

OFFICE OF ACQUISITIONS  
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CM67000-11

Amendment No.: 2

Date of Issuance: 03/09/2016

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors is changed to: **2:00 PM EST March 23, 2016.**

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified for receipt of offers in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

**FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.**

This Amendment revises the RFP as stated below:

The purpose of this amendment is to extend the hour and date specified for receipt of proposals to **2:00 PM EST on March 23, 2016**, revise Article B.2. Prices/Costs, Section L - Instructions, Conditions, and Notices to Offerors, subparagraph Sample Task Orders, Section L - Instructions, Conditions, and Notices to Offerors, subparagraph (2)(b) Technical Proposal Instructions, Section M - Evaluation Factors for Award, Additional Technical Proposal Instructions and provide responses to questions received under this RFP.

**ARTICLE B.2. PRICES/COSTS** subparagraph (a) is hereby revised to reduce the minimum to be reimbursed to an amount no less than a total of \$1,000 per contract.

**SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS**, paragraph (1.) General Information, subparagraph Sample Task Orders is hereby revised as follows:

Please submit a complete business proposal (i.e. including qualifying documentation, salary verification, supply price lists, etc) for ALL TASK ORDERS (1-5). Certificate of Current Price and Data is required for TASK ORDERS 1 & 2 ONLY. Task Orders 1 & 2 will be awarded as Cost Reimbursement and Task Orders 3, 4, 5 will be awarded as Fixed Price.

**SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS**, subparagraph (b.) Technical Proposal Instructions item (7) Instructions to Offerors-Sustainable Acquisition, HHSAR Provision 352.223-71 (December 2015) is hereby added.

**(7) Sustainable Acquisition Plan**

Offerors must include a Sustainable Acquisition Plan in their technical proposals. The Plan must describe their approach and the quality assurance mechanisms in place for applying FAR 23.1 Sustainable Acquisition Policy (and other Federal Laws, regulations and Executive Orders governing sustainable acquisition purchasing) to this acquisition. The Plan shall clearly identify those products and services included in Federal sustainable acquisition preference programs by categorizing them along with their respective price/cost in the following eight groups: Recycled Content, Energy Efficient, Biobased, Environmentally Preferable, Electronic Product Environment Assessment Tool, Water-Efficient, Non-Ozone Depleting Substances, and Alternative Fuels.

(End of Provision)

**SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS**, subparagraph (b.) Technical Proposal Instructions item (8) BioPreferred Products is hereby added.

## **(8) BioPreferred Products**

Offerors shall submit a list of the biobased products to be purchased and used under this contract. For each biobased product, the Offeror shall specify the percentage of biobased content, and for the USDA-designated biobased content products, the offeror shall demonstrate that the products to be used under this contract contain the percentage specified in the USDA recommendations or the highest level of biobased material practicable, consistent with USDA's recommended percentages of biobased content.

The offeror shall document prior experience in specifying, purchasing, using, and installing biobased products by providing a list of all relevant contracts over the past two years involving the specification, purchase, and/or use of biobased products including a list of the biobased products specified, purchased, used, and installed.

**SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS**, subparagraph (c.) Business Proposal Instructions) (1.) Basic Cost/Price Information, is hereby amended to add the following as paragraph two:

The Offeror must adhere to a 120-page limit for the Business Proposal. Pages in excess of this limitation will be removed from the proposal and will not be provided to the reviewers to be read or evaluated. Pages shall be of standard size (8.5x11) with a font size of 10 points or larger. Proposal pages shall be numbered. Hardcopies of proposals should be printed double-sided (2 sides = 2 pages), single-spaced flip up. The 120-page limit excludes the cover sheet, resumes, and all appendices or attachments.

This does not include the Task Orders which have their own page limit. Please reference the page limits indicated on each separate Task Order.

**SECTION M - EVALUATION FACTORS FOR AWARD**, subparagraph (5) Technical Evaluation Factors (A) PERSONNEL - are hereby added as follows:

- He or she must have attained doctorate level (or equivalent) educational status in pharmacology, pharmaceutical sciences, or a closely related discipline.

**SECTION M - EVALUATION FACTORS FOR AWARD**, subparagraph (5) Technical Evaluation Factors (C) FACILITIES AND EQUIPMENT - hereby adds the following:

- Describe in detail the laboratory space and equipment available for the performance of the work proposed. A floor plan to scale, indicating relevant dimensions must be provided for all laboratory space available to this project, identifying the areas where different facets of work are conducted.

**SECTION M - EVALUATION FACTORS FOR AWARD**, subparagraph (5) Technical Evaluation Factors hereby adds subparagraph (8) Sustainable Acquisition Plan:

Sustainable Acquisition Plan -

The Offeror's proposal must demonstrate compliance with FAR 23.1, "Sustainable Acquisition Policy" and the interim rule entitled, "Sustainable Acquisition" at <http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-12851.pdf> (FAR case 2010-001, FAC 2005-52). If the proposal does not include a Sustainable Acquisition Plan that addresses the environmental products and services to be utilized under the resulting contract, or if the Plan is considered "unacceptable" and the Government includes your proposal in the competitive range, the Offeror will be afforded the opportunity to further discuss, clarify or modify the Plan during discussions and in their Final Proposal Revision (FPR). The Government is seeking to determine whether the Offeror has demonstrated a commitment to advance sustainable products and services. The following evaluation criteria will be used in review of the Sustainable Acquisition Plan:

**SECTION M - EVALUATION FACTORS FOR AWARD**, subparagraph (5) Technical Evaluation Factors hereby adds subparagraph (9) Sustainable Acquisition Plan:

Offeror's Sustainable Acquisition Plan information will be evaluated on an acceptable/unacceptable basis subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is

determined to be technically unacceptable. The evaluation will be based on information obtained from the information provided by the offeror.

(a) Identification of all biobased products to be acquired, used, and installed in the performance of operations, maintenance, and contraction;

(b) Identification of past biobased contracts performed using biobased products, dollar amount, and experience with the product(s).

**ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS**, are hereby added as follows:

The Offeror must adhere to a 120-page limit for the Technical Proposal. Pages in excess of this limitation will be removed from the proposal and will not be provided to the reviewers to be read or evaluated.

Pages shall be of standard size (8.5x11) with a font size of 10 points or larger. Proposal pages shall be numbered. Hardcopies of proposals should be printed double-sided (2 sides = 2 pages), single-spaced flip up. The 120-page limit excludes the cover sheet, resumes, and all appendices or attachments.

This does not include the Task Orders which have their own page limit. Please reference the page limits indicated on each separate Task Order.

**ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS**, are hereby added to include the following Sustainable Acquisitions language:

#### **SUSTAINABLE ACQUISITION**

**Offerors must include a Sustainable Acquisition Plan in their technical proposals that describes their approach and the quality assurance mechanisms in place for applying FAR 23.1 - sustainable Acquisition Policy (and other Federal laws, regulations and Executive orders governing green purchasing) to this acquisition.**

#### **DEFINITIONS:**

##### **A. Recycled Content Products**

Recycled content products are products that are made from or contain recovered materials. That means replacing virgin materials with recycled materials, including post-consumer materials. There are currently more than 60 designated products in eight categories: paper and paper products, vehicular, construction, landscaping, park and recreation, transportation, non-paper office, and miscellaneous products. Examples of designated products include structural fiberboard, printing and writing papers. The current list of designated products, EPA's guidance, and related technical information can be found on EPA's web site at <http://www.epa.gov>.

##### **B. Energy-Efficient Products: Energy Star®, FEMP-Designated, and Low Standby Power**

EPAct of 2005, Section 104 and FAR 23.203 require federal agencies to purchase Energy Star® qualified or Department of Energy's (DOE's) Federal Energy Management Program (FEMP)-designated products when procuring energy-consuming products.

The technical requirements that each product must meet to become Energy Star® qualified are available at ENERGY STAR Qualified Products : ENERGY STAR. Information on FEMP-designated products can be found at <http://www.eere.energy.gov/>. Information on low standby power products can be found on FEMP's web site at: <http://www.eere.energy.gov/>.

##### **C. Biobased Products**

Biobased products are products determined by the Secretary of Agriculture to be commercial or industrial products (other than food or feed) that are composed in whole, or in significant part, of biological products or renewable domestic agricultural materials and forestry materials. Examples of USDA-designated biobased products include

mobile equipment, hydraulic fluids, roof coatings, diesel fuel additives, and towels. USDA is responsible for implementing the BioPreferred procurement preference program. Information on these designated products, USDA's guidance, and related documentation can be found at USDA's web site at <http://www.biopreferred.gov>. (The FAR is being revised to require that Federal agencies procure designated items composed of the highest percentage of biobased content practicable [FAR Case 2010-004].)

#### **D. Environmentally Preferable Products and Services**

Environmentally Preferable Products (EPP) are products or services that have a lesser or reduced effect on human health and the environment when compared with competing products or services that serve the same purpose. This comparison may consider raw materials acquisition, production, manufacturing, packaging, distribution, reuse, operation, maintenance, or disposal of the products or services. Examples of environmentally preferable products include cleaning products that are non-toxic, non-volatile, and biodegradable; and paint with no or low volatile organic compounds. This program is managed by EPA which maintains a database of products and specifications defined by federal, state, and local agencies, and other nations. The database can be found at <http://www.epa.gov/epp> along with EPA's **Guidance on the Acquisition of Environmentally Preferable Products and Services** located at <http://www.epa.gov/epp/pubs/index.htm>.

#### **E. Electronic Product Environmental Assessment Tool (EPEAT) Products**

EPEAT is a tool for evaluating the environmental performance of electronic products throughout their life cycle. EPEAT is intended to help purchasers in the public and private sectors evaluate, compare and select desktop computers, notebooks and monitors based on their environmental attributes. EPEAT also provides a clear and consistent set of performance criteria for the design of products, and provides an opportunity for manufacturers to secure market recognition for efforts to reduce the environmental impact of its products. Available at: <http://www.epeat.net/>.

#### **F. Water-Efficient Products**

A water-efficient product is in the upper 25% of water efficiency for all similar products, or is at least 10% more efficient than the minimum level meeting U.S. Federal Government standards. Examples of products that have met the EPA WaterSense label include: high efficiency toilets, sink faucets, showerheads, urinals, and landscape irrigation systems. Information about the WaterSense Program is available at [www.epa.gov/watersense](http://www.epa.gov/watersense).

#### **G. Non-Ozone Depleting Substances**

E.O. 13423 and the Council on Environmental Quality (CEQ) Implementing Instructions require that each agency give preference to the purchase of non-ozone depleting substances, as identified in EPA's Significant New Alternatives Policy (SNAP) program. **FAR 23.803** states that agencies shall give preference to the procurement of alternative products that reduce overall risks to human health and the environment by lessening the depletion of ozone in the upper stratosphere. It further requires that in preparing specifications and purchase descriptions, and the acquisition of supplies and services, agencies shall comply with the requirements of the Clean Air Act and substitute safe alternatives to ozone-depleting substances.

SNAP provides lists of acceptable and unacceptable substitutes in the following sectors: fire suppressants, aerosol solvents and propellants, refrigeration and air conditioning equipments, and adhesives and coatings. SNAP is managed by EPA. Information about the SNAP Program is available on <http://www.epa.gov/ozone/strathome.html>.

#### **H. Alternative Fuel Vehicles and Alternative Fuels**

Under EPCAct, alternative fuel vehicles are defined as any dedicated, flexible-fuel, or dual-fuel vehicle designed to operate on at least one alternative fuel. As defined by EPCAct, alternative fuels are substantially non-petroleum based fuels and include (but are not limited to) the following: ethanol at a 85% blend or higher (E85); liquefied petroleum gas (propane); compressed natural gas (CNG); biodiesel; electricity; hydrogen; and P-series fuels. DOE's FEMP manages this program. Information on these federal fleet requirements can be found at [http://www1.eere.energy.gov/femp/program/fedfleet\\_requirements.html](http://www1.eere.energy.gov/femp/program/fedfleet_requirements.html).

## Responses to Questions

### Question 1:

In TORFP 3: Are the contractors to implement an existing method as stated under "The following specific efforts", point 1 "implement LC-MS/MS methodology for the quantification of the compound in plasma and tumor samples and perform limited validation as required"

OR As stated under "Evaluation Factors" Point 2 "Schedule (weight 30%): Documented ability to rapidly initiate method development once notified the samples will be available." Implementing an existing method is different from developing a method from scratch and require different efforts. Which are we to do? Implement a method or develop a method?

### Answer 1:

The extent of method development will vary depending on the circumstances for each Task Order. If prior methodological information is available it will be provided to guide method "implementation." In the absence of a prior method, the contractor will need to "develop" a method. However, it is expected that the rigor of method development and validation will be commensurate with its intended application. For discovery PK Task Orders (as illustrated in TORFP 3) it is anticipated that contractors will have experience with generic LC-MS/MS platforms that facilitate rapid development of bioanalytical methods for small drug-like molecules. Assays for late-stage studies or clinical samples will obviously require more extensive validation. Your proposed approach and cost estimates should be tailored to the requirements of each sample Task Order.

### Question 2:

For pricing this RFP on a yearly basis and for the 5 years, it is not clear to us which tasks will be performed during the 1st year in order to calculate the personnel required and their time commitments as well as the budget.

For determining the budget, will all tasks be performed in the first year?

Will only the base periods of each task be in the first year or will options be executed as well?

Will tasks overlap during the first year so that both base period and options of several tasks can be conducted simultaneously?

Do we assume that for cost and personnel estimates, the same number of tasks and/or options will be performed in years 2-5?

### Answer 2:

Please propose for the Statement of Work (SOW) and propose on all five Sample Task Orders in a separate section. Please refer to Section L, "Sample Task Orders," within the RFP for further instructions.

### Question 3:

Sample Task Order #4 specifies the implementation of a validated LC-MC/MS methodology for the quantification of the test compound. This means that the method validation for this task will need to be monitored by our Quality Assurance (QA) personnel. Please clarify if the sample analysis, pharmacokinetic analysis, data and study reports will also need to be audited by QA for this task.

### Answer 3:

The studies assigned will not require GLP, so even having a QA unit is not required.

### Question 4:

Could you advise what the Small Business Plan should be based on. The sum of the sample task orders or the Maximum Award of \$9.9M?

### Answer 4:

The Small Business Subcontracting Plan should be based on the \$9.9M. Please reference the Business Proposal Instructions, "Small Business Subcontracting Plan," within the RFP.

### Question 5:

The Sample TO#1 and TO#2 are both listed as Cost Reimbursement. Please confirm these tasks will be CPFF.

### Answer 5:

The type of Task Order will be identified when the individual Task Order Request for Proposals (TORFP) are issued. For the Cost Reimbursement Task Orders, if your proposal is technically acceptable and your organization is eligible to earn fixed fee, then the Task Order may be awarded as Cost Plus Fixed Fee.

**Question 6:**

- Document Name: Section L - Instructions, Conditions, and Notices to Offerors
- Page: 37
- Paragraph: 3 (Line 4)
- Clause: Sample Task Orders
- Query: We find there is a discrepancy in the request to provide separate Cost Proposals for each task order, versus the direction to submit a complete business proposal for Sample Task Order #1. Can you please clarify?

**Answer 6:**

Please refer to Section L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS, subparagraph Sample Task Orders as amended above.

**Question 7:**

- Document Name: Section L - Instructions, Conditions, and Notices to Offerors
- Page: 45
- Paragraph: 3
- Clause: Authorized Official and Submission of Proposal
- Query: Are there page and font limitations for the technical and business proposal?

**Answer 7:**

Please reference Section L - Instructions, Conditions, and Notices to Offerors, subparagraph (c.) Business Proposal Instructions) (1.) Basic Cost/Price Information and the Additional Technical Proposal Instructions amended above.

**Question 8:**

- Document Name: Scope of Work (Attachment 3)
- Page: 2
- Paragraph: 8
- Clause: Sample Task Orders (Task 2)
- Query: Does the offeror have a cell line to recommend to use for costing purposes?

**Answer 8:**

No, but assume a cancer cell line readily available from a commercial source and which grows well in a xenograft model.

**Question 9:**

- Document Name: Scope of Work (Attachment 3)
- Page: 2
- Paragraph: 10
- Clause: Sample Task Orders (Task 4)
- Query: Do the tasks described in Task 4 need to comply with any regulatory standards?

**Answer 9:**

Assume the assay for Task 4 will be validated consistent with FDA guidelines for bioanalytical methods in human clinical trials.

**Question 10:**

Are there any Mandatory Qualifications?

**Answer 10:**

No, there are no mandatory qualifications.

**Question 11:**

Will we be asked to use radiolabeled drugs?

**Answer 11:**

Your capability in this area should be discussed in the technical proposal. The Sample Task Orders do not include use of radiolabelled drugs.

**Question 12:**

How many Prime contracts does the Government expect to award?

**Answer 12:**

Please reference Section L. Instructions, Conditions, and Notices to Offerors, section titled, "Type of Contract and Number of Awards."

**Question 13:**

Task Orders #1 & #2 are currently listed as Cost Reimbursement contracts. Would the Government accept a Fixed Price contract for these Task Orders?

**Answer 13:**

No.

**Question 14:**

There are multiple items in the SOW that are not addressed in any of the Sample Task Orders. For example, formulations (#6), in vitro PPB (#7), more extensive met ID (#9), and sample storage (#10). Should we address these areas in the technical discussions section of the technical approach? Will we be required to provide costs for these items?

**Answer 14:**

Yes, address these areas in the technical discussion section of the technical approach. Please address and provide costs for all five of the task orders.

**Question 15:**

Task Order #1: Is a standalone PK report required or are tables/figures included in the main report preferred?

**Answer 15:**

Standalone study reports will be required for the base period and for any options exercised. Assume for costing of Task 1 that these reports will be the same reports indicated in the sample protocol under Deliverables (e.g., one protocol per option = one report)

**Question 16:**

Task Order #2: The sample protocol provided indicates that all plasma and tumor samples will be shipped to another facility for analysis, but there is no mention of PK calculations. Should we include PK calculations (tables/figures added to main report or standalone report) as an option for this task order?

**Answer 16:**

Assume for technical and cost proposal purposes that no PK calculations or reporting thereof will be required for Sample Task Order #2.

**Question 17:**

Task Order #3: For the met ID portion, is the Government looking for only m/z values (e.g. +16, etc.)? Will fragmentation interpretation for structure elucidation also be required?

o Are standalone reports required for the PK or met ID portions or only tables/figures?

o If a stand-alone PK report?

**Answer 17:**

In this sample Task Order, only reporting of m/z values is required.

o As indicated in Paragraph C. Deliverables of Task Order#3, a separate standalone analysis report is required for the base period and for any options exercised. The sample TO indicates 100 samples, one compound, and one or two matrices per base/option. The report should include analytical methodology and validation, tabulation of the c vs. t data, any PK analyses performed, and met ID results.

o The report will contain C vs. t data for up to 100 samples per base/option. Specific protocols containing the information below will be provide with actual Task Orders competed after award.

**Question 18:**

- Please provide the number of treated groups.
- Will both males and females be included?
- Please provide the number of intervals (both tissue and plasma).
- Please provide the number of time points per interval (both tissue and plasma).

**Answer 18:**

The specific parameters in would be part of an actual TORFP and appended protocol. However, some hypothetical numbers for estimating purposes for the RFP are provided below.

Assumptions provided are as follows:

- Please provide the number of treated groups: 4
- Will both males and females be included? No, one gender
- Please provide the number of intervals (both tissue and plasma): Single dose, sampling to 48 hr
- Please provide the number of time points per interval (both tissue and plasma). 8

**Question 19:**

The document states that full validation to GLP standards is not required. Would a qualification of each matrix with 1 day of precision and accuracy, specificity at

**Answer 19:**

Your proposed approach should reflect your understanding of and justification for bioanalytical method validation for non-GLP preclinical PK (or PK/PD) studies conducted in support of drug discovery or development project.

**Question 20:**

Should stability assessment in plasma and tumor homogenate be included with the qualifications?

**Answer 20:**

No

**Question 21:**

With nonGLP support, do the criteria below meet the expectations?

**Answer 21:**

At this stage we will not be evaluating proposed approached.

**Question 22:**

Task order #4: Will a client-specific format be required for the report?

Can we assume method validations will follow our established SOPs for small and large molecule assays? If not, please provide clarification regarding requirements.

**A nswer 22:**

There is no rigid template for these reports.

Yes, but keeping in mind that Task #4 is in support of clinical pharmacology determinations in human clinical trials.

**Question 23:**

The Section K Reps and Certs link isn't working, could you send me a copy of the Attachment 4 Reps and Certs.

**Answer 23:**

Please reference the RFP posting on Federal Business Opportunities website at <https://www.fbo.gov/spg/HHS/NIH/FCRF2/N02CM67000-11/listing.html>. On the right hand side of the page please reference "RFP N02CM67000-11 Attachments. Please click on the RFP Attachment number Four to download the Section K - Reps and Certs attachment. All attachments to the RFP are provided here as separate documents for downloading purposes.

**Question 24:**

They have indicated that they will need to know the protocol required or should they use the Task Order #1 or #2 to use as a guide to generate work plan and response to Sample Task Order #3.

**Answer 24:**

Sample Task #3 requires determination of one drug-like compound in 100 plasma or tumor samples to be provided by NCI. This Task is unrelated to Tasks #1 & #2. For costing PK analysis in Task #3, assume the following:

- Please provide the number of treated groups: 4
- Will both males and females be included? No, one gender
- Please provide the number of intervals (both tissue and plasma): Single dose, sampling to 48 hr
- Please provide the number of time points per interval (both tissue and plasma). 8