three (3) weeks of the meeting.

v. Meeting Location(s): The site of the meeting shall be either at the annual scientific meetings of professional associations such as the College on Problems of Drug Dependence and the Society for Neuroscience, the DEA headquarters or other locations as specified by the DEA. This agreement shall not be responsible for the payment of DEA consultants' expenses. Meetings via video teleconference to discuss status and other issues may be held, but could be cancelled at the DEA’s discretion.

V. Period of Performance

The period of performance for this agreement shall be for 12 month duration with the option to extend for four additional years and is subject to renewal by DEA and vendor after each performance year. The exact dates of the period of performance are to be determined. If the agreement at the end of one year is terminated by one or both parties, the period of performance will no longer extend to subsequent years. Prior to shortening the period of performance, a written notification shall be provided with 90-day notice.

VI. Deliverables

If a report on any of the requested studies cannot be provided by the specified timelines, the vendor must notify the DEA immediately upon obtaining this knowledge. This notification shall be followed up by a letter to the DEA stating the reason for the delay, the anticipated date of completion of investigations, and the anticipated delivery of the study.

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DELIVERABLE</th>
<th>DELIVERY SCHEDULE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Project kick-off meeting to discuss overall project expectations, timelines, and deliverables.</td>
<td>Within 2 working days following receipt of protocol.</td>
</tr>
<tr>
<td></td>
<td>Agreed protocols of the <em>in vivo</em> locomotor activity or other dose-finding studies, analgesia, drug discrimination assays studies</td>
<td>Initial protocols to be provided to DEA within 30 calendar days after start of the agreement period.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modified or revised</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>----------------------</td>
<td>-----------------------------------------------------------------</td>
</tr>
<tr>
<td>2</td>
<td>Monthly Status Reports</td>
<td>30 days from contract award date and monthly thereafter.</td>
</tr>
<tr>
<td>3</td>
<td>Study Reports</td>
<td>To DEA no later than 30 calendar days after study completion date.</td>
</tr>
<tr>
<td>5</td>
<td>Annual Progress Reports</td>
<td>To DEA on or before the 5th working day following each year.</td>
</tr>
<tr>
<td>6</td>
<td>Final Report</td>
<td>To DEA on or before the expiration of the agreement period.</td>
</tr>
<tr>
<td>7</td>
<td>Laboratory Records and Test Substances</td>
<td>To DEA on or before the expiration of the agreement period.</td>
</tr>
</tbody>
</table>

### VII. Use of Data

All documents, data, materials, records, and information sources provided to the vendor, developed or maintained by the vendor in the performance of this contract under this SOW are deemed to be the property of the DEA. All data collected, generated, manipulated or otherwise processed under this agreement are confidential information unless or until DEA authorizes its release. None of these data may be used at any time for any purpose except to generate reports or other requirements specified in the Statement of Work, without prior written approval of the DEA. The DEA and the vendor will mutually agree to discuss matters of Freedom of Information Act (FOIA) policy before each agency independently discloses requested information.

On or before the agreement year expiration, the vendor shall deliver (or otherwise dispose per the DEA) all data, including raw databases (electronic or hard copies), tapes, software programs used to interpret or manipulate data, weight calculation files, data collection forms, file definitions, and various edited databases generated under this contract to the DEA (except for data necessary only to comply with other Federal data retention requirements, such as
requirements pertaining to clinical trials or the Food and Drug Administration's rules pertaining to drug applications).

During or after the agreement, no data may be released, presented or published except upon prior approval of the DEA. All requests which the vendor will receive from third parties for access to the data must be referred to the DEA.

VIII. Retention of Information

The vendor shall retain, for 5 years beyond the duration of this agreement, all laboratory notebooks (which shall include paper copies of raw data) and electronic data files. Electronic data files shall be labeled and recorded in a manner that allows their association with corresponding laboratory notebook entries and paper copies of raw data. On or before the expiration date of this agreement, if so instructed by the DEA, the vendor shall ship these items to the DEA representative in Arlington, VA.

IX. Optional In Vivo Studies

The DEA is open to the inclusion of other behavioral studies (e.g., respiratory depression, conditioned place preference, rotorod assays) that can provide further information on the pharmacological properties of this class of substances. Please note that inability to perform any of the suggested optional studies will not exclude a researcher for consideration if the DEA representative and the vendor mutually agree on all matters (i.e., feasibility, cost, etc.) regarding these optional in vivo studies then these study can be added to the BPA. In the event additional behavioral studies are agreed upon a bilateral modification will be executed, incorporating a revised Statement of Work, Contract Line Items (CLINS).

DEA Representative (Scientific and Technical Contact): Will be provided at time of award
SECTION 3- INSTRUCTIONS TO OFFERORS

The U.S. Drug Enforcement Administration (DEA) intends to establish a firm fixed price Multi Award, Blanket Purchase Agreement (BPA) for Evaluation of Abuse Potential of NPS Using In Vivo Pharmacological Studies in accordance with FAR Part 13 to the responsive, responsible contractor who provides the best value to the Government. Items shall be quoted on an all or none basis. Partial quotes will not be accepted. The contractor shall propose a quote for all years of the anticipated BPA including the Base Year and Option Periods (total of five years). The services that will be issued under the BPA are described in Section 2 of the Request for Quotation (RFQ). The contractor shall furnish the services identified if and when requested by a Contracting Officer who is duly warranted by DEA to authorize the expenditure of funds during the period of performance of BPA.

DURATION OF THE BPA AGREEMENT

The anticipated period of performance for services described herein is established from 12 months after the award. If the DEA requires services for additional years, the period of performance will be:

Option Period I: 12 months after the Base Year
Option Period II: 12 months after Option Period I
Option Period III: 12 months after Option Period II
Option Period IV: 12 months after Option Period III

PRICING INFORMATION

The Contractor shall propose individual pricing for each contract line item on the Schedule of Services and include a total price for the quote.

DELIVERY AND DESTINATION

Delivery and destination requirements will be clearly defined at the time individual call orders are placed. Deliveries shall be accompanied by a delivery ticket that shall contain the following information: name of supplier, BPA number, date of order; order number; itemized list of items; quantity and price of each item; and date of delivery.

CALL LIMITATIONS (FAR 13.303-5(b))

No single call placed under this Agreement shall exceed the simplified acquisition dollar threshold. Requirements shall not be split for the purpose of staying under the simplified acquisition threshold or individuals delegated limits of authority.

INDIVIDUALS AUTHORIZED TO PURCHASE UNDER THIS BPA
The individuals authorized to place calls under this Blanket Purchase Agreement, and the limits of their purchase authority are shown below:

**UNLIMITED**

DEA Headquarters Contracting Officers

All call orders shall be placed prior to the start of the service period of performance.

**INVOICES**

See DEA Provision and Clause Matrix, DEA clause DEA-2852.242-71 (Invoice Requirements (MAY 2012) on Page 19.

**INSTRUCTIONS TO OFFERORS**

This is an all-or-none procurement. The contractor, using the line item numbers included in Schedule of Services and Sample BPA Call Order, shall propose a rate for all years of the anticipated BPA including the Base Year and each BPA Option Period (total of five years).

OFFER ACCEPTANCE PERIOD – The contractor shall provide an offer acceptance period of **not less than 90 calendar days**.

QUESTIONS / COMMUNICATIONS – All communications concerning the solicitation, including any of a technical nature, shall be made through the Contract Specialist. All questions, technical or otherwise, shall be in writing and received by the Contract Specialist at Jacqueline.P.Schottler@usdoj.gov later than January 11, 2019 at 10:00 am EST. All questions and answers will be provided to contractors as an amendment to the solicitation prior to the quote due date.

**TIME, DATE, AND PLACE FOR SUBMISSION OF QUOTE**

The Government may reject all offers received in response to this solicitation, if doing so is in the best interest of the Government. Late submissions will not be accepted. No telephone or fax requests will be accepted. This solicitation does not commit the Government to pay any costs incurred in the submission of a quotation. Quotes shall be submitted electronically to Jacqueline Schottler by January 31, 2019 at 10:00 AM EST via email at Jacqueline.P.Schottler@usdoj.gov. Please reference 15DDHQ19Q00000012 in the subject line of the email quote submission.

**GENERAL INSTRUCTIONS**

To aid its evaluation, the proposal shall be clearly and concisely written as well as being neat, indexed, and logically assembled addressing each factor in the order specified by the solicitation. All pages of each part shall be appropriately numbered and identified with the name of the contractor, the date, and RFQ number.
Proposal Volumes

I. Technical Proposal
II. Past Performance
III. Business Proposal

Technical Proposal (Volume I)

The proposal shall be specific and complete in every detail. The proposal shall be practical, straightforward with concise delineation of what it is the contractor will do to satisfy the requirements of the Statement of Work.

The proposal shall not merely offer to perform work in accordance with the scope of the work. It shall outline the actual work proposed as specifically as practical. Statement of Work reflects the objectives of the program, therefore merely stating or affirming that the contractor will execute the performance requirements without sufficient elaboration will not be acceptable.

The proposal shall be typed, single spaced, with one inch margins, using Time New Roman font, 12 point type (Or Equivalent), unreduced in size, on 8 ½” by 11” paper, **not exceeding 15 pages for the Technical Proposal (Volume I).** The **first 15 pages** of the Technical Proposal will be evaluated; **pages in excess of this 15 page limit will not be considered.** Title page, table of contents, and resumes, will not be counted in the page count limitation. Supporting Documents/Appendixes shall not exceed the **5 pages.** Past performance references in Volume 2 shall not exceed **10 pages for Volume II** and business proposal in Volume III shall not **exceed 10 pages** for the Business Proposal.

Evaluation Factor:

**FACTOR 1: TECHNICAL CAPABILITY (Volume I):**

The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how each TASK will be structured and executed.

The Offeror shall also provide:

- The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how Task 1 **Drug source, storage, and record keeping** will be structured and executed.
- The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how Task 2 **Protocols of in vivo pharmacological studies (locomotor activity, drug discrimination studies, and other optional studies (e.g. conditioned place preference, rotorod assays)) in laboratory rodent animals** will be structured and executed.
• The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how Task 3 *Evaluation of test substances in in vivo analgesic effects* will be structured and executed.
• The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how Task 4, *Evaluation of test substances in in vivo drug discrimination assay* will be structured and executed.
• The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how Task 5 *Final study report for each substance tested* will be structured and executed.
• The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how Task 6 *Reporting Requirements* will be structured and executed.
• The Offeror shall demonstrate the understanding of the requirement as stated in the Statement of Work by providing a narrative as to how Task 7 *Level of Effort* will be structured and executed.

**Past Performance Proposal (Volume II)**

Offerors (prime and subcontractor(s)) shall submit with its offer a minimum of three (3) contracts or task orders, performed during the past three (3) years that are representative of the Offeror’s capability to provide services with similar scope, magnitude, and complexity of prior performance, similar to that stated in the Statement of Work (SOW). The Offeror shall also specifically address its resilience in the face of trouble, resourcefulness, and management determination to see that the organization lived up to commitments or standards. The offeror shall provide Contracts or task orders listed and may include those entered into by the Federal Government, agencies of state and local Governments and commercial customers. Include the following information for each contract:

• Project title
• Whether the contractor performed as the prime or subcontractor
• Agency Managing Project
• Client/Agency Point of Contact (POC) to include name, phone number, and email address
• Project Agency Contract / Order Number
• Period of Performance
• Value by year of contract/order
• Discuss in detail their performance
In addition, the Offeror’s Past Performance Questionnaire (Attachment 1) should be completed by those contracting organizations listed above.

The Government will supplement the information provided by the offeror with information the Government obtains through reference checks, its own knowledge/experience, and/or from other sources. These sources may include, but are not necessarily limited to, other Government contracting offices, the Contractor Performance Assessment Reporting System (CPARS), and the Past Performance Information Retrieval System (PPIRS).

**Business Proposal (Volume III)**

**BUSINESS INFORMATION TO BE FURNISHED** – The contractor shall provide the following business information with their business proposal:

- Company Name, Address, Point of Contact
- DUNS number
- CAGE CODE number
- Business Size
- The Standard Form 18 fully executed. Include one (1) originally signed copy of the form and with blocks 13, 14 and 15 completed.
- Completion of DEA-2852.209-70 – Organizational Conflicts of Interest – The Contractor shall refer to clause DEA-2852.209-70 Organizational Conflicts of Interest (MAY 2012) located in attached clause matrix.
- Any changes or updates to the representations and certifications on file in the System for Award Management as required by paragraph (b) of Federal Acquisition Regulation provision 52.212-3 Contractor Representations and Certifications – Commercial Items.
- Completion of DEA-2852.242-74 – Contract Administration Points of Contact.
- Price Proposal – Contractors shall complete the worksheets in I. Section of Services (for base and all option periods to be considered on an all-or-non basis per the instructions in the solicitation. Failure to provide pricing for all CLINS may result in elimination from further consideration. The offeror shall complete Attachment 2 - Sample BPA Call.

**COMPLIANCE WITH INSTRUCTIONS**

When evaluating a contractor’s capability to perform the prospective BPA, the DEA will also consider compliance with these instructions. The Government will consider a contractor’s noncompliance with these instructions, or any attempt to evade the requirements imposed by these instructions, as indicative of the conduct the Government may expect from the contractor during BPA performance. The Government reserves the right to treat noncompliance with these
instructions as a risk, and may treat such risk as grounds to eliminate any contractor from award consideration.

EXPENSES RELATED TO CONTRACTORS SUBMISSION

The Government will not pay any cost incurred in the preparation and submission of any proposals.

DETERMINATION OF CONTRACTOR RESPONSIBILITY

Separate and independent of this evaluation, the Contracting Officer will make a determination of responsibility using the standards listed in FAR 9.104-1. In the event a contractor is deemed not responsible, that contractor will be notified and removed from participation in this procurement.

EVALUATION

An Award will be made to the technically acceptable, legally eligible, responsible contractor, who proposes the lowest technically acceptable price and received a PASS rating for past performance. All proposals received will be subject to the technical and price evaluation by the technical proposal evaluation team. The Government reserves the right to award without discussions.

Three (3) Phase Evaluation:

1. If a contractor does not receive a PASS rating for Factors 1, the contractor shall not be further evaluated. If a contractor does receive a PASS rating for Factors 1, the contractor’s Past Performance shall be evaluated.

2. If a contractor does not receive a PASS rating for Past Performance, the contractor shall not be further evaluated. If a contractor does receive a PASS rating based on the ratings specified above, the contractor’s price shall be evaluated.

3. If a contractor received a PASS rating for Factors 1 and received a PASS rating for Past Performance, price will be the determining factor. (Attachment 2 - Sample Call Order)

Technical Evaluation Factor 1 and Past Performance shall be evaluated on a PASS/FAIL basis.

PASS – Proposal clearly meets the minimum requirements of the solicitation, and is technically acceptable. The offeror must receive a pass rating for all Tasks in order to be determined technically acceptable.

FAIL – Proposal does not clearly meet the requirements of the solicitation, and is technically unacceptable.

AWARD SELECTION
The following evaluation factors will be used in the source selection process:

a.) TECHNICAL CAPABILITY

Technical Proposals will be evaluated based upon:

The contractor’s ability to thoroughly address the technical criteria referenced in Section 2.

The government will evaluate the offeror’s:

- The government will evaluate the offeror’s ability to structure and execute TASK 1
- The government will evaluate the offeror’s ability to structure and execute TASK 2
- The government will evaluate the offeror’s ability to structure and execute TASK 3
- The government will evaluate the offeror’s ability to structure and execute TASK 4
- The government will evaluate the offeror’s ability to structure and execute TASK 5
- The government will evaluate the offeror’s ability to structure and execute TASK 6
- The government will evaluate the offeror’s ability to structure and execute TASK 7

b.) PAST PERFORMANCE

The Government will evaluate the contractor’s ability to thoroughly address the past performance referenced in Section V.

1. Up to three (3) contracts / task orders performed by the Offeror and for proposed subcontractor(s) during the past five (5) years that are representative of the Offeror’s capability to provide services with similar scope, magnitude, and complexity of prior performance, similar to that stated in the Statement of Work (SOW).

2. The Offeror’s description of its resilience in the face of trouble, resourcefulness, and management determination to see that the organization lived up to commitments or standards.

3. The Offeror’s description of the similarities and differences between this proposed effort and the specifications of those contracts / task orders and description of the expectations and scopes of each of the contracts.

4. Completed Past Performance Questionnaire, Attachment 1

5. Reference checks, its own knowledge/experience, and/or information obtained from other sources which may include, but not necessarily be limited to, other Government contracting
offices, the Contractor Performance Assessment Reporting System (CPARS), and the Past Performance Information Retrieval System (PPIRS).

c.) PRICE

Prices will be evaluated by summing the grand total Base and All Option Periods, in the Sample BPA Call Order, Attachment 2.

**Important:** Only the proposals that are deemed technically acceptable, legally eligible, and received a PASS rating for Factor 1: Technical Capability and Past performance will be forwarded for price analysis to determine lowest price. Price alone shall be the determining factor for the award. This is Lowest Price Technically Acceptable procurement. A proposal containing unreasonable or incomplete pricing may be rated as FAIL.

**SELECTION OF CONTRACTOR**

The Government reserves the right to make a single best value, Lowest Price Technically Acceptable (LPTA) award or no award as a result of this RFQ.
The purpose of this questionnaire is to obtain an evaluation of past performance on a contract that has been completed or is currently being performed by the Contractor listed above. You have received this questionnaire because the Contractor selected you to provide this evaluation in response to a request by the Drug Enforcement Administration (DEA) for past performance information. DEA will use the information you provide to assess the Contractor’s ability to perform the requirements of a contract. The information is to be provided directly to DEA. The information you provide may be released to the Contractor during debriefings; however, the source of the information will not be released.

It is requested that the Program Manager or the Contracting Officer Representative (COR) complete the evaluation. Please complete this past performance questionnaire, and submit your responses via email to jacqueline.p.schottler@usdoj.gov, no later than January 31, 2019 at 10:00 AM EST.

Thank you for your assistance in this Past Performance Evaluation process.

Jacqueline Schottler
DEA Contract Support Specialist

Please rate the Contractor on the abilities listed in this questionnaire by circling the appropriate number to the right. The following definitions apply:

1 = Unacceptable Performance: Requirements were not achieved with significant consequences.
2 = Marginal Performance: Requirements were frequently not fully achieved, often with significant consequences.
3 = Satisfactory Performance: Requirements were generally achieved with occasional exceptions, and in most cases with minor consequences.
4 = Good Performance: Requirements were achieved with only rare exceptions, and the exceptions had minor consequences.
5 = Excellent Performance: Requirements were essentially always achieved or exceeded.
NA = Not Applicable: This does not apply to the work that was performed.
## Evaluation of Abuse Potential of Synthetic Opioids Using In Vivo Pharmacological Studies

**RFQ- 15DDHQ19Q00000012**

### CONTRACT & EVALUATOR INFORMATION

<table>
<thead>
<tr>
<th>Block 1</th>
<th>Block 2</th>
<th>Block 3</th>
<th>Block 4</th>
<th>Block 5</th>
<th>Block 6</th>
<th>Block 7</th>
</tr>
</thead>
</table>

### BLOCKS 8 AND 9 TO BE COMPLETED BY EVALUATION ORGANIZATION REPRESENTATIVE

<table>
<thead>
<tr>
<th>Block 8</th>
<th>Block 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. EVALUATION: a. EVALUATOR’S NAME, POSITION (PM/COR/OTHER) AND ORGANIZATION:</td>
<td>b. EVALUATOR’S PHONE NUMBER:</td>
</tr>
<tr>
<td>c. MONTHS CONTRACTOR PERFORMANCE MONITORED BY EVALUATOR:</td>
<td>d. RATINGS Please circle the response code which best reflects your evaluation of the contractor’s performance.</td>
</tr>
</tbody>
</table>

---

Attachment 1
U.S. DRUG ENFORCEMENT ADMINISTRATION
PAST PERFORMANCE QUESTIONNAIRE

Evaluation of Abuse Potential of Synthetic Opioids Using In Vivo Pharmacological Studies  RFQ- 15DDHQ19Q00000012

<table>
<thead>
<tr>
<th>QUESTIONS</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstrated commitment to success of customer mission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effectively manage resources and personnel.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall, risk management for the program.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to manage daily operational and contractual tasks.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall, cost control (avoid overruns) of the program.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timeliness in planning and meeting task schedules and performance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to submit required reports and deliverables on schedule.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality assurance of products and services delivered.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solving problems and resolution processes.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employing of partnering and teaming strategies with government representatives and other contractors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to adapt to changing requirements to meet customer needs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sufficient certified/qualified personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effectiveness of support in communicating efforts and results</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to prepare and submit accurate and timely invoices for completed work</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall timeliness of delivery.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ability to effectively manage subcontractors, facilitate information exchanges and expedite work flows</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall commitment to customer satisfaction.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please provide any additional comments to describe the Contractor’s performance:

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

Would you hire this contractor again? (please check one)  _____YES  _____NO

If “no,” please explain why you would not hire this contractor again:

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

Thank you for completing this past performance survey.

Attachment 1
ATTACHMENT 2: SAMPLE BPA CALL ORDER

The purpose of this BPA Call Order is to provide contractors DEA’s projected annual estimates to be ordered against the BPA.

(FOR PRICING EVALUATION PURPOSES ONLY)

The Sample BPA Call Order will be used for evaluating the contractor’s proposed price for each BPA year. The contractor shall enter its proposed unit price by contract line item number (CLIN) for the base period and each option period. The contractor shall enter the total price for each period and grand total for all periods combined. The contractor shall complete all calculations and fill in all spaces provided on the form.

Proposals that do not include pricing in the Sample BPA Call Order in its entirety (“all or none basis”) will not be evaluated by the government.

The completed Sample BPA Call Order shall be submitted with the contractor’s Proposal – the evaluation of which shall be considered for award of the resulting single BPA. In addition, the contractor shall enter the proposed, fixed, hourly rates from the Sample BPA Call Order for the base and option periods in Section 2 of the RFQ. The proposed fixed, hourly rates from the Sample BPA Call Order shall be identical to the proposed fixed, hourly rates in Section 2. Failure to provide pricing for all CLINS in the Sample BPA Call Order and in Section 2 will result in elimination from further consideration.

Note: The estimated maximum hours below are specific only to the Sample BPA Call Order.

Base Year – 12 months after the Award. (DO NOT QUANTITY OR UNIT)

<table>
<thead>
<tr>
<th>CLIN</th>
<th>SUPPLY/ SERVICES</th>
<th>QUANTITY</th>
<th>UNIT</th>
<th>UNIT PRICE</th>
<th>ESTIMATED TOTAL PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0001</td>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0002</td>
<td>Drug Discrimination of test drug</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0003</td>
<td>Locomotor Activity</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0004</td>
<td>Drug Cost Not to Exceed</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0005</td>
<td>Incidentals</td>
<td>1</td>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GRAND TOTAL $
Option Year I – 12 months after the Base Year. (DO NOT QUANTITY OR UNIT)

<table>
<thead>
<tr>
<th>CLIN</th>
<th>SUPPLY/ SERVICES</th>
<th>QUANTITY</th>
<th>UNIT</th>
<th>UNIT PRICE</th>
<th>ESTIMATED TOTAL PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1001</td>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1002</td>
<td>Drug Discrimination of test drug</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1003</td>
<td>Locomotor Activity</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1004</td>
<td>Drug Cost Not to Exceed</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1005</td>
<td>Incidentals</td>
<td>1</td>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GRAND TOTAL $ 

Option Year II – 12 months after the Option Year I. (DO NOT QUANTITY OR UNIT)

<table>
<thead>
<tr>
<th>CLIN</th>
<th>SUPPLY/ SERVICES</th>
<th>QUANTITY</th>
<th>UNIT</th>
<th>UNIT PRICE</th>
<th>ESTIMATED TOTAL PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>Drug Discrimination of test drug</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>Locomotor Activity</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>Drug Cost Not to Exceed</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>Incidentals</td>
<td>1</td>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GRAND TOTAL $
Option Year III – 12 months after the Option Year II. (DO NOT QUANTITY OR UNIT)

<table>
<thead>
<tr>
<th>CLIN</th>
<th>SUPPLY/ SERVICES</th>
<th>QUANTITY</th>
<th>UNIT</th>
<th>UNIT PRICE</th>
<th>ESTIMATED TOTAL PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3001</td>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3002</td>
<td>Drug Discrimination of test drug</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3003</td>
<td>Locomotor Activity</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3004</td>
<td>Drug Cost Not to Exceed</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3005</td>
<td>Incidentals</td>
<td>1</td>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**GRAND TOTAL**

Option Year IV – 12 months after the Option Year II. (DO NOT QUANTITY OR UNIT)

<table>
<thead>
<tr>
<th>CLIN</th>
<th>SUPPLY/ SERVICES</th>
<th>QUANTITY</th>
<th>UNIT</th>
<th>UNIT PRICE</th>
<th>ESTIMATED TOTAL PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>4001</td>
<td>Drug Discrimination (monthly maintenance of training drug)</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4002</td>
<td>Drug Discrimination of test drug</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4003</td>
<td>Locomotor Activity</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4004</td>
<td>Drug Cost Not to Exceed</td>
<td>1</td>
<td>EA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4005</td>
<td>Incidentals</td>
<td>1</td>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**GRAND TOTAL**

**GRAND TOTAL**

<table>
<thead>
<tr>
<th>BASE YEAR</th>
<th>OPTION YEAR 1</th>
<th>OPTION YEAR 2</th>
<th>OPTION YEAR 3</th>
<th>OPTION YEAR 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

Grand Total

$
Solicitation #: 15DDHQ19Q0000012

52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: https://www.acquisition.gov/sites/default/files/current/far/html/FARTOCP52.html#wp372482.

(CONTRACTING OFFICER: Check the corresponding box for the provisions and clauses applicable to this procurement.)

☐ 52.204-6 UNIQUE ENTITY IDENTIFIER (OCT 2016)
☒ 52.204-7 SYSTEM FOR AWARD MANAGEMENT (OCT 2018)
☐ 52.204-7 ALT I SYSTEM FOR AWARD MANAGEMENT (OCT 2018) WITH ALTERNATE I OCT 2018
☑ 52.204-16 COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING (JUL 2016)
☐ 52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (JUL 2013)
☐ 52.209-12 CERTIFICATION REGARDING TAX MATTERS (FEB 2016)
☐ 52.211-6 BRAND NAME OR EQUAL (AUG 1999)
☒ 52.212-1 INSTRUCTIONS TO OFFERORS—COMMERCIAL ITEMS (OCT 2018)
☒ 52.212-2 EVALUATION—COMMERCIAL ITEMS (OCT 2014)

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

- Technical Capability
- Past Performance
- Price

[Contracting Officer shall insert the significant evaluation factors, such as (i) technical capability of the item offered to meet the Government requirement; (ii) price; (iii) past performance (see FAR 12.301(c))]

Technical and past performance, when combined, are [Contracting Officer state, in accordance with FAR 12.602]

(b) Options. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

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

(End of provision)

☒ 52.212-3 OFFEROR REPRESENTATIONS AND CERTIFICATIONS—COMMERCIAL ITEMS (OCT 2018)

Note: Effective 2/26/2016, this provision was revised to incorporate a new paragraph (q) entitled “Representation by Corporation Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law.” Any offeror whose annual representations and certifications posted in the System for Award Management does not include the FEB 2016 or later version of provision 52.212-3 must either

(a) Update its annual representations and certifications with the FEB 2016 or later version of provision 52.212-3, or
(b) Complete paragraph (b)(2) and provide this representation with its offer.

Attention is drawn to paragraph (b) of provision 52.212-3, which requests offeror-provided fill-in information in (b)(2), when applicable:

(b)(1) Annual Representations and Certifications. Any changes provided by the Offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications in SAM.

(End of provision)
(2) The offeror has completed the annual representations and certifications electronically in SAM accessed through http://www.sam.gov. After reviewing SAM information, the Offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications—Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), at the time this offer is submitted and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs ____________.

[Offeror to identify the applicable paragraphs at (c) through (u) of this provision that the offeror has completed for the purposes of this solicitation only, if any.]

These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

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

***Paragraph (i) contracting officer fill-in information***

Note: Paragraph (i)(1): The end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor are listed by Schedule of Supplies/Services Item Number as follows:

[when applicable, enter item numbers with country of origin in parentheses and separated by commas]

***Paragraph (k) contracting officer fill-in information***

Contracting officer — select applicable item when an exemption to the Service Contract Labor Standards statute applies.

☐ Paragraph k(1) is applicable. ☐ Paragraph k(2) is applicable.

☐ 52.222-56 CERTIFICATION REGARDING TRAFFICKING IN PERSONS COMPLIANCE PLAN (MAR 2015)
☐ 52.225-7 WAIVER OF BUY AMERICAN STATUTE FOR CIVIL AIRCRAFT AND RELATED ARTICLES (FEB 2016)
☐ 52.233-2 SERVICE OF PROTEST (SEPT 2006)

***fill-in information***

[Designate the official or location where a protest may be served on the Contracting Officer.]

☐ DEA-2852.209-75 NATIONAL SECURITY RISK ASSESSMENT (JUN 2014)

(a) Any offeror responding to this solicitation acknowledges that before acquiring information technology equipment or software, the U.S. Department of Justice and its component entities will assess the supply chain risk of cyber-espionage or sabotage associated with the acquisition of such equipment or software, including any risk associated with such equipment or software being produced, manufactured, or assembled by one or more entities identified as posing a cyber-threat, including but not limited to, those that may be owned, directed, or subsidized by the People’s Republic of China.

(b) By submitting an offer to this solicitation, the Offeror understands and agrees that the Government retains the right to reject any offer or response to this solicitation made by the Offeror, without any further recourse by, or explanation to, the Offeror, if the Government determines the Offeror or the equipment or software offered by the Offeror, in whole or in part, presents an unacceptable risk to national security.

(c) To assist the Government in assessing whether the acquisition poses a national security risk, offerors are required to complete and submit with its offer or quotation the National Security Acquisition Risk Assessment Questions, which are attached to this solicitation. Offerors must answer all questions completely and accurately to the best of their knowledge and belief. All answers are to be reflective of the parent and subsidiary levels of an organization.

(d) Offerors are also required to request, collect, and forward with its offer or quotation completed National Security Acquisition Risk Assessment Questions from all subcontractors that will provide any equipment or software in performance of the contract or order. Offerors are responsible for the thoroughness and completeness of each subcontractor’s submission.

(e) Failure to provide any such requested information may render a proposal unacceptable.

(End of provision)
DEA PROVISION & CLAUSE MATRIX – COMMERCIAL ITEMS
Updated through FAC 2005-101 (10/26/2018)

SOLICITATION #: 15DDHQ19Q0000012

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address:

(The end of clause)

**CONTRACTING OFFICER:** Check the appropriate box only for clauses that are applicable to this procurement.

- ☒ 52.203-16 PREVENTING PERSONAL CONFLICTS OF INTEREST (DEC 2011)
- ☒ 52.203-17 CONTRACTOR EMPLOYEE WHISTLEBLOWER RIGHTS AND REQUIREMENT TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS (APR 2014)
- ☐ 52.204-4 PRINTED OR COPIED DOUBLE-SIDED ON POSTCONSUMER FIBER CONTENT PAPER (MAY 2011)
- ☒ 52.204-9 PERSONAL IDENTITY VERIFICATION OF CONTRACTOR PERSONNEL (JAN 2011)
- ☐ 52.204-12 UNIQUE ENTITY IDENTIFIER MAINTENANCE (OCT 2016)
- ☒ 52.204-13 SYSTEM FOR AWARD MANAGEMENT MAINTENANCE (OCT 2018)
- ☐ 52.204-18 COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE (JUL 2016)
- ☒ 52.204-19 INCORPORATION BY REFERENCE OF REPRESENTATIONS AND CERTIFICATIONS (DEC 2014)
- ☐ 52.204-21 BASIC SAFEGUARDING OF COVERED CONTRACTOR INFORMATION SYSTEMS (JUN 2016)
- ☒ 52.204-23 PROHIBITION ON CONTRACTING FOR HARDWARE, SOFTWARE, AND SERVICES DEVELOPED OR PROVIDED BY KASPERSKY LAB AND OTHER COVERED ENTITIES, IN ALL SOLICITATIONS AND CONTRACTS (JUL 2018)
- ☐ 52.207-5 OPTION TO PURCHASE EQUIPMENT (FEB 1995)
- ☐ 52.209-12 CERTIFICATION REGARDING TAX MATTERS (FEB 2016)
- ☒ 52.212-4 CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS (OCT 2018)
- ☐ 52.212-4 ALT I CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS (JAN 2017) WITH ALTERNATE I (JAN 2017)
- ☒ 52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (OCT 2018)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

1. 52.203-19, Prohibition on Requiring Certain Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

2. 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).


(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]


(Appplies to contracts funded by the American Recovery and Reinvestment Act of 2009.)


5. [Reserved]


DEA PROVISION & CLAUSE MATRIX – COMMERCIAL ITEMS
Updated through FAC 2005-101 (10/26/2018)

SOLICITATION #: 15DDHQ19Q00000012

☐ (10) [Reserved]
   ☐ (ii) Alternate I (Nov 2011) of 52.219-3.
☐ (12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
   ☐ (ii) Alternate I (Jan 2011) of 52.219-4.
☐ (13) [Reserved]
   ☐ (ii) Alternate I (Nov 2011).
   ☐ (iii) Alternate II (Nov 2011).
   ☐ (iii) Alternate II (Mar 2004) of 52.219-7.
☐ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
☐ (17)(i) 52.219-9, Small Business Subcontracting Plan (AUG 2018) (15 U.S.C. 637(d)(4)).
   ☐ (ii) Alternate I (Nov 2016) of 52.219-9.
   ☐ (iii) Alternate II (Nov 2016) of 52.219-9.
   ☐ (iv) Alternate III (Nov 2016) of 52.219-9.
   ☐ (v) Alternate IV (AUG 2018) of 52.219-9.
☐ (18) 52.219-13, Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(c)).
☐ (19) 52.219-14, Limitations on Subcontracting (Nov 2011) (15 U.S.C. 637(a)(14)).
☐ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(G)).
☐ (22) 52.219-28, Post Award Small Business Program Rerepresentation (Jul 2013) (15 U.S.C. 632a(2)).
☐ (23) 52.219-29, Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (Dec 2015) (15 U.S.C. 637(m)).
☐ (24) 52.219-30, Notice of Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (Dec 2015) (15 U.S.C. 637(m)).
☐ (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Jan 2018) (E.O. 13126).
☐ (27) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
   ☐ (ii) Alternate I (FEB 1999) of 52.222-26.
   ☐ (ii) Alternate I (JULY 2014) of 52.222-35.
<table>
<thead>
<tr>
<th>Provision/Clause</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>52.222-40</td>
<td>Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).</td>
</tr>
<tr>
<td>52.222-54</td>
<td>Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)</td>
</tr>
<tr>
<td>52.223-9</td>
<td>Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)</td>
</tr>
<tr>
<td>52.223-11</td>
<td>Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).</td>
</tr>
<tr>
<td>52.223-12</td>
<td>Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).</td>
</tr>
<tr>
<td>52.223-13</td>
<td>Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).</td>
</tr>
<tr>
<td>52.223-14</td>
<td>Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O. 13423 and 13514).</td>
</tr>
<tr>
<td>52.223-16</td>
<td>Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O. 13423).</td>
</tr>
<tr>
<td>52.223-20</td>
<td>Aerosols (Jun 2016) (E.O. 13693).</td>
</tr>
<tr>
<td>52.223-21</td>
<td>Foams (Jun 2016) (E.O. 13693).</td>
</tr>
<tr>
<td>52.225-13</td>
<td>Restrictions on Certain Foreign Purchases (JUNE 2008) (E.O.’s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).</td>
</tr>
<tr>
<td>52.226-5</td>
<td>Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).</td>
</tr>
</tbody>
</table>
SOLICITATION #: 15D0H019Q0000012

☐ (56) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
☐ (59) 52.242-5, Payments to Small Business Subcontractors (JAN 2017) (15 U.S.C. 637(d)).
☐ (60)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
☐ (ii) Alternate I (Apr 2003) of 52.247-64.
☐ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer: check as appropriate.]

☐ (1) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495).
☐ (8) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
☐ (10) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor’s directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (Pub. L. 110-252, Title VI, Chapter 1 (41 U.S.C. 3509)).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204–23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 113–91).

(iv) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 3509 (d) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(v) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause 52.222-17.

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

(vii) 52.222-26, Equal Opportunity (Sept 2016) (E.O. 11246).


(x) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.


(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).


(B) Alternate I (Jan 2017) of 52.224-3.


(xxii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 30 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)
52.225-8 DUTY-FREE ENTRY (OCT 2010)
52.232-18 AVAILABILITY OF FUNDS (APR 1984)
52.232-39 UNENFORCEABILITY OF UNAUTHORIZED OBLIGATIONS (JUN 2013)
52.232-40 PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (DEC 2013)

CONTRACTING OFFICER: List additional FAR clauses below, as needed, by entering the clause number, title, and date for each clause added.

52.2178 OPTION TO EXTEND SERVICES (NOV 1999)
52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MARCH 2000)
52.227-14 RIGHTS IN DATA - GENERAL (MAY 2014)
52.227-17 RIGHTS IN DATA - SPECIAL WORKS (DEC 2007)
52.227-18 RIGHTS IN DATA - EXISTING WORKS (DEC 2007)

The following clauses are also applicable as indicated below.

52.203-70 FORMER EMPLOYMENT OR ASSIGNMENT WITH THE DEA (DEC 2017)

(a) Any offeror or contractor who intends to employ any individual who either currently works for DEA, or had been employed with DEA as a Federal employee within the previous five (5) years for work supporting a prospective or active DEA contract must notify DEA of its intent as described in this clause.

(b) The offeror or contractor shall instruct any prospective or current employee meeting the criteria in paragraph (a), above, to complete and sign a DEA Contractor Ethics Questionnaire. The questionnaire is available for download at http://www.dea.gov/resource-center/doing-business_acq_policies.shtml. When the intent to employ such individual is known prior to the award of a new contract or order, the contractor shall submit the employee’s completed questionnaire and résumé to DEA concurrently with its proposal. When the intent is to employ such individual under an existing contract or order, the contractor shall submit the completed questionnaire and résumé electronically to the cognizant DEA contracting officer AND ethicsFAC@usdoj.gov.

(c) The offeror or contractor understands that any such employees described in paragraph (a) are prohibited from appearing before, or communicating with, the Federal Government on behalf of a contractor regarding a Government contract, investigation or other particular matter that they participated in personally and substantially as a Federal employee with the intent to influence Government officials in those matters for the lifetime of those matters.

(d) The offeror or contractor further understands that for two (2) years after leaving the Federal Government, such employees described in paragraph (a) are prohibited from appearing before, or communicating with, the Government with the intent to influence on behalf of a contractor regarding a Government contract, investigation or other particular matter that they did not participate in personally and substantially as a Federal employee, but that was under their official responsibility during their last year in the Government. For purposes of this clause, an employee is defined as one appointed under Title 5, Section 2015 or Title 21, Section 878 of the United States Code.

(e) If DEA determines after reviewing questionnaire responses or conducting other inquiries that the prospective employee is disqualified for assignment to the contract based on an unfavorable suitability and/or security determination, or may violate the post-employment restrictions described in paragraphs (c) or (d), above, or other applicable laws if allowed to work on or support the contract/task order, at DEA’s request, the offeror or contractor must not assign such employee to work under a prospective or active contract.

(f) If an offeror or contractor fails to provide a required Questionnaire, the prospective employee will not be approved to work under the DEA contract or order until such time as the Questionnaire is submitted, reviewed, and approved in accordance with established procedures.

(End of clause)

52.203-71 REQUIREMENT FOR NOTIFICATION OF CONTRACTOR EMPLOYEES OF WHISTLEBLOWER RIGHTS (JAN 2017)

(a) This contract/order includes clause 52.203-17, Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights. This clause imposes a requirement on the contractor to inform its employees in writing of their whistleblower rights and protections set forth under 41 U.S.C. 4712, as described in section 3.908 of the Federal Acquisition Regulation, and to include the substance of the clause in all subcontracts exceeding the simplified
acquisition threshold. A summary of these rights as well as key information and points of contact for reporting suspected waste, fraud, abuse, misconduct, or whistleblower reprisal is provided in the attached document entitled “Whistleblower Information for Department of Justice Contractors, Subcontractors, and Grantees.”

(b) The contractor shall comply with the requirement to inform its employees of their whistleblower rights and protections by distributing a copy of the Whistleblower Information document to each employee or a translated version of the document in the principle language of the employee; provided, that the translated version includes all of the information in the English language document.
(c) Not later than 30 days after the award of the contract or order, or 30 days after the effective date of the modification incorporating clause DEA-2852.203-71, the contractor shall provide written notice informing the Contracting Officer that it has fully complied with the notification requirements in clause 52.203-17 and DEA-2852.203-71 or the reasons why compliance has not been met.

(End of clause)

DEA-2852.204-78 CONTRACTOR PERSONNEL REPORTING REQUIREMENTS (CPRR) (APR 2018)

(a) During the life of the contract, the contractor shall report all personnel assigned to perform under the contract using the Contractor Personnel Reporting Requirements (CPRR) template available at http://www.dea.gov/resource-center/doing-business_acq_policies.shtml.

(b) The report shall be updated quarterly to include any additions, updates, or changes in status. This information will be maintained by DEA’s Office of Acquisition & Relocation Management (FA), to ensure compliance with Homeland Security Presidential Directive 12 (HSPD-12).

(c) By the 10th of January, April, July, and October, the Contractor shall submit the report directly to the CPRR Mailbox at CPRR.Mailbox@usdoj.gov.

(d) Failure to submit timely updates on the quarterly CPRR report will be documented by FA and reported to the Contracting Officer’s Representative (COR) or Contracting Officer for appropriate action and may result in adverse comments on the Contractor Performance Assessment Reporting System (CPARS).

(e) In the event of repetitive failures to provide this report, the contract may be terminated for default.

(End of Clause)

DEA-2852.209-70 ORGANIZATIONAL CONFLICTS OF INTEREST (MAY 2012)

(a) The Contractor warrants that, to the best of its knowledge and belief, there are no relevant facts or circumstances that would give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, or that the Contractor has disclosed all such relevant information.

(b) In the event that an actual, potential, or apparent organizational conflict of interest is discovered after award, the Contractor shall make full disclosure of the particular facts and circumstances to the Contracting Officer in writing. This disclosure shall include a description of the actions that the Contractor has taken, or proposes to take in order to avoid, mitigate, or neutralize the risk to the Government.

(c) Remedies. The Contracting Officer may terminate this contract for convenience, in whole or in part, if deemed necessary to avoid or mitigate an actual or apparent organizational conflict of interest. In the event that the Contractor failed to disclose in a timely manner, or misrepresented the facts and circumstances of, an actual, potential, or apparent organizational conflict of interest of which it had prior knowledge, the Contracting Officer may terminate this contract for default or cause, and pursue additional remedies, including debarment, as may be provided by law.

(d) Failure to submit timely updates on the quarterly CPRR report will be documented by FA and reported to the Contracting Officer’s Representative (COR) or Contracting Officer for appropriate action and may result in adverse comments on the Contractor Performance Assessment Reporting System (CPARS).

(e) In the event of repetitive failures to provide this report, the contract may be terminated for default.

(End of clause)

DEA-2852.209-79 CONTRACTOR INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS PROHIBITING OR RestrictING REPORTING OF WASTE, FRAUD, AND ABUSE (DEViation 2015-02) (APR 2016)

None of the funds appropriated to the Department under its current Appropriations Act may be used to enter into a contract, grant, or cooperative agreement with an entity that requires employees or contractors of such entity seeking to report fraud, waste, and abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. By submitting a response to this solicitation, the contractor certifies that it does not require employees or contractors of the contractor seeking to report fraud, waste, and abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contractors from lawfully reporting waste, fraud, and abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(End of clause)

DEA-2852.211-71 SCHEDULED AND UNSCHEDULED CLOSURES OF GOVERNMENT OFFICES (NOV 2012)

(a) In accordance with 5 U.S.C. 6103, Federal Government offices are closed for ordinary business in observance of the following holidays:

- New Year’s Day
- Birthday of Martin Luther King, Jr.
(b) Federal offices may close at other times without advance notice due to emergencies, inclement weather, interruption of utilities, or other reasons. Such closures may be declared by the President, Office of Personnel Management, Office of Management and Budget, the Administrator of the DEA, or other appropriate executive authority. The duration of such closures may range from an early closure with normal operations expected on the next business day to a period of indeterminate length.

(c) At the time that a closure is declared, appropriate information, notifications, and instructions will be provided regarding the return to normal operations. The Contractor shall comply with all directives issued in regards to such closures. The Contractor shall follow agency procedures for registering emergency contact information and shall monitor appropriate broadcast mediums for receiving emergency information.

(d) When a closure is declared, contractor personnel must vacate the facility as directed except personnel designated in accordance with agency procedures by the contracting officer to remain onsite to continue performance. Evacuated personnel will not be allowed to reenter the facility for the duration of the closure. Performance of work at alternate sites is not permissible except in accordance with the terms of the contract and written authorization by the contracting officer.

(e) Whenever it is necessary for contractor employees to continue performance during such closures, the contracting officer will provide written authorization for such work. Such written authorization will designate the specific individuals authorized to continue performance, alternate work sites when applicable, work schedules, work dates, and special instructions and information. Telework may be authorized if permitted by the terms of the contract. Any services scheduled to be performed at Government facilities shall not be performed elsewhere unless specifically authorized in accordance with the terms of this contract.

(f) For firm fixed priced contracts, the terms for invoicing and payment in the contract will remain unchanged unless changed by a fully executed modification to the contract.

(g) For other than firm fixed priced contracts, the contractor shall invoice in accordance with the Payments and Prompt Payment clauses of the contract only for work performed. Employee compensation for the period of the closure shall be governed by corporate policy.

(h) Agency-sponsored events such as picnics or other social events are not considered to be official office closures. The Contractor shall not invoice for time spent by its employees attending or participating in such events.

(i) In no case will any compensable administrative leave, which might be approved for Federal employees in connection with official holidays or other events, extend to contractor personnel.

[End of clause]

□ DEA-2852.218-70 CONTINUING CONTRACT PERFORMANCE DURING A PANDEMIC INFLUENZA OUTBREAK OR OTHER BIOMEDICAL EMERGENCY OR CATASTROPHE (MAY 2012)

(a) It has been determined that the services provided under this contract are mission-critical and essential to the ongoing operations of the Drug Enforcement Administration.

(b) In the event of a pandemic influenza outbreak or other biomedical emergency or catastrophe, the Contractor shall continue performance of this contract without delay or interruption.

(c) The Government will provide notice, information, and instructions to the Contractor regarding any such event. If it is determined that changes to the performance requirements are necessary, the Government will implement the necessary changes by the issuance of Change Orders in accordance with the Changes clause of the contract, and the Contractor may assert its right for an equitable adjustment accordingly. Additional information and guidance is provided in the attached notice entitled, “Continuing Contract Performance during a Pandemic Influenza or Other National Emergency.”

(End of clause)
DEA-2852.219-70 SECTION 8(a) DIRECT AWARD (MAY 2012)

(a) Pursuant to the Partnership Agreement (PA) between the U.S. Small Business Administration (SBA) and the U.S. Department of Justice (DOJ), the U.S. Drug Enforcement Administration (DEA), a component of the DOJ, hereby executes a direct award to [enter name of 8(a) concern] under the authority delegated to it by the SBA in accordance with 13 CFR 124.501 and the PA. DEA will perform all contract execution and review functions pertaining to this award in accordance with the delegation. The DEA will notify the SBA of this award, as required by 13 CFR 124.503(a)(4)(ii), and provide SBA with a copy of the award.

(b) Notwithstanding the identification of the parties on the award form, the prime Contractor for this award is the U.S. Small Business Administration, and [enter name of 8(a) concern] is the Subcontractor.

(c) The cognizant SBA district office is:

[SBA district office]
[street address]
[city, state and zip code]

(d) [enter name of the 8(a) concern] shall:

(1) Notify the Contracting Officer, simultaneous with its notification to the SBA (as required by SBA’s 8(a) regulations at 13 CFR 124.308), when the owner or owners upon whom 8(a) eligibility is based plan to relinquish ownership or control of the concern. Consistent with Section 407 of Public Law 100-656, transfer of ownership or control shall result in termination of the contract for convenience, unless the SBA waives the requirement for termination prior to the actual relinquishing of ownership and control;

(2) Comply with the applicable performance requirements of clause 52.219-14, Limitations on Subcontracting as checked below: [Contracting officer: check only one performance standard based on the primary purpose of the contract.]

- Services (except construction) — At least 50 percent of the cost of contract performance incurred for personnel shall be expended for employees of the concern.

- Supplies (other than procurement from a nonmanufacturer of such supplies) — The concern shall perform work for at least 50 percent of the cost of manufacturing the supplies, not including the cost of materials.

- General construction — The concern will perform at least 15 percent of the cost of the contract, not including the cost of materials, with its own employees

- Construction by special trade contractors — The concern will perform at least 25 percent of the cost of the contract, not including the cost of materials, with its own employees.

(3) Provide the contracting officer with evidence of compliance with the applicable performance standard. This report shall show total dollars expended in the cost category specified in the performance standard both for the reporting period and cumulative to date along with the dollars and percentage of total dollars expended from the contractor’s resources. This report shall be submitted annually. A final report covering the entire period of the contract shall be submitted upon expiration of the contract.

(4) Not subcontract the performance of any of the requirements of this contract without the prior written approval of the Contracting Officer.

(e) Compliance with the Limitation on Subcontracting clause is a mandatory performance requirement of this contract.

(End of clause)

DEA-2852.222-70 APPLICABLE WAGE DETERMINATION (SERVICE CONTRACT LABOR STANDARDS) (JUN 2014)

(a) In accordance with clause 52.222-41, Service Contract Labor Standards, the minimum monetary wages and fringe benefits applicable to this contract are set forth in the attached Wage Determination(s):
DEA PROVISION & CLAUSE MATRIX – COMMERCIAL ITEMS
Updated through FAC 2005-101 (10/26/2018)

SOLICITATION #: 15DDHQ19Q00000012

<table>
<thead>
<tr>
<th>Wage Determination #</th>
<th>Revision #</th>
<th>Date</th>
<th>Section J Attachment #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(b) The Contractor shall attach a copy of this (these) wage determination(s) to Wage and Hour Division (WHD) poster WH-1313, Employee Rights on Government Contracts, and shall post both the publication and the wage determination(s) in a prominent and accessible location in the workplace as required by Federal Acquisition Regulation 22.1018(c), WH-1313 is available for downloading at http://www.dol.gov/whd/regs/compliance/posters/sca.htm [Spanish language version available at http://www.dol.gov/whd/regs/compliance/pdf/sca espanol.pdf].

(c) The Contractor shall classify each service employee who will perform under this contract by the applicable wage determination according to the work performed by the employee. If the applicable wage determination does not include an appropriate occupational code, title, and wage rate for a service employee, it is essential for all contractor personnel for this contract performing at Drug Enforcement Administration (DEA) designated worksites to receive supervision from their parent company and avoid employer-employee relationships with government officials. In addition, it is important for contractor personnel to recognize and avoid circumstances that may appear to be personal services. Federal Acquisition Regulation (FAR) subpart 37.104 provides important information to be aware of to avoid performing these types of duties. The contractor awarded this contract shall ensure their employees and subcontractors comply with this requirement and receive supervision from their parent company to avoid performance of a personal services contract.

(End of clause)

☑ DEA-2852.237-70 PREVENTING PERSONAL SERVICES CONTRACTS AND PERFORMANCE OF INHERENTLY GOVERNMENT FUNCTIONS (JUN 2018)

(a) A personal services contract is characterized by the employer-employee relationship it creates between the Government and the contractor’s personnel. This contract action is for non-personal services and is not a personal services contract action. Due to the need for close interaction of government and contractor personnel, it is essential for all contractor personnel for this contract performing at Drug Enforcement Administration (DEA) designated worksites to receive supervision from their parent company and avoid employer-employee relationships with government officials. In addition, it is important for contractor personnel to recognize and avoid circumstances that may appear to be personal services. Federal Acquisition Regulation (FAR) subpart 37.104 provides important information to be aware of to avoid performing these types of duties. The contractor awarded this contract shall ensure their employees and subcontractors comply with this requirement.

(b) “Inherently governmental function” means, as a matter of policy, a function so intimately related to the public interest as to mandate performance by Government employees. An inherently governmental function includes activities requiring either the exercise of discretion in applying Government authority, or the making of value judgments in making decisions for the Government. Governmental functions normally fall into two categories: the act of governing, i.e., the discretionary exercise of Government authority, and monetary transactions and entitlements. It is essential for all contractor personnel performing services at DEA designated worksites to recognize and understand what inherently government functions are. Federal Acquisition Regulation (FAR) subpart 7.5 - Inherently Governmental Functions and the Office of Management and Budget’s (OMB) Office of Federal Procurement Policy (OFPP) Policy Letter 11-01, Performance of Inherently Governmental and Critical Functions, provide important information regarding inherently governmental functions to be aware of to avoid performing these types of duties. The contractor awarded this contract shall ensure their employees and subcontractors comply with this requirement.

(c) Contractors providing personnel who perform services on-site at DEA offices must certify via the “Contractor Employee Certification Concerning Prohibition of Personal Services Contracts and Inherently Governmental Functions” form that its on-site employee(s) have read and understand FAR 37.104, Personal services contracts, and FAR subpart 7.5 before they may begin work at an on-site DEA office. The Contractor on-site supervisor shall address any questions or concerns with the Contracting Officer’s Representative (COR) or Contracting Officer.

(End of Clause)

☐ DEA-2852.239-71 INFORMATION RESELLERS OR DATA BROKERS (MAY2012)

(a) Under this contract, the Drug Enforcement Administration (DEA) obtains personally identifiable information about individuals from the contractor.

(b) The Contractor certifies that it has a security policy in place that contains procedures to promptly notify any individual whose personally identifiable information (as defined by OMB) was, or is reasonable believed to have been, breached. Any notification shall be coordinated with the DEA, and shall not proceed until the DEA has made a determination that notification would not impede a law enforcement investigation or jeopardize national security.

(c) The method and content of any notification by the contractor shall be coordinated with, and be subject to the approval of, the DEA/DOJ. The Contractor assumes full responsibility for taking corrective action consistent with the DEA’s Guidelines for Data Breach Notification (December 2, 2011), which may include offering credit monitoring when appropriate.

(End of clause)
I. APPLICABILITY TO CONTRACTORS AND SUBCONTRACTORS

This clause applies to all contractors and subcontractors, including cloud service providers ("CSPs"), and personnel of contractors, subcontractors, and CSPs (hereinafter collectively, "Contractor") that may access, collect, store, process, maintain, use, share, retrieve, disseminate, transmit, or dispose of U.S. Department of Justice (DOJ) information. It establishes and implements specific DOJ requirements applicable to this Contract. The requirements established herein are in addition to those required by the Federal Acquisition Regulation ("FAR"), including FAR 11.002(g) and 52.239-1, the Privacy Act of 1974, and any other applicable laws, mandates, Procurement Guidance Documents, and Executive Orders pertaining to the development and operation of Information Systems and the protection of Government information. This clause does not alter or diminish any existing rights, obligation or liability under any other civil and/or criminal law, rule, regulation or mandate.

II. GENERAL DEFINITIONS

The following general definitions apply to this clause. Specific definitions also apply as set forth in other paragraphs.

A. **Information** means any communication or representation of knowledge such as facts, data, or opinions, in any form or medium, including textual, numerical, graphic, cartographic, narrative, or audiovisual. Information includes information in an electronic format that allows it be stored, retrieved or transmitted, also referred to as “data,” and “personally identifiable information” ("PII"), regardless of form.

B. **Personally Identifiable Information (or PII)** means any information about an individual maintained by an agency, including, but not limited to, information related to education, financial transactions, medical history, and criminal or employment history and information, which can be used to distinguish or trace an individual’s identity, such as his or her name, social security number, date and place of birth, mother’s maiden name, biometric records, etc., including any other personal information which is linked or linkable to an individual.

C. **DOJ Information** means any Information that is owned, produced, controlled, protected by, or otherwise within the custody or responsibility of the DOJ, including, without limitation, Information related to DOJ programs or personnel. It includes, without limitation, Information (1) provided by or generated for the DOJ, (2) managed or acquired by Contractor for the DOJ in connection with the performance of the contract, and/or (3) acquired in order to perform the contract.

D. **Information System** means any resources, or set of resources organized for accessing, collecting, storing, processing, maintaining, using, sharing, retrieving, disseminating, transmitting, or disposing of (hereinafter collectively, “processing, storing, or transmitting”) Information.

E. **Covered Information System** means any information system used for, involved with, or allowing, the processing, storing, or transmitting of DOJ Information.

III. CONFIDENTIALITY AND NON-DISCLOSURE OF DOJ INFORMATION

Preliminary and final deliverables and all associated working papers and material generated by Contractor containing DOJ Information are the property of the U.S. Government and must be submitted to the Contracting Officer ("CO") or the CO’s Representative ("COR") at the conclusion of the contract. The U.S. Government has unlimited data rights to all such deliverables and associated working papers and materials in accordance with FAR 52.227-14.

A. All documents produced in the performance of this contract containing DOJ Information are the property of the U.S. Government and Contractor shall neither reproduce nor release to any third-party at any time, including during or at expiration or termination of the contract without the prior written permission of the CO.

B. Any DOJ information made available to Contractor under this contract shall be used only for the purpose of performance of this contract and shall not be divulged or made known in any manner to any persons except as may be necessary in the performance of this contract. In performance of this contract, Contractor assumes responsibility for the protection of the confidentiality of any and all DOJ Information processed, stored, or transmitted by the Contractor. When requested by the CO (typically no more than annually), Contractor shall provide a report to the CO identifying, to the best of Contractor’s knowledge and belief, the type, amount, and level of sensitivity of the DOJ Information processed, stored, or transmitted under the Contract, including an estimate of the number of individuals for whom PII has been processed, stored or transmitted under the Contract and whether such information includes social security numbers (in whole or in part).
IV. COMPLIANCE WITH INFORMATION TECHNOLOGY SECURITY POLICIES, PROCEDURES AND REQUIREMENTS

A. For all Covered Information Systems, Contractor shall comply with all security requirements, including but not limited to the regulations and guidance found in the Federal Information Security Management Act of 2014 ("FISMA"), Privacy Act of 1974, E-Government Act of 2002, National Institute of Standards and Technology ("NIST") Special Publications ("SP"), including NIST SP 800-37, 800-53, and 800-60 Volumes I and II, Federal Information Processing Standards ("FIPS") Publications 140-2, 199, and 200, OMB Memoranda, Federal Risk and Authorization Management Program ("FedRAMP"), DOJ IT Security Standards, including DOJ Order 2640.2, as amended. These requirements include but are not limited to:

1. Limiting access to DOJ Information and Covered Information Systems to authorized users and to transactions and functions that authorized users are permitted to exercise;
2. Providing security awareness training including, but not limited to, recognizing and reporting potential indicators of insider threats to users and managers of DOJ Information and Covered Information Systems;
3. Creating, protecting, and retaining Covered Information System audit records, reports, and supporting documentation to enable reviewing, monitoring, analysis, investigation, reconstruction, and reporting of unlawful, unauthorized, or inappropriate activity related to such Covered Information Systems and/or DOJ Information;
4. Maintaining authorizations to operate any Covered Information System;
5. Performing continuous monitoring on all Covered Information Systems;
6. Establishing and maintaining baseline configurations and inventories of Covered Information Systems, including hardware, software, firmware, and documentation, throughout the Information System Development Lifecycle, and establishing and enforcing security configuration settings for IT products employed in Information Systems;
7. Ensuring appropriate contingency planning has been performed, including DOJ Information and Covered Information System backups;
8. Identifying Covered Information System users, processes acting on behalf of users, or devices, and authenticating and verifying the identities of such users, processes, or devices, using multifactor authentication or HSPD-12 compliant authentication methods where required;
9. Establishing an operational incident handling capability for Covered Information Systems that includes adequate preparation, detection, analysis, containment, recovery, and user response activities, and tracking, documenting, and reporting incidents to appropriate officials and authorities within Contractor’s organization and the DOJ;
10. Performing periodic and timely maintenance on Covered Information Systems, and providing effective controls on tools, techniques, mechanisms, and personnel used to conduct such maintenance;
11. Protecting Covered Information System media containing DOJ Information, including paper, digital and electronic media; limiting access to DOJ Information to authorized users; and sanitizing or destroying Covered Information System media containing DOJ Information before disposal, release or reuse of such media;
12. Limiting physical access to Covered Information Systems, equipment, and physical facilities housing such Covered Information Systems to authorized U.S. citizens unless a waiver has been granted by the Contracting Officer ("CO"), and protecting the physical facilities and support infrastructure for such Information Systems;
13. Screening individuals prior to authorizing access to Covered Information Systems to ensure compliance with DOJ Security standards;
14. Assessing the risk to DOJ Information in Covered Information Systems periodically, including scanning for vulnerabilities and remediating such vulnerabilities in accordance with DOJ policy and ensuring the timely removal of assets no longer supported by the Contractor;
15. Assessing the security controls of Covered Information Systems periodically to determine if the controls are effective in their application, developing and implementing plans of action designed to correct deficiencies and eliminate or reduce vulnerabilities in such Information Systems, and monitoring security controls on an ongoing basis to ensure the continued effectiveness of the controls;
16. Monitoring, controlling, and protecting information transmitted or received by Covered Information Systems at the external boundaries and key internal boundaries of such Information Systems, and employing architectural designs, software development techniques, and systems engineering principles that promote effective security; and
SOLICITATION #: 15DDHQ19Q0000012

DEA PROVISION & CLAUSE MATRIX – COMMERCIAL ITEMS
Updated through FAC 2005-101 (10/26/2018)

17. Identifying, reporting, and correcting Covered Information System security flaws in a timely manner, providing protection from malicious code at appropriate locations, monitoring security alerts and advisories and taking appropriate action in response.

B. Contractor shall not process, store, or transmit DOJ Information using a Covered Information System without first obtaining an Authority to Operate ("ATO") for each Covered Information System. The ATO shall be signed by the Authorizing Official for the DOJ component responsible for maintaining the security, confidentiality, integrity, and availability of the DOJ Information under this contract. The DOJ standards and requirements for obtaining an ATO may be found at DOJ Order 2640.2, as amended. (For Cloud Computing Systems, see Section V, below.)

C. Contractor shall ensure that no Non-U.S. citizen accesses or assists in the development, operation, management, or maintenance of any DOJ Information System, unless a waiver has been granted by the by the DOJ Component Head (or his or her designee) responsible for the DOJ Information System, the DOJ Chief Information Officer, and the DOJ Security Officer.

D. When requested by the DOJ CO or COR, or other DOJ official as described below, in connection with DOJ’s efforts to ensure compliance with security requirements and to maintain and safeguard against threats and hazards to the security, confidentiality, integrity, and availability of DOJ Information, Contractor shall provide DOJ, including the Office of Inspector General ("OIG") and Federal law enforcement components, (1) access to any and all information and records, including electronic information, regarding a Covered Information System, and (2) physical access to Contractor’s facilities, installations, systems, operations, documents, records, and databases. Such access may include independent validation testing of controls, system penetration testing, and FISMA data reviews by DOJ or agents acting on behalf of DOJ, and such access shall be provided within 72 hours of the request. Additionally, Contractor shall cooperate with DOJ’s efforts to ensure, maintain, and safeguard the security, confidentiality, integrity, and availability of DOJ Information.

E. The use of Contractor-owned laptops or other portable digital or electronic media to process or store DOJ Information covered by this clause is prohibited until Contractor provides a letter to the DOJ CO, and obtains the CO’s approval, certifying compliance with the following requirements:

1. Media must be encrypted using a NIST FIPS 140-2 approved product;

2. Contractor must develop and implement a process to ensure that security and other applications software is kept up-to-date;

3. Where applicable, media must utilize antivirus software and a host-based firewall mechanism;

4. Contractor must log all computer-readable data extracts from databases holding DOJ Information and verify that each extract including such data has been erased within 90 days of extraction or that its use is still required. All DOJ Information is sensitive information unless specifically designated as non-sensitive by the DOJ; and,

5. A Rules of Behavior ("ROB") form must be signed by users. These rules must address, at a minimum, authorized and official use, prohibition against unauthorized users and use, and the protection of DOJ Information. The form also must notify the user that he or she has no reasonable expectation of privacy regarding any communications transmitted through or data stored on Contractor-owned laptops or other portable digital or electronic media.

F. Contractor-owned removable media containing DOJ Information shall not be removed from DOJ facilities without prior approval of the DOJ CO or COR.

G. When no longer needed, all media must be processed (sanitized, degaussed, or destroyed) in accordance with DOJ security requirements.

H. Contractor must keep an accurate inventory of digital or electronic media used in the performance of DOJ contracts.

I. Contractor must remove all DOJ Information from Contractor media and return all such information to the DOJ within 15 days of the expiration or termination of the contract, unless otherwise extended by the CO, or waived (in part or whole) by the CO, and all such information shall be returned to the DOJ in a format and form acceptable to the DOJ. The removal and return of all DOJ Information must be accomplished in accordance with DOJ IT Security Standard requirements, and an official of the Contractor shall provide a written certification certifying the removal and return of all such information to the CO within 15 days of the removal and return of all DOJ Information.

J. DOJ, at its discretion, may suspend Contractor’s access to any DOJ Information, or terminate the contract, when DOJ suspects that Contractor has failed to comply with any security requirement, or in the event of an Information System Security Incident (see Section V.E, below), where the Department determines that either event gives cause for such action. The suspension of access to DOJ Information may last until such time as DOJ, in its sole discretion, determines that the situation giving rise to such action has been corrected or no longer exists. Contractor understands that any suspension or termination in accordance with this provision shall be at no cost to the DOJ, and that upon request by the CO, Contractor must immediately return all DOJ Information to DOJ, as well as any media upon which DOJ Information resides, at Contractor’s expense.
V. CLOUD COMPUTING

A. **Cloud Computing** means an Information System having the essential characteristics described in NIST SP 800-145, *The NIST Definition of Cloud Computing*. For the sake of this provision and clause, Cloud Computing includes Software as a Service, Platform as a Service, and Infrastructure as a Service, and deployment in a Private Cloud, Community Cloud, Public Cloud, or Hybrid Cloud.

B. Contractor may not utilize the Cloud system of any CSP unless:

1. The Cloud system and CSP have been evaluated and approved by a 3PAO certified under FedRAMP and Contractor has provided the most current Security Assessment Report ("SAR") to the DOJ CO for consideration as part of Contractor’s overall System Security Plan, and any subsequent SARs within 30 days of issuance, and has received an ATO from the Authorizing Official for the DOJ component responsible for maintaining the security confidentiality, integrity, and availability of the DOJ Information under contract; or,

2. If not certified under FedRAMP, the Cloud System and CSP have received an ATO signed by the Authorizing Official for the DOJ component responsible for maintaining the security, confidentiality, integrity, and availability of the DOJ Information under the contract.

C. Contractor must ensure that the CSP allows DOJ to access and retrieve any DOJ Information processed, stored or transmitted in a Cloud system under this Contract within a reasonable time of any such request, but in no event less than 48 hours from the request. To ensure that the DOJ can fully and appropriately search and retrieve DOJ Information from the Cloud system, access shall include any schemas, meta-data, and other associated data artifacts.

VI. INFORMATION SYSTEM SECURITY BREACH OR INCIDENT

A. Definitions

1. **Confirmed Security Breach** (hereinafter, "Confirmed Breach") means any confirmed unauthorized exposure, loss of control, compromise, exfiltration, manipulation, disclosure, acquisition, or accessing of any Covered Information System or any DOJ Information accessed by, retrievable from, processed by, stored on, or transmitted within, to or from any such system.


B. **Confirmed Breach.** Contractor shall immediately (and in no event later than within 1 hour of discovery) report any Confirmed Breach to the DOJ CO and the CO’s Representative ("COR"). If the Confirmed Breach occurs outside of regular business hours and/or neither the DOJ CO nor the COR can be reached, Contractor must call DOJ-CERT at 1-866-US4-CERT (1-866-874-2378) immediately (and in no event later than within 1 hour of discovery of the Confirmed Breach), and shall notify the CO and COR as soon as practicable.

C. **Potential Breach.**

1. Contractor shall report any Potential Breach within 72 hours of detection to the DOJ CO and the COR, unless Contractor has (a) completed its investigation of the Potential Breach in accordance with its own internal policies and procedures for identification, investigation and mitigation of Security Incidents and (b) determined that there has been no Confirmed Breach.

2. If Contractor has not made a determination within 72 hours of detection of the Potential Breach whether an Confirmed Breach has occurred, Contractor shall report the Potential Breach to the DOJ CO and COR within one-hour (i.e., 73 hours from detection of the Potential Breach). If the time by which to report the Potential Breach occurs outside of regular business hours and/or neither the DOJ CO nor the COR can be reached, Contractor must call the DOJ Computer Emergency Readiness Team (DOJ-CERT) at 1-866-US4-CERT (1-866-874-2378) within one-hour (i.e., 73 hours from detection of the Potential Breach) and contact the DOJ CO and COR as soon as practicable.

D. Any report submitted in accordance with paragraphs (B) and (C), above, shall identify (1) both the Information Systems and DOJ Information involved or at risk, including the type, amount, and level of sensitivity of the DOJ Information and, if the DOJ Information contains PII, the estimated number of unique instances of PII, (2) all steps and processes being undertaken by Contractor to minimize, remedy, and/or investigate the Security Incident, (3) any and all other information as required by the US- CERT Federal Incident Notification Guidelines, including the functional impact, information impact, impact to recoverability, threat vector, mitigation details, and all available incident details; and (4) any other information specifically requested by the DOJ. Contractor shall continue to provide written updates to the DOJ CO regarding the status of the Security Incident at least every three (3) calendar days until informed otherwise by the DOJ CO.
E. All determinations regarding whether and when to notify individuals and/or federal agencies potentially affected by a Security Incident will be made by DOJ senior officials or the DOJ Core Management Team at DOJ’s discretion.

F. Upon notification of a Security Incident in accordance with this section, Contractor must provide to DOJ full access to any affected or potentially affected facility and/or Information System, including access by the DOJ OIG and Federal law enforcement organizations, and undertake any and all response actions DOJ determines are required to ensure the protection of DOJ Information, including providing all requested images, log files, and event information to facilitate rapid resolution of any Security Incident.

G. DOJ, at its sole discretion, may obtain, and Contractor will permit, the assistance of other federal agencies and/or third party contractors or firms to aid in response activities related to any Security Incident. Additionally, DOJ, at its sole discretion, may require Contractor to retain, at Contractor’s expense, a Third Party Assessing Organization (3PAO), acceptable to DOJ, with expertise in incident response, compromise assessment, and federal security control requirements, to conduct a thorough vulnerability and security assessment of all affected Information Systems.

H. Response activities related to any Security Incident undertaken by DOJ, including activities undertaken by Contractor, other federal agencies, and any third-party contractors or firms at the request or direction of DOJ, may include inspections, investigations, forensic reviews, data analyses and processing, and final determinations of responsibility for the Security Incident and/or liability for any additional response activities. Contractor shall be responsible for all costs and related resource allocations required for all such response activities related to any Security Incident, including the cost of any penetration testing.

VII. PERSONALLY IDENTIFIABLE INFORMATION NOTIFICATION REQUIREMENT

Contractor certifies that it has a security policy in place that contains procedures to promptly notify any individual whose Personally Identifiable Information (“PII”) was, or is reasonably determined by DOJ to have been, compromised. Any notification shall be coordinated with the DOJ CO and shall not proceed until the DOJ has made a determination that notification would not impede a law enforcement investigation or jeopardize national security. The method and content of any notification by Contractor shall be coordinated with, and subject to the approval of, DOJ. Contractor shall be responsible for taking corrective action consistent with DOJ Data Breach Notification Procedures and as directed by the DOJ CO, including all costs and expenses associated with such corrective action, which may include providing credit monitoring to any individuals whose PII was actually or potentially compromised.

VIII. PASS-THROUGH OF SECURITY REQUIREMENTS TO SUBCONTRACTORS AND CSPS

The requirements set forth in the preceding paragraphs of this clause apply to all subcontractors and CSPs who perform work in connection with this Contract, including any CSP providing services for any other CSP under this Contract, and Contractor shall flow down this clause to all subcontractors and CSPs performing under this contract. Any breach by any subcontractor or CSP of any of the provisions set forth in this clause will be attributed to Contractor.

☐ DEA-2852.239-74 CERTIFICATION OF OPERABILITY ON SYSTEMS USING THE FEDERAL DESKTOP CORE CONFIGURATION OR THE UNITED STATES GOVERNMENT CONFIGURATION BASELINE (MAY 2012)

(a) The provider of information technology shall certify applications are fully functional and operate correctly as intended on systems using the Federal Desktop Core Configuration (FDCC) or the United States Government Configuration Baseline (USGCB). This includes Internet Explorer 7 and 8 configured to operate on Windows XP, Windows Vista, and Windows 7 (in Protected Mode on Windows Vista and Windows 7).

- For Windows 7 settings, see: [http://usgcb.nist.gov/usgcb_content.html](http://usgcb.nist.gov/usgcb_content.html).

(b) The standard installation, operation, maintenance, updating, and/or patching of software shall not alter the configuration settings from the approved FDCC or USGCB configuration. The information technology should also use the Windows Installer Service for installation to the default “program files” directory and should be able to silently install and uninstall.

(c) Applications designed for normal end users shall run in the standard user context without elevated system administration privileges.
DEA PROVISION & CLAUSE MATRIX – COMMERCIAL ITEMS
Updated through FAC 2005-101 (10/26/2018)

SOLICITATION #: 15DDHQ19Q00000012

DEA-2852.242-70 CONTRACTOR PERFORMANCE ASSESSMENT (JUL 2014)

(a) Pursuant to FAR subpart 42.15, the Government will assess the Contractor’s performance under this contract. Performance assessment information may be used by the Government for decision-making on exercise of options, source selection, and other purposes, and will be made available to other federal agencies for similar purposes.

(b) Performance will be assessed in the following areas:
   (1) Quality of product or service;
   (2) Schedule;
   (3) Cost control;
   (4) Business relations;
   (5) Management of key personnel; and
   (6) Other appropriate areas.

(c) For contracts that include the clause at 52.219-9, Small Business Subcontracting Plan, performance assessments will consider performance against, and efforts to achieve, small business subcontracting goals set forth in the small business subcontracting plan.

(d) For any contract with a performance period exceeding 18 months, inclusive of all options, the Government will perform interim performance assessments annually and a final performance assessment upon completion of the contract.

(e) The Government will prepare contractor performance assessment reports electronically using the Contractor Performance Assessment Reporting System (CPARS), which is the approved feeder system for the Past Performance Information Retrieval System (PPIRS). Additional information on CPARS may be found at www.cpars.gov and on PPIRS at www.ppirs.gov.

(f) The Contractor will be provided access to CPARS to review performance assessments. The Contractor shall designate a CPARS point-of-contact for each contract subject to performance assessment reporting. Upon setup of a contract in CPARS, the Contractor’s CPARS point-of-contact will receive a system-generated e-mail with information and instructions for using CPARS. Prior to finalizing any contractor performance assessment, the Contractor shall be given 14 calendar days to review the report and submit comments, rebutting statements, or additional information. Disagreements between the Contractor and the Government performance assessment official will be resolved by a Government Reviewing Official, whose decision on the matter will be final. Upon finalization of each performance assessment, CPARS will upload the performance assessment data to PPIRS.

(g) The Government will also report in the Federal Awardee Performance and Integrity Information System (FAPIIS) module of PPIRS information related to:
   (1) A Contracting Officer’s final determination that a contractor has submitted defective cost or pricing data;
   (2) Any subsequent change to a final determination concerning defective cost or pricing data pursuant to 15.407-1(d);
   (3) Any issuance of a final termination for default or cause notice; or
   (4) Any subsequent withdrawal or a conversion of a termination for default to a termination for convenience.

DEA-2852.242-71 INVOICE REQUIREMENTS (MAY 2012)

(a) The Contractor shall submit scanned or electronic images of invoice(s) to the following e-mail addresses:
   (1) INVOICE.DIVERSION@USDOJ.GOV;
   (2) JACQUELINE SCHOTTLER; 202-598-8829; JACQUELINE.P.SCHOTTLER@USDOJ.GOV; and
   (3) XXXX.

(b) The date of record for invoice receipt is established on the day of receipt of the e-mail if it arrives before the end of standard business hours (5 p.m. local), or the next business day if the invoice arrives outside of normal business hours. Scanned documents with original signatures in .pdf or other graphic formats attached to the e-mail are acceptable. Digital/electronic signatures and certificates cannot be processed by DEA and will be returned.

(c) In addition to the items required in FAR 32.905(b), a proper invoice shall also include the following minimum additional information and/or attached documentation:
   (1) Total/cumulative charges for the billing period for each Contract Line Item Number (CLIN);
   (2) Dates upon which items/services were delivered; and
SOLICITATION #: 15DDHQ19Q0000012

(3) The Contractor’s Taxpayer Identification Number (TIN).

(d) Invoices will be rejected if they are illegible or otherwise unreadable, or if they do not contain the required information or signatures.

(End of Clause)

**DEA-2852.242-72 FINAL INVOICE AND RELEASE OF RESIDUAL FUNDS (MAY 2012)**

(a) The Contractor shall submit a copy of the final invoice to the Contracting Officer at the address listed in clause DEA-2852.242-71, Invoice Requirements. The final invoice must be marked “Informational Copy – Final Invoice.”

(b) By submission of the final invoice and upon receipt of final payment, the Contractor releases the Government from any and all claims arising under, or by virtue of, this contract. Accordingly, the Government shall not be liable for the payment of any future invoices that may be submitted under the above referenced order.

(c) If residual funds on the contract total $100 or less after payment of the final invoice, the Government will automatically deobligate the residual funds without further communication with the vendor.

(d) If funds greater than $100 remain on this order after payment of the final invoice, the Government will issue a bilateral modification to deobligate the residual funds. The contractor will have up to 30 calendar days after issuance of the modification to sign and return it. The contractor’s signature on the modification shall constitute a release of all claims against the Government arising by virtue of this contract, other than claims, in stated amounts, that the Contractor has specifically exempted from the operation of the release. If the contractor fails to sign the modification or assert a claim within the stated period, the Government will deobligate the residual balance and proceed with close-out of the contract.

(End of clause)

**DEA-2852.242-80 CONTRACTOR TELEWORK**

(a) Definitions.

"Telework" means a work flexibility arrangement, including situational telework (weather or event-related) that allows Contractor and/or Subcontractors to perform the duties and responsibilities of their position from an approved alternative work site. The arrangement may not include hours that exceed the normal hours worked during an invoice pay period.

"Contracting Officer’s Representative" (COR) means an individual designated and authorized in writing by the Drug Enforcement Administration (DEA) to perform specific technical or administrative functions.

"Contractor" means an employee of the Parent Company currently working onsite at a DEA facility.

"Contractor Program Manager" means the onsite supervisor or designated supervisor for Contractors.

"Parent Company" means a business entity holding a current contract with the DEA under which its employees (the Contractor) is performing.

"Program Office" includes the Office Head, Special Agent in Charge, Laboratory Director, Regional Director, Country Attaché or their designees.

"Task Monitor" means an individual designated and authorized in writing by DEA to conduct and document day to day contract administration functions in the field.

(b) The Program Office may approve a telework plan and have overall responsibility for the administration of this clause within their organizational jurisdiction.

(c) The COR/TM, in conjunction with the Program Office must make a written determination that:

1. Certain work functions or the missions of certain work units are suitable for a telework arrangement;
2. The Contractor is suitable for telework based on individual performance, program requirements and mission objectives;
3. Summary of work performed during teleworked hours is submitted to the COR/TM on a bimonthly basis;
4. The Contractor shall sign and submit the completed DEA Contractor Telework Agreement Form;
5. The COR/TM shall retain the signed DEA Contractor Telework Agreement Form in the contract file for record keeping;
6. The Contractor shall obtain the necessary technology prior to teleworking:
   i. Firebird Anywhere - [http://intranet/sites/si/Mobile/fba/Pages/default.aspx](http://intranet/sites/si/Mobile/fba/Pages/default.aspx); OR
   ii. DEA issued Laptop--If the contractor’s current computer is a desktop, the Program Office may request a laptop using a DEA-19 form for the Contractor to take home when teleworking.
The COR/TM and the Contractor shall review and re-sign, if approved, the DEA Contractor Telework Agreement on an annual basis. (7)

The Program Office or the Contractor reserve the right to terminate the Contractor Telework Agreement at any time. (8)

Within thirty (30) days of the date this clause is incorporated into the contract, the Program Office shall submit to the COR/TM and the cognizant Contracting Officer a plan for how it will implement authorizations for approved telework locations. The plan will describe the specific work and tasks that may be suitable for performance at a temporary work location, the personnel who may be assigned to perform the work, the methods the Program Office will use to manage, supervise, and perform quality control, and any other relevant information. Hours worked, as well as performance shall be tracked on a daily basis. (9)

Under no circumstance will the Contractor be authorized to perform any work requiring access to DOJ/DEA information or information systems unless such access will be made exclusively using DEA equipment or property issued for this purpose. (d)

No authorization for telework shall be construed as an indication of past performance, an increase in the price of the contract, an approval of overtime, a change in the contract schedule, or approval of an accelerated rate of expenditures. (e)

Local commuting expenses incurred in traveling to or from any approved telework location are not reimbursable. Any incidental costs incurred in performing work at approved telework locations will be reimbursable in accordance with the Allowable Cost and Payment clause and the Payments clause of the contract, provided that such costs are segregated and allocable to the contract. (f)

The contractor is responsible for protecting and using any DEA-owned or provided equipment or other property for official purposes only. DEA is responsible for servicing, and maintaining any DEA-provided equipment issued to the Contractor. DEA is not liable for injuries or damages to the Contractor’s personal or real property while the Contractor is working at the approved telework location. (g)

(Under no circumstance will the Contractor be authorized to perform any work requiring access to DOJ/DEA information or information systems unless such access will be made exclusively using DEA equipment or property issued for this purpose.)

All deliverables shall clearly indicate the contract number and/or task (delivery) order number, as appropriate, on or adjacent to the exterior shipping label. (b)

It is DOJ policy to enhance workplace awareness of and safety for victims of domestic violence, sexual assault, and stalking. This policy is summarized in “DOJ Policy Statement 1200.02, Federal Workforce Responses to Domestic Violence, Sexual Assault, and Stalking”, available in full for public viewing at: http://www.justice.gov/sites/default/files/ovw/legacy/2013/12/19/federal-workplace-responses-to-domesticviolence-sexualassault-stalking.pdf. (a)

Vendor agrees, upon contract award, to provide notice of this Policy Statement, including at a minimum the above-listed URL, to all Vendor’s employees and employees of subcontractors who will be assigned to work on DOJ premises. (b)

Upon contract award, DOJ will provide the Contractor with the name and contact information of the point of contact for victims of domestic violence, sexual assault, and stalking; for the component or components where the Contractor will be performing. The Contractor agrees to inform its employees and employees of subcontractors, who will be assigned to work on DOJ premises, with the name and contact information of the point of contact for victims of domestic violence, sexual assault, and stalking. (c)
SOLICITATION #: 15DDHQ19Q00000012

☐ JAR 2852.233-70 PROTESTS FILED DIRECTLY WITH THE DEPARTMENT OF JUSTICE (JAN 1998)

(Full text may be found at http://www.ecfr.gov/cgi-bin/text-idx?SID=a2b96ac0d03ae14bfc1e2ac908f1b3e0&mc=true&node=se48.6.2852_1233_670&rgn=div8)

CONTRACTING OFFICER: List the recommended security clause in the approved DD 254 in the space provided below by clause number, title, and date of clause.

CONTRACTOR: The full text of the clause may be found at http://www.dea.gov/resource-center/doing-business_acq_securityClauses.shtml.

DEA-2852.204.94 (January 2013) SECURITY REQUIREMENTS FOR NON-SENSITIVE POSITION ESCORTED ACCESS—U. S. CITIZENSHIP REQUIRED