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| AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | | 1. CONTRACT ID CODE N/A | PAGE OF PAGES 1 10 |
| 2. AMENDMENT/MODIFICATION NO. 0001 | 3. EFFECTIVE DATE May 7, 2014 | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (If applicable) N/A |
| 6. ISSUED BY National Institutes of Health National Cancer Institute Office of Acquisitions 9609 Medical Center Dr Rockville, MD 20850 | CODE | 7. ADMINISTERED BY (If other than Item 6) | CODE N/A |
| 8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP: Code) | | (S) | 9A. AMENDMENT OF SOLICITATION NO. N02CP41010-32 |
| TO ALL POTENTIAL OFFERORS | | | 9B. DATED (SEE ITEM 11) April 24, 2014 |
| | | | 10A. MODIFICATION OF CONTRACT/ORDER NO. |
| CODE | FACILITY CODE | | 10B. DATED (SEE ITEM 13) |

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

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| (S) | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). |
| | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: |
| | D. OTHER (Specify type of modification and authority) |

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

PURPOSE: To provide questions and answers and amend Attachment 11, "Additional Technical Proposal Instructions" and Attachment 18, "Additional Business Proposal Instructions."

Deadline for Questions: May 9, 2014; 10AM (Local Time, Rockville, MD) (Unchanged)

Proposal Due Date: May 28, 2014; 10AM (Local Time, Rockville, MD) (Unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

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| 15A. NAME AND TITLE OF SIGNER (Type or print) | | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) | |
| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
| _____ (Signature of person authorized to sign) | | BY _____ (Signature of Contracting Officer) | |

NATIONAL CANCER INSTITUTE
N02CP41010-32

QUESTIONS AND ANSWERS

The following are answers to questions received from potential offerors.

Q1a: Page 2 of Attachment 11, “Additional Technical Proposal Instructions,” indicates that **SECTION 2: TECHNICAL DISCUSSIONS** includes:

- A. Personnel;
- B. Technical Approach;
- C. Organizational Experience; and
- D. Facilities and Equipment.

Within the B. Technical Approach section, the offeror is instructed to provide a response to each Sample Task Order. Should this section only include the Sample Task Orders within the specified page limits? In other words, should the B. Technical Approach section include no more than 10 pages for Sample Task Order 1, no more than 100 pages for Sample Task Order 2 and no more than 25 pages for Sample Task Order 3?

A1a: No. The page limits are for each technical proposal submission, inclusive of criteria A. through D., for each Sample Task Order. The mix of pages for each section in each Sample Task Order’s technical proposal is at the discretion of each offeror.

Q1b: If this is the correct interpretation, what are the page limits for the other sections including A. Personnel; C. Organizational Experience; and D. Facilities and Equipment?

A1b: Please see above answer.

Q2: Does Attachment 11, “Additional Technical Proposal Instructions,” for each Sample Task Order take precedence over the instructions provided in the “Statement of Work for each Sample Task Order? The “Additional Technical Proposal Instructions” indicate a separate section for A. Personnel, whereas each Sample Task Order in the “Statement of Work” asks for personnel qualifications and resumes within each sample task.

A2: No. Attachment 11, “Additional Technical Proposal Instructions,” are intended to complement the instructions provided in the “Statement of Work” for each Sample Task Order. Offerors should discuss personnel qualifications and experience in their technical proposal for each Sample Task Order. All resumes for proposed personnel should be submitted separately under one tab.

Q3: Should offerors assume that the discussion of Human Subjects Protections, IT Security Plan, 508 Compliance Plan and Sustainability Acquisition Plan may be provided in appendices – and not count toward the page limit?

A3: The discussion of Human Subject Protections, IT Security Plan, 508 Compliance Plan, and Sustainability Acquisition Plan do not count toward the page limit.

Q4: The “Statement of Work” includes Task Area IV – Phase Out, however, the offeror is not asked to provide a technical approach for this task in the instructions. Should it be included? If so, where should it be placed and what is the page limit?

A4: No. Offerors are not asked to provide a technical approach for Task Area IV – Phase Out.

Q5: Can you please provide uniform cost assumptions for subcontracts for each of the task orders?

A5: There are no uniform cost assumptions for subcontracts for each task order.

Q6: Can you please provide uniform cost assumptions for consultants for each of the task orders?

A6: There are no uniform cost assumptions for consultants for each task order.

Q7: Attachment 18, “Additional Business Proposal Instructions,” indicates that it is expected that there will be five (5) international trips per year under Core Support Services and one (1) international trip per year under New Full Studies. Please provide the locations for these international trips.

A7: Please use the following assumptions:

Core Support Service

Two (2) trips to Kyiv, Ukraine

Two (2) trips to Minsk, Belarus

One (1) trip to Beijing, China

New Full Studies

One (1) trip to Chiba, Japan

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

The following additional Technical Proposal instructions reflect the requirements of the Request for Proposals (RFP) and are meant to provide additional instructions as well as a uniform format for technical proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors shall follow the instructions in Section L of the solicitation, plus include the information requested in this Attachment.

Offerors are advised to give careful consideration to the Statement of Work (SOW), all reference material, and attachments, the technical evaluation criteria, and the RFP as a whole, in the development of their Technical Proposal.

Offerors who propose subcontracts to perform portions of the Statement of Work should clearly identify the specific sections for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

The Government encourages the Offerors to be complete but succinct in the presentation. The following limitations apply to each sample Task Order:

- Sample Task Order 1: Phase-In - 10 pages
- Sample Task Order 2: REB Core Support Services – 100 pages
- Sample Task Order 3: Support Services for New Full Studies – 25 pages

The page limits are for each technical proposal submission, inclusive of criteria A. through D., for each Sample Task Order. The mix of pages for each section in each Sample Task Order's technical proposal is at the discretion of each offeror.

Please note, OFFERORS MUST PROPOSE FOR TASK AREAS I, II, and III. In addition, this RFP will be a single-award IDIQ contract.

TOTAL PAGE COUNT DOES NOT INCLUDE (some of which may be added as appendices): Title and Back Page, NIH-2043, Table of Contents, Section Dividers that do not contain information other than title of Section, **Key Personnel's resume/Curriculum Vitae (CV), with highlights of any items that are directly related to the subject project, indicated by preceding them with a double asterisk (**)**, Resumes/CVs of non-key personnel (same information and format as used for key personnel); sample questionnaires or surveys; certificates and licensures, examples of protocols, Standard Operating Procedures (SOP), Health and Safety Manual, letters of commitment by proposed consultants and subcontractors, **Human Subject Protections, IT Security Plan, 508 Compliance Plan, and Sustainability Acquisition Plan.**

FORMATTING AND LAYOUT:

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch of each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11").
- Offerors shall NOT use 8.5x14" legal size paper.
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers/reviewers to alternate sources of information.
- Additional appendices may be added as needed.
- The proposal with pagination, including appendices, shall be formatted sections, cross referenced, and include a detailed Table of Contents with page references.

TECHNICAL PROPOSAL - TABLE OF CONTENTS

General Instructions

SECTION 1

- A. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
- B. PROJECT OBJECTIVES (NIH FORM 1688-1)
- C. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
- D. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
- E. TABLE OF CONTENTS

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

SECTION 2: TECHNICAL DISCUSSIONS

A. Personnel

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Clearly identify who is to be assigned as Key Personnel. Limit Curriculum Vitae (CVs) for Key Personnel to 2-3 pages and provide selected references for publications relevant to the scope of the RFP, and include experience with projects of similar scope, size and complexity. CVs for all non-key personnel shall be limited to one-page.

Contract management shall be performed by a team comprised of key personnel functioning as Project Director and Senior Study Managers.

1. Project Director (Key Personnel): The Project Director shall retain overall responsibilities for the project management to coordinate and integrate all of the contract activities

including staffing decisions, development and implementation of Standard Operating Procedures (SOPs) across studies, prioritizing support for studies in the pipeline, preparing required reports, deliverables and other official documentation, and equipment purchases. The Project Director is also responsible for ensuring quality assessment/quality control (QA/QC) of the work performed, fostering internal/external communications, tracking studies, and monitoring the budget.

Please demonstrate the following:

- a. Has a Master's degree and at least 5 years of relevant experience, **or** a Bachelor's degree and at least 10 years of relevant experience..
 - b. Has at least three (3) years of experience specific to the conduct of studies that have involved multiple centers and/or non-U.S. centers.
 - c. Has managed personnel and all aspects of administration for multiple epidemiologic projects successfully completed on-time and within or under budget.
 - d. Has supervised multiple epidemiologic studies, some of which have involved molecular, international components or subcontracts, and prioritizing tasks for multiple projects simultaneously.
 - e. Has managed small and large epidemiologic studies, and complex staff and subcontracts, including arranging for collection of radiotherapy records and collection and transport of biological or environmental samples.
 - f. Has trained abstractors and interviewers, and coordinating other aspects of field studies such as obtaining medical records and death certificates.
 - g. Has responded quickly to changes in study priorities or to support urgent new efforts in existing projects by making appropriate personnel available.
2. Senior Study Manager (Key Personnel): The Senior Study Managers shall guide overall project management support for contract management issues. Senior Study Managers shall lead the contracting activities specific to each study including communicating with NCI COR to understand the task requirements and ensure that adequate staff is provided to perform the tasks. The Senior Study Managers across the different studies must maintain effective communication with each other to ensure that they comprehend the diverse overarching needs of this support contract. The Senior Study Managers shall insure that appropriate up-to-date and standardized approaches in the performance of study-related activities be instituted so the development of similar procedures, activities, forms, or methods are not duplicated and study efficiencies are gained.

Please demonstrate the following:

- a. Has a Master's degree and at least 3 years of relevant experience, **or** a Bachelor's degree and at least 5 years of relevant experience.
- b. Has prepared, monitored, and optimized quality and progress of all field operations, including overseeing the daily operations of small and large, complex, interdisciplinary, multi-center domestic and international studies, tracking assignments, ensuring adherence to internal policies and procedures, collecting biological or environmental specimens and/or medical radiation records, and assisting

- the resolution of deficiencies and problems.
- c. Has trained abstractors and interviewers, coordinating field aspects of individual epidemiologic studies, monitoring data collection and data manipulation, and managing project staff.
 - d. Has suggested innovative approaches to fulfilling tasks.
 - e. Has coordinated with co-senior study managers for multiple studies.
3. Senior Data Analyst (Non-Key Personnel): Please demonstrate the following:
- a. Has developed data management systems with capabilities for editing, quality control and documentation for multiple epidemiologic studies;
 - b. Has constructed analytic data files using Statistical Analysis System (SAS) or other similar statistical programs for epidemiologic studies;
 - c. Has manipulated large data sets.
4. Other (Non-Key Personnel): Please demonstrate the following:
- a. Has experience, capabilities and availability of abstractors, interviewers, keyers, coders, and other field personnel, including interviewer supervisors, coding supervisors, keying supervisors, telephone center supervisors, and other mid-level personnel.
 - b. Has availability of, or ability to recruit on an as-needed basis, other personnel that may be required for the conduct of variety of studies. This includes but is not limited to: forms designers, statistical sampling design specialists, nosologists, dosimetrists, coding specialists in specific areas such as chemotherapeutic drugs, occupations, etc. These personnel shall have adequate and appropriate training, experience, qualifications, and availability to perform the function required.
5. Staffing Plan: The Contractor shall provide well-trained staff with necessary expertise and experience to ensure adequate support, which may include domestic or international travel, for all existing projects.

A staffing plan/matrix outlining areas of responsibility, reporting and level of effort shall be provided. The staffing plan shall demonstrate cross training and back-up coverage.

B. TECHNICAL APPROACH

Offerors shall submit a proposal that addresses all areas in the Statement of Work. Only proposals from Offerors who demonstrate the capability to perform all aspects of the Statement of Work, either at their institution or through their subcontracts, will be considered for award. If the proposed approach will involve a subcontracting arrangement, then the Offeror shall include a letter(s) of commitment from the subcontractor(s), plus documentation of subcontractor's expertise, qualifications and prior performance, as well as a narrative describing how the Contractor will manage the subcontractor(s).

OFFERORS SHALL PROPOSE FOR TASK AREAS I, II, AND III.

Offerors shall provide a response to each of the below sample task orders for the following as described in the individual Sample Task Orders:

- **Sample Task Order 1: Phase-In**
The Contractor shall develop and submit a draft initial transition phase-in plan at the time of proposal, which will describe the Contractor's strategy for taking over work from the incumbent Contractor, if required, to ensure continuity and fidelity of REB services. The plan must include provision of key personnel, transfer and safe receipt of relevant files, forms, records, materials, and data; transition of all activities; and transition of all REB applications from the incumbent Contractor to a secure server space.
- **Sample Task Order 2: REB Core Support Services**
The Contractor shall demonstrate and provide their understanding and capability to meet all sub-tasks.
- **Sample Task Order 3: Support Services for New Full Studies**
The Contractor shall demonstrate and provide their understanding and capability to meet all sub-tasks.

See also the Additional Business Proposal Instructions regarding development of budgets for the sample Task Order Response.

Please note that offerors shall respond to each Sample Task.

C. ORGANIZATIONAL EXPERIENCE

Discuss prior experience with projects of similar size and scope to those outlined within each section of the SOW.

Organizational Experience Conducting and Simultaneously Managing Large, Multiple Epidemiologic and Molecular Studies (Domestic and International) as described in this RFP.

The experience of the Offeror and success in performance in the simultaneous management of multiple large cohort and case-control studies should be described. Provide specific examples or overview of procedures that illustrate the following types of work:

- a. Conducting survey research or the conduct of field and molecular epidemiologic studies by the Offeror.
- b. Responding quickly to changes in priorities and to supply support to urgent new efforts.
- c. Managing multiple studies including the demonstrated examples of cost effective methods and reduction in duplication of costs and effort in the performance of the contract.
- d. Provide evidence of previous experience executing subcontracts in support of

epidemiologic studies.

- e. Provide evidence of project management systems and quality control methods that will ensure the effective initiation, implementation, conduct and completion of contract activities; and monitoring, tracking and reporting on Contractor and subcontractor costs and performance.

Subcontracts - In the event the Offeror does not have facilities, equipment, or personnel for performing any component of the described in each section, then the Offeror shall be prepared to implement the work through a suitable subcontractor(s). The proposal shall include the sub-contractors' experience with projects of similar size and scope to those which they are assigned. Letters of commitment from and qualifications of all proposed subcontractors shall be included in the proposal. The Offeror shall describe any previous working relationship with proposed subcontractors. Furthermore, the Offeror shall address how they will handle privacy of contract issues, i.e. the Offeror should explain how information will flow between NCI, the prime Contractor (Offeror), and any subcontractors, since the prime Contractor's presence is required for any discussions.

D. FACILITIES AND EQUIPMENT

The Contractor shall provide a description of their facilities and equipment that will be provided to support all facets of the proposal. In addition, any specialized facilities and equipment necessary to address specific technical requirements shall be provided for each section of the SOW.

Futhermore, the offeror shall provide:

- a. Documented capacity, adequacy, suitability and availability of the proposed facilities, equipment, and other resources necessary to carry out the requirements specified in the Statement of Work including:
- b. Availability and accessibility of Information technology (IT) systems and equipment to interface with multiple databases of DCEG, other NCI/DCEG-funded support contractors, and consortial and collaborative projects.

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS

In addition to the instructions and format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this attachment is intended to provide uniform cost assumptions that apply to the solicitation. Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the technical evaluation criteria, and the RFP as a whole, in the development of your proposal. The information requested here should be used as further guidance for the development of your Business Proposal. For proposal purposes, the offeror shall propose based on the following budget assumptions (Note: all workload assumptions are approximations):

1. **Phase-In:** One trip from Contractor's location to NCI's office in Rockville, MD.
2. **REB Core Support Services:**
 - a. A monthly meeting to review status and expenses at NCI's office in Rockville, MD or teleconference.
 - b. It is expected that there will be two (2) pilot studies a year.
 - c. It is expected there will be four (4) domestic and five (5) international trips a year, lasting one week on average. **It is expected that there will be 2 travelers on each trip on average.**
Please assume the international trips will be:
Two (2) trips to Kyiv, Ukraine
Two (2) trips to Minsk, Belarus
One (1) trip to Beijing, China
3. **Support Services for New Full Studies**
 - a. It is expected that there will be two (2) new full studies a year.
 - b. It is expected there will be one (1) domestic and one (1) international trip a year, lasting one week on average. **It is expected that there will be 2 travelers on each trip on average.**
Please assume the international trip will be: One (1) trip to Chiba, Japan