

OFFICE OF ACQUISITIONS
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CM91008-48

Amendment No.: 1

Date of Issuance: 10/21/2008

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors remains unchanged: _____.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified 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:

SECTION J - LIST OF ATTACHMENTS, ATTACHMENT 3: STATEMENT OF WORK, item 5.8.4, is revised to read as follows:

The Contractor shall provide storage and filing space to accommodate approximately 1,400 square feet of filing and storage space. The Contractor shall be responsible for removing all data currently stored at the incumbent Contractor's facility, if awarded to an offeror other than the incumbent.

SECTION J - LIST OF ATTACHMENTS, ATTACHMENT 3: STATEMENT OF WORK, item 5.8.7, is revised to read as follows:

When requested by CTEP staff, the Contractor shall retrieve a document and provide the document (or a copy, if requested to do so) to the requestor within no later than one (1) business day of the request. In the event that a request is received on a Friday or before/during a federal holiday or Government closure, the Contractor shall provide a copy to the requester on the first business day following the Friday or federal holiday or Government closure. In the event of inclement weather and the Government remains open or any other extenuating circumstances, the Contractor shall request any exceptions to the Project Officer and make further arrangements per the direction of the Project Officer. For requests made after 1500 ET, the Contractor shall fulfill the request by 1700 ET, the following day that the Government is open for business.

SECTION J - LIST OF ATTACHMENTS, ATTACHMENT 3: STATEMENT OF WORK, item 5.11.1, is revised to read as follows:

The Contractor shall conduct two (2) satisfaction surveys annually. One survey will measure the satisfaction of CTEP personnel (including CTEP contractors) with PIO services. The other survey will measure the satisfaction of the customers that the PIO serves, outside of CTEP personnel. The Contractor shall be responsible for developing the survey tool(s), including the survey questions. The PO shall have the opportunity to review the survey tool(s), including the survey questions, prior to distribution. The Contractor shall collect, analyze and report the findings of the survey to the PO within one month following the completion of the survey.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS, item 1.f., ESTIMATE OF EFFORT is revised to read as follows:

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 11 full-time equivalents (FTEs) or 20,680 labor hours per year, for a total of 144,760 labor hours over the total seven (7) year period. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

The following are the Government's answers to questions asked by Offerors, related to the solicitation:

1. **Question:** Is the "index" referenced on page 53, paragraph B., the same as the "Table of Contents", or is this an additional requirement?

Answer: Yes, the "index" is considered the table of contents for the Business/Cost proposal.

2. **Question:** Please provide confirmation of the labor hours presented in the RFP (11,800) as the total labor effort for each year of the project. Is this the same as the current level of effort for this project?

Answer: Per this amendment, Section L., item 1.f. of the RFP, has been revised to state that the Government's Estimate of Effort is approximately 11 full-time equivalents (FTEs) or 20,680 labor hours per year, for a total of 144,760 labor hours over the total seven (7) year period. The level of effort under the incumbent requirement is not germane for the purposes of the new requirement.

3. **Question:** Are there any page limits, regarding the size of the Technical Proposal?

Answer: There is no maximum page limit.

4. **Question:** What system is used for management and generation of honorarium disbursement (e.g., is it generated from PATS, a commercial package, etc.)? Will this system be transferable if there is a new award?

Answer: We are unsure what you are referring to and are assuming your question was asked in error, as there is no requirement for the management and generation of honorarium disbursement under this requirement.

5. **Question:** Is there still a requirement to provide 650 linear feet of space for filing cabinets? Has this grown since the last award (by 45 linear feet per year)? Are existing files and/or documents now being stored at the incumbent site? If so, they will need to be moved. Who owns those file cabinets? Are there any special requirements for the type of file cabinets? For example, do they need to be fireproof?

Answer: Per Section 5.8 of the Statement of Work, the Contractor is required to provide 1,400 square feet of filing and storage space. Yes, existing files are currently being stored in Rockville, Maryland, and offerors must be prepared to move the files, if awarded to a new Contractor. The Government owns the file cabinets, which will be provided to the successful Contractor. The fire-suppression and physical security requirements, as stated in Section 5.8 of the Statement of Work, are for the facilities/specific location at which the file cabinets will be stored (rather than for the file cabinets themselves). There are currently 84 standard, upright, 5-drawer, metal filing cabinets.

6. **Question:** Will there be travel costs (e.g., associated with training as well as to Contractor corporate offices)?

Answer: Travel is not anticipated for this contract.

7. **Question:** Is there already a method that will be transitioned providing "Cost Control" that shows that work is being performed in the most cost effective manner possible, and if this is serviced by an application or COTS software product that automates the cost/document ratio, will it be transferable to a new vendor if awarded?

Answer: The cost control measure on the Quality Assurance Surveillance Plan is calculated based upon cost per document for documents received and processed within the PIO (e.g., LOIs, Concepts, Protocols, etc.). The Government uses the CTEP Enterprise system to generate information used to calculate this cost per document amount and it will be available during the next contract cycle.

8. **Question:** To what extent, if any, will the Contractor be expected to assist investigators directly in the writing of protocols? If so, what level of medical training will be required of contract staff?

Answer: The Contractor and Contractor staff are not involved in the direct authoring of protocols. Protocols are authored by the submitting site and reviewed for approval by the Government. The Contractor generates information already contained in the protocol into a summary format, such as the Treatment Assignment Codes and Descriptors.

9. **Question:** Is there still a required response time of 4 hours to retrieve files? What is the current response time? Does the Government make allowances for rush hour and inclement weather? Also, after what time does the 4 hour turnaround rollover the next day without penalty to the Contractor? During what period of time is the 4-hour turnaround in effect? For example, if the request is made at 3:30pm, a four-hour turnaround would be 7:30pm. Will the Government expect deliveries to be made after 5:00pm? Also, is there any historical data on the number and frequency of requests under the current contract? Does the Government anticipate an increase or a decline in the amount of requests?

Answer: Per this amendment, Attachment 3 - Statement of Work, item 5.8.7 has been revised to provide greater clarification of the requirement. No, there is no historical data available on the volume and frequency of requests. The number of requests can fluctuate, depending on a variety of circumstances. As such, it is unknown whether there will be a potential increase or decrease and unknown by how much.

10. **Question:** The Government stated back in 2000, that the level of effort for PIO support would increase by approximately 25%. Has it increased? What is the current staffing model?

Answer: The level of effort under the incumbent requirement is not germane for the purposes of the new requirement. Per this amendment, the estimated level of effort for this requirement is approximately 11 full-time equivalents (FTEs) or 20,680 labor hours per year, for a total of 144,760 labor hours over the total seven (7) year period, as stated in Section L, item 1.f. of the RFP.

11. **Question:** Will there be a change in the underlying computer system environment used by the PIO staff during the base year?

Answer: No, the Government will continue to provide equipment to enable the Contractor's on-site staff to complete the tasks required by the Statement of Work. New computers may be purchased by the Government, for use by the Contractor's on-site staff, if the current ones do not meet technological or workload needs. The same is true for copiers, printers, fax machines, scanners or any other pieces of equipment provided by the Government for use by the Contractor's on-site staff.

12. **Question:** For the surveys sent out, as per the RFP, Statement of Work, Section 5.11.1, will the Contractor have the ability to design the questions that the Government approves for use?

Answer: Yes, per this amendment, and as stated in Attachment 3 - Statement of Work, item 5.11.1, the Government requires that the Contractor, who is responsible for serving as the group that directly interfaces with the survey respondents, shall design/develop the survey tool(s), including the survey questions, and provide them to the PO, for review, prior to distribution.

13. **Question:** As per the RFP, Statement of Work, Section 5.5.6, please clarify what is included in trial information. If this trial information consists of LOI, Concepts, and Protocols, then please clarify how Section 5.5.6 differs from Section 5.5.7.

Answer: There are data fields that require the abstraction of information into them. Depending on the document type (LOI, Concept, etc.) some of the fields are not applicable (N/A) for a particular document type. There are approximately 80 elements that can be abstracted depending on document type. A review of the user guides and Protocol Authoring Handbook can provide an overview of those elements. Section 5.5.7 is to inform the Contractor that additional free text information may need to be entered into the system where a related data field doesn't already exist.

14. **Question:** Can you identify the current off-site storage vendor? Will potential bidders be able to visit the current off-site storage site?

Answer: The incumbent Contractor is currently responsible for providing off-site storage. It is up to the offeror to propose storage facilities to meet the requirements of the Statement of Work. The Government does not consider it necessary for offerors to visit the current off-site storage location. For the purposes of estimating costs, offerors should consider the response to question # 5 of this amendment, which provides specific details of the current volume of files necessary to be maintained.

15. **Question:** Can you provide us with the current inventory of the materials stored off-site and the SOPs related to them; that is, what procedures were followed to assign them and place them into off-site storage at the time they were sent? How long is the transition period of the incumbent contract? Will this transition period take place during the incumbent contract period or during the new award?

Answer: The majority of materials are LOIs, Concepts, and Protocols that have a terminal status of closed, complete, administratively complete, etc. Studies with an active or open status are stored on-site, at the Government facility. Once a study reaches a terminal or closed status, the Contractor should move the file to the off-site location. There is no transition period, and if the requirement is awarded to a new Contractor, it is the new Contractor's responsibility to pick up all the files at the start date of the new contract.

16. **Question:** What transitional duties does the incumbent Contractor have with regard to the off-site storage (for example, are they to confirm and certify the contents of the stored files or records at the time of transition)? Will the awarded Contractor have access to the off-site storage location of the incumbent prior to the actual start of work under the contract?

Answer: In the event of transition to a new Contractor, the incumbent Contractor is expected to confirm and certify to the new Contractor, the contents of the stored files or records, at the time of file pickup. The new Contractor will have access to the off-site storage location, for the purposes of picking up all data, beginning on the start date of the new contract.