

OFFICE OF ACQUISITIONS
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CM47001-42

Amendment No.: 7

Date of Issuance: 11/20/2014

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 answers additional questions:

1. Please clarify: Section A states "E-mail proposals will not be accepted". Attachment 1 calls for submission of an electronic copy of the technical and business proposals. Please clarify.

Answer: The original and official copy of the proposal response shall be sent to the mailing address specified in Attachment 1. The Government is requesting a courtesy copy to be sent to the email address listed. Please note, the courtesy copy is not official and a contractor SHALL submit paper copies using the instruction in Attachment 1 if they wish to be considered for award.

2. Seeking to clarify previous Q&As regarding the Business Proposal. Under the previous RFP (basis for the current existing contract awards) the information provided for the Sample Tasks were: Attachment 10 and the proposers' cost detail information. The Sample Tasks cost information was included in the Business volume. For the current RFP, can the Sample Task responses and Task Order 1 be limited to the cost information only (Attachment 10 and cost details) and included in a single business volume?

Answer: Each task order should include technical and business information in sufficient detail to ensure the reviewers are able to evaluate the sample task order submissions in accordance with the evaluation criteria included with each individual sample task orders included in the RFP, in addition to all costs. The sample task orders responses are to be submitted in accordance with the instructions located under Attachment #16, by task order. The preference is for this information to be tabbed by task order.

3. Table F.1 - Item (1) Study Reports and item (8) Final Task Order Report. In accordance with Article C.2. a.2. Study Reports - "the final report for each study/Task ORDER will be due between 15 and 45 working days following completion of the in-life phase of the study...". Please clarify what each item - the Study Report and the Final Task Order Report is to include. They appear to be the same requirement.

Answer: The final report for each study will accurately and completely describe the study design, procedures and findings, present an analysis and summary of the data followed by the conclusions derived from the analyses. Protocol modifications and/or deviations will be presented and discussed as well. The report will also include: (a) a cover page which will include the title, contract number, authors, laboratory name and address, dates of initiation and completion, and sponsor; (b) the NTIS Report Documentation Page, to be placed at the beginning of the final report; (c) a comprehensive summary to be placed after the NTIS page; (d) the dated signature of the Study Director and any others deemed necessary; (e) a table of contents; and (f) a statement prepared and signed by the Quality Assurance Unit which will refer to all phases of the study and where the raw data records, reports and samples are

stored. In addition, the following items must be included in each report. Additional items may be required per Principal Investigator/COR discussions.

1. Compound information
 - a. Identity data
 - b. Lot number
 - c. History (dates received, on test and study completed)
 - d. Stability
2. All data requested
3. Animal history (source, sex, age, weight, immunization, procedure used for unique identification, etc.)
4. Baseline data (pre-test)
5. Control animals
6. Vehicle controls (if requested)
7. Dose formulation information
8. Route of administration
9. Rate of injection
10. Urinalysis data, if specifically requested
11. Methodologies of all test procedures
12. Days of sacrifice
13. Time period from death to necropsy
14. Gross and microscopic pathology
15. Rationale and documentation of all deviations from protocol
16. Statistical methods for analyzing data
17. Corrections or additions to reports are to be submitted in form of amendment clearly identifying that part of report being added to or corrected, reasons for addition or correction and dated signature of person responsible
18. All portions of the studies and reports must be in compliance with the GLP Regulations as published in the Friday, December 22, 1978 Federal Register, Vol. 43, No. 247, pp.59986-60025
19. All portions of the studies and report as designated by the COR must be in compliance with GLP Regulations as published in the Friday, December 22, 1978 Federal Register, Vol. 43, No. 247, pp 59986-60025.

The final task order report is to include a summation of the work performed and the results obtained for the task order, including salient results achieved during the performance of the task order and a summary of costs (status of funds) for the entire task order performance. This report will be used to close out the task order.

The Contractor shall submit final study reports following completion of the in-life phase of study. Each report must be acceptable to the COR for filing as Attachment 6a of an Investigational New Drug Application with the Food and Drug Administration.