OFFICE OF ACQUISITIONS
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02PC85002-29

Amendment No.: 4

Date of Issuance: 06/13/2008

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 FOURTH amendment to date for this RFP.

1. The RFP instructions for the business proposal refer to the FAR 15.4, cost-pricing regulations and a certification of such (Far 15.406-2). Do we need to submit a signed certification with the business proposal?

No, you do not need to submit a signed certification. You need to include the information that is noted in Section L - Business Proposal Instructions - Information Other than Cost or Pricing Data (page 65).

2. Do the qualifications for the PI listed on pages 61 and 78 of the RFP have to come from a single individual or can they come from a PI and co-PI?

As noted in Section L - Technical Proposal Instructions (Page 47), a single Principal Investigator is required. There may be co-investigators but you must identify the Principal Investigator who will be responsible for the overall implementation of any awarded contract.

3. Does the PI have to be an employee of the Prime contractor or can they be an independent consultant for or subcontractor to the Prime?

It is the responsibility of your organization to make this decision; however it is strongly advised that the PI be an employee of the prime contractor.

4. To what degree will Patient Reported Outcomes version of the Common Terminology Criteria for Adverse Reporting need to be integrated with other PRO systems such as Patient Reported Outcomes Measurement Information System?

The PROMIS (Patient-Reported Outcomes Measurement Information System) is developing item banks to measure symptoms and health-related quality of life domains across a variety of chronic conditions including cancer. There is no requirement that the PRO-CTCAE be integrated with or include PROMIS measures; however, PROMIS items/scales may be a potential test bed of items to be considered for the PRO-CTCAE.

5. In Phase 1 Part D of the SOW, the Government indicates that contractor should create a blueprint for PRO-CTCAE to interact with AdEERS. To what degree does the Government expect PRO-CTCAE to interoperate with other adverse event reporting systems such as caAERS or FDA's FAERS?

We intend to have the PRO-CTCAE be interoperable with the caAERS. As stated in the Statement of Work, the offeror shall review adverse event reporting systems used by other federal agencies (FDA, NIH, AHRQ) and identify opportunities for integrating with NIH Roadmap initiatives to harmonize the Federal adverse event reporting system. The extent of interoperability with the FDA adverse event reporting system is unknown at this time.