

OFFICE OF ACQUISITIONS  
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02PC85002-29

Amendment No.: 1

Date of Issuance: 05/21/2008

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offers remains unchanged: June 23, 2008 at 3:00PM local time.

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:

RFP # N02-PC-85002-29 is hereby amended to answer questions received from interested parties. The due date for submission of proposals is NOT extended. All other articles remain unchanged. As opposed to Federal Business Opportunities' modification numbering, this is the only amendment to date for this RFP.

**The final day for asking questions regarding this RFP is June 9, 2008.**

1. The solicitation (p. 39) states that the government estimates the effort for the contract at 10,192 hours. Is that for Phase I or both Phase I and Phase II?

**The 10,192 labor hours includes both Phase I and Phase II.**

2. Would it be possible and/or advisable for the PI to speak with you directly once he has a list of specific questions?

**Anyone from your organization can submit questions to the Contract Specialist and/or Contracting Officer. Please submit all questions in writing. If programmatic clarification is needed, the Contract Specialist will obtain that information and respond.**

3. Are you looking for a software developer to build a tool that you will purchase and maintain or the services of survey research service provider who will use their internal tools to achieve your data collection needs?

**The proposed PRO-CTCAE will collect cancer patient responses to questions about their health status, symptoms, functioning and health-related quality of life and integrate this information within the NCI adverse event reporting system. Thus, the offeror must have a full understanding of the NCI-sponsored clinical trials enterprise and expertise and experience in assessing patient-reported outcomes as they relate to symptoms that are captured in adverse event reporting systems. Further, the offeror must have expertise in software development to create a user-friendly interface for patients, secure to protect their information, and interoperable to be integrated within the CTCAE reporting system.**

**The ideal offeror will have on their team a range of expertise including subject matter expertise about measuring symptoms using patient-reported outcomes (PROs) questionnaires in NCI sponsored trials and technology expertise to design and develop a software system that will collect patient-reported symptoms and integrate their responses into the appropriate grading of symptoms that is reported into NCI's adverse event system. The software system created under this contract will be property of the National Cancer Institute and all rights to the use and dissemination of the software will be solely of the NCI.**

4. Will the envisioned data collection systems actually be installed at selected sites or be provided as an internet service from a central location

**NCI's AdEERs system is a web-based central data collection system that is not installed at selected sites, but available to any NCI registered investigator. The PRO-CTCAE will be an adjunct to CTCAE and would be incorporated into whatever new AE collecting system is on the horizon. The substantive approach is part of the evaluation criteria. Final decisions about the specifications of the system will be made during the project period.**

5. Will the clinician or patient data collection system need to be directly attached to NCI or other databases and exchange data in real time, or just provide one way, communication of regular formatted data uploads of current activity

**Ideally, the PRO-CTCAE will be integrated into the current (or soon to exist) AE systems.**

6. Will the selected vendor be required to have the subject matter expertise to develop the content, or just to provide the data collection instrument designs, layout and production using content provided by others

**The ideal offeror will have both the subject matter expertise and IT expertise to develop the PRO-CTCAE. Specific criteria is addressed in the Solicitation under Section M [Evaluation Factors of Award], specifically Part 4 (Technical Evaluation Criteria), p. 78 and in Part 4, section L,2,b,15 "Additional Technical Proposal Instructions".**

7. The need for a patient data entry system is mentioned to include mail based paper surveys and the internet. How will patients be enrolled and receive their forms? Will patients receive only one, or a series of forms? How frequently?

**It is anticipated that the offeror will understand the scope of the clinical trials program and provide a proposal that addresses an effective means of incorporating patient reported outcomes into the reporting of adverse events.**

8. Besides software development, there are also requirements associated with the development, production and distribution and ongoing data collection efforts of the mail based surveys, will the same contractor provide these services on an on-going basis, or is there a possibility that multiple vendors could be selected, each providing a subset of the services requested?

**As stated in Section L of the solicitation, it is anticipated that one award will be made. It is expected that the successful offeror will be responsible for all tasks included in the solicitation. Subcontract arrangements are acceptable.**

9. Does the \$550,000 threshold for the Small Business Subcontracting Plan pertain to Phase I or both Phase I and Phase II.

**If your budget proposal for Phase I is less than \$550,000 (regardless of what your Phase II budget proposal is) then you do not need to submit a small business subcontracting plan at this time.**

10. Should the budget in the business plan include costs for Phase I and Phase II - since Phase II is optional?

**Yes, per Section L(c) 14. - Additional Business Proposal Instructions, the offeror should submit a separate budget for Phase I and Phase II as well as a cumulative budget. The Government reserves the right to unilaterally exercise the Phase II option (ARTICLE H.6, Option Provision and I.3., Option to Extend Term of the Contract).**

11. Is there a guideline regarding page limitations?

**There is no page limit for proposals.**

12. Form Procurement of Certain Equipment, NIH(RC)-7, instructions say that the contract will not pay for various items including general purpose computing equipment. What if these items are needed to perform the tasks?

**The Procurement of Certain Equipment clause will be included in a resultant contract. You can put these costs into the budget proposal and they will be reviewed for both necessity and cost. Any proposal that includes equipment must provide at least three quotes documenting the proposed cost and specifications.**

**13. The Proposal Summary and Data Record only needs to be completed by the prime offeror/contractor. As stated in the RFP, complete cost proposals for each subcontract must be provided in the same format as the offeror's cost proposal. Please include the subcontract budget pages as a part of the complete proposal. The Small Business Subcontracting Plan is only submitted by the prime offeror/contractor at this time.**

14. What do we do if a subcontractor (especially a for-profit concern) does not have a negotiated rate agreement with an agency of the Federal government?

**If a subcontractor does not have a negotiated rate agreement, they will need to obtain one if your proposal is determined to be within the competitive range. For commercial organizations, the NIH Division of Financial Advisory Services (DFAS) can be contacted at 301-496-2444. For purposes of proposal submission, estimate what the rate will likely be. A copy of the indirect rate agreement for each subcontractor should be submitted with the proposal.**

15. What intellectual property rights are retained by the prime contractor or subcontractors? Will the organization retain any rights to royalties or license fees for future use of its software?

**Please review FAR 52.227-17, Rights in Data - Special Works. As stated in the Solicitation, all documents (including source code and documentation), software, training material, and other material developed under this contract are property of the National Cancer Institute, National Institutes of Health. The government will retain all intellectual property rights.**

**The final day for asking questions regarding this RFP is June 9, 2008.**