

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.2. CLINICAL RESEARCH

H.2.4. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit ~~copies~~ information to the responsible BARDA Contracting Officer's representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the BARDA program officer or the contracting officer's technical representative within 24 hours ~~of FDA notification of the occurrence of the event.~~
2. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 24 hours ~~of FDA notification of the occurrence of the event.~~
3. *IDE reports of unanticipated adverse device effect* – ~~A copy of any~~ Any reports of unanticipated adverse device effect ~~submitted to FDA~~ must be submitted to the BARDA Contracting Officer's Representative within 24 hours ~~of FDA notification of the occurrence of the event.~~
4. *Expedited safety reports* – should be sent to the BARDA COR concurrently with the report to FDA.
5. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

~~In a future task order where BARDA is not the IND sponsor, the reporting requirements would be defined accordingly.~~

Safety reporting for research not performed under an IND or IDE

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the BARDA Contracting Officer's Representative and the Contractor.

ATTACHMENT #2

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0002

Attachment 2E – Submission Instructions

Volume 1 – Technical Submission.

[...]

The Technical Proposal must be included in ~~both hard copy and~~ electronic format. Electronic versions of the price response should be submitted via email ~~and on a CD/USB Drive~~ in MS Office Word format, and shall not be read only or password protected. All tables and links should be intact, and no links should exist to files not included with the response. ~~The hard copy version will take precedence for any differences noted between the hard and electronic versions of a response.~~ Failure to comply with these formatting requirements may result in rejection of your response.

QUESTIONS & ANSWERS

1. In Amendment 5, the government is now responsible for all elements of Item 17, Vendor Management - Attachment 2B. Additionally, in response to question 15, page 7, the amendment states that the Offeror is not responsible for processing and storing samples on site. Given that this will be a large trial with rolling enrollment, potentially over a long period of time, during a PHE, at an unknown time and location, with potentially multiple IRBs, PIs and clinical/research staff, is it the government's intention that: 1) Offeror truly has no obligations in regards to item 17; 2) That the Offeror has no role in processing/packing assistance via internal site capabilities or assistance from the SEMT, and 3) will not provide short term storage of samples while awaiting shipment?

ANSWER: 1) As defined in sample Request for Task Order 2, the Offeror is not responsible for processing and storage of samples on site. 2) As defined in the scope of sample RTOR 0002, the Offeror has no obligations related to Table 2A item 17. 3) As defined in the scope of sample RTOR 0002, the Offeror will not provide short term storage of samples while awaiting shipment.

Can the Offeror propose to collaborate with HHS BARDA to accomplish these critical functions?

ANSWER: Offerors are advised to respond to the requirements established by HHS for sample RTOR 0002. However, this requirement may be specified differently in future Task Orders.

2. Amendment 5 (Question 67, page 26) states “a cost proposal for the base IDIQ contract is required” but the RFP (page 101) states “The respondent shall include a price response per the Contract Line Item Number (CLIN) Structure shown in Table 1.” Does the overall IDIQ contract administrative support include CLIN #0001 or will the government release a new CLIN number for overall administrative support for the entire period of IDIQ contract (60 months)?

ANSWER: The reference to the language on p.101 is related to sample RTOR 001. Table 1 of Sample RTOR 001 has been removed via previous amendment.

3. While the timeline for RTOR 0001 was clarified in the amendments to be 26 months the study parameters provided on page 81 don't add up to 26 months. *Please confirm that we may propose our own timeframe for completion of the project including start up and close out as long as it is 26 months or less in total and first patient in to last patient out is 14 months.*

ANSWER: For sample RTOR0001, Offerors are permitted to propose their own timeframe for completion of the project.

4. Amendment 5 (Attachment 1C, page 15) Task Order 1 eliminates the requirement for reporting SAEs to BARDA (delivery # 6) and eliminates the requirement to report Grade3/4 AEs to BARDA (delivery # 8. However in the RFP (F.3.2.7, page 23) it states that Safety report of “events” be reported within 24 hours to the CO and COR. *Please confirm that these events should still be reported to BARDA, but it is no longer considered a deliverable.*

ANSWER: For sample RTOR 0001, safety report requirements are defined sufficiently in the RFP. Terms established in the RFP apply to both sample RTOR's and future task orders, unless specified otherwise.

5. In the RFP (L.2.1.1., page 58), it states “A brief description of activities to be performed by the Offeror and all proposed subcontractors, including identification of all proposed subcontractors and a list of key personnel for the Offeror and the proposed subcontractors with degrees, titles and role within the project. A summary of staff expertise including the total

number trained, number available to be assigned to this contract for the Offeror and all proposed subcontractors, and the total number of additional staff to be hired and trained. How is BARDA defining subcontractor and does it include vendors such as the drug distribution and labs? If so, do you want this same level of detail (e.g., summary of staff expertise) for all subcontractors in this section of the proposal?

ANSWER: In this context the term subcontractor is intended to only include those subcontractors deemed as significant by the Offeror. It is not anticipated that vendors will constitute significant subcontractors under this proposal, however this is left to the Offeror's discretion.

6. Amendment 3 in Section L.3.4 (6) Other Administrative Data on page 12, offerors are asked to *“provide the most recent pending/established rate agreement with this proposal, if applicable.”* We intend to include a copy of our FY2013 provisional rate letter and supporting schedules that we submitted to DCAA as required at the beginning of the year. Please confirm that, as with the Financial Statements also needed in L.3.4, this documentation does not count against the Business Volume page limits?

ANSWER: Unless otherwise stated, only the Attachments listed in Section J of the RFP are uncounted. Therefore, these would be counted in the page limit for the Business Proposal.

7. Based on the number of plans, Gantt charts, matrices, etc. to be included in the Technical Proposal appendix, is the 50 page limit for the Technical Proposal appendix still applicable?

ANSWER: Yes, the 50 page limit for the Technical Proposal appendix still applicable, except as provided in previous amendments.

8. For Sample RTOR 0001 and RTOR 0002, should Table 1 from Attachment 1B and 2B once completed with costs, be included in the Technical Proposal or the Cost Proposal?

ANSWER: The Business Proposal.

9. Section H.2.4 – Required Time-Sensitive Notification: Will items 1, 2, and 3 be updated as stated in the answer for question 48 in Amendment 4? The answer to question 48 is “BARDA will communicate with the FDA,” however, items 1, 2, and 3 still have the contractor reporting to the FDA and then BARDA within 24 hours.

ANSWER: Section H.2.4. has been updated in the current amendment to clarify the Contractor's reporting responsibilities

10. Amendment 4, L.2.2 – Quality Metrics: This section states “The Offeror shall provide the following Quality Metrics for the past year for all active clinical trials:

- a. Should the Offeror consider the past year to be from May 2012 through May 2013?

ANSWER: Any date is acceptable so long as a calendar year is represented.

- b. In reference to “all active clinical trials”, is this all active, FDA-regulated clinical trials or does this include non-FDA-regulated clinical trials?

ANSWER: This reference is only intended to include FDA-regulated trials.

11. Under Attachment 2E, the Technical Proposal instructions state “The Technical Proposal must be included in both hard copy and electronic format. Electronic versions of the price response should be submitted via email and on a CD/USB Drive in MS Office Word format, and shall not be read only or password protected.” This is the only reference to submitting any portion of the Offeror's proposal as a hard copy. Can the Government confirm that the proposal in response to Sample RTOR 0002 should be submitted as a hard copy and electronic copy?

ANSWER: All submissions should be submitted electronically. The current amendment updates Attachment #2 to remove the requirement for hard copy submissions.

12. Section L.3.2(6) Past Performance identifies “major subcontractors.” What does that entail and will this be counted against the page limit?

ANSWER: Major subcontractors should include any subcontractors who will provide relevant services/support to the proposal. It is left to the Offeror’s discretion as to what constitutes relevant. These will be counted against the page limit for the Business Proposal.