

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE N/A	PAGE OF PAGES 1 6
2. AMENDMENT/MODIFICATION NO. 0002	3. EFFECTIVE DATE April 16, 2013	4. REQUISITION/PURCHASE REQ. NO. N/A		5. PROJECT NO. (If applicable)
6. ISSUED BY HHS/OS/ASPR/AMCG 330 Independence Avenue, S.W., Room G640 Washington, D.C. 20201		7. ADMINISTERED BY (If other than Item 6)		CODE
8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP: Code)			() 9A. AMENDMENT OF SOLICITATION NO. X RFP-13-100-SOL-00008	9B. DATED (SEE ITEM 11) April 16, 2013
			10A. MODIFICATION OF CONTRACT/ORDER NO.	10B. DATED (SEE ITEM 13)
CODE	FACILITY CODE			

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

()	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

PURPOSE OF AMENDMENT:

- (1) Update Section J and Section L of RFP.
- (2) Provide answers to inquiries received regarding the solicitation.

See page 2

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Jason Bell Contracting Officer, AMCG, OS, ASPR, HHS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY  (Signature of Contracting Officer)	16C. DATE SIGNED 4/16/13
(Signature of person authorized to sign)			

The following sections of the RFP are hereby replaced with the following (additions in red, deletions in red strikethrough):

SECTION C – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

C.3.2. Objective 2: Clinical Trial Response Readiness

C.3.2.1.Preparedness

Offerors may be required to perform the following activities to prepare for a clinical trial during a public health emergency:

- Provide a plan that is ready to execute for the trial to include but not limited to personnel, documentation, regulatory approvals, material and management plans as appropriate
- Test the plan
- Provide Clinical Protocol (CPs)
- Provide Case Report Forms (CRFs)
- Provide Informed Consent forms (ICFs)
- Develop a clinical and safety database in preparation for Clinical database readiness
- Pre-identify clinical research sites including study budget and contracts in place
- Pre-qualify central laboratories for validated assays
- Provide documented product delivery, storage and pharmaceutical product accountability procedures
- Obtain Institutional Review Board (IRB) approval of the clinical protocols, annotated CRFs and ICFs. (National IRB if available/appropriate)
- Establish an identified project team. The project team may include a clinical research associate, safety monitor, data manager, regulatory specialist, medical writer, project manager and pharmacovigilance specialist.
- Document data flow and sample handling processes (lab manual)
- **Provide an operational strategy to gather clinical data**
- Annual review and renewal of the plan

Specific roles for BARDA and the Contractor will be established at the time of TO.

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.2. TECHNICAL PROPOSAL

L.2.1. Technical Proposal Instructions

L.2.1.1. Technical Proposal – Components

(3) Section 3: Mandatory Evaluation Criteria

Offerors must show completion of at least one infectious disease or chemical, biological, radiological or nuclear clinical study under a FDA Investigational New Drug (IND) application in the last 5 years in order to be considered for award. **A clinical study is deemed “complete” for purposes of this criterion when a final clinical study report is produced.** Offerors shall submit the title of the clinical study, ~~the identity of the sponsor~~, the IND number as documentation.

(5) Section 5: Technical Evaluation Criteria

F. Sample Request for Task Order Response 0002

Describe in detail the Offeror's plan to prepare for and execute a clinical study described in the timeframe indicated. This plan should detail the activities that must be completed prior to study execution, activities required to maintain readiness capability and include a clear, executable process for initiating the study within the timeframe required. The Offeror shall submit a Gantt chart presented electronically as an integrated project plan in Microsoft Project 2007 format. The Gantt chart must contain sufficient detail to permit reviewers to make a realistic evaluation of the Offeror's likelihood of success. The Gantt chart should contain and track to a Work Breakdown Structure (WBS). The Gantt chart should show successors and predecessors, and milestones. The Offeror shall submit an Integrated Project Plan that outlines key, critical path milestones, with "go/no go" decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, ~~milestones in manufacturing, regulatory submissions, and storage and delivery of product.~~

The business portion of the Offeror's response to Sample Request for Task Order Response 0002 shall be limited to 15 pages and shall be included in the Offeror's business proposal as described in SECTION L.3.

SECTION M – EVALUATION FACTORS FOR AWARD**M.1. TECHNICAL EVALUATION****M.1.2. Mandatory Criteria for Eligibility**

Offerors shall have completed at least one infectious disease or chemical, biological, radiological or nuclear clinical study under a FDA Investigational New Drug (IND) application in the last 5 years. ~~A clinical study is deemed "complete" for purposes of this criterion when a final clinical study report is produced.~~

The mandatory criteria for eligibility must be met at the time of proposal submission. Offeror proposals that do not meet the mandatory criteria for eligibility will not be eligible for further evaluation.

(End of Summary of Changes to the text of the RFP)

Questions and Answers

The following questions have been submitted by prospective offerors and are addressed below. .

(1) QUESTION:

“You note in the amendment that participation by teleconference and webinar will be permitted for foreign nationals. Is there a possibility that our representative could attend via this method as well?”

ANSWER:

Yes, participation by teleconference and/or webinar for interested parties unable to attend in person IS permitted. However, teleconference and webinar participation still requires an RSVP to MCM-CSN@hhs.gov.

(2) QUESTION:

The RFP language states: " Offerors must show completion of at least one infectious disease or chemical, biological, radiological or nuclear clinical study under a FDA Investigational New Drug (IND) application in the last 5 years in order to be considered for award. Offerors shall submit the title of the clinical study, the identity of the sponsor, the IND number as documentation."

This language is ambiguous. How do you define "completion"? For example, often sponsors develop the protocol, whereas in other cases a CRO may develop the protocol in conjunction with the sponsor. What constitutes “completion” of the study? Often BARDA defines this as completed final study report, but final study report may be the responsibility of the CRO or the sponsor.

Just to illustrate, based on common industry jargon of "completed study," within our team we have individual sites which have completed 30 or more biodefense or vaccine studies over the last five years. Within some of our site networks, there are over 200 such studies completed over the last five years - documenting IND#, sponsor name, study name has taken many hours of labor.

ANSWER:

Completion is defined as a final clinical study report. A network of clinical sites is not anticipated to be responsive to the mandatory criteria or BARDA’s requirements as they relate to this RFP.

(3) QUESTION :

Many sponsors require confidentiality, and so CRO’s and sites are not at liberty to disclose sponsor and protocol details. Accordingly, these may have to be redacted or anonymized, or (in some cases) the IND number may not have been provided.

Just to provide some sense of how I currently interpret the RFP guidance as it is worded, in my mandatory response criteria section response, I currently anticipate providing a table with selected examples (perhaps 15 or so) as well as some summary statistics for the number of completed studies parsed by study stage (Phase 1, 2, or 3) as well as category (therapeutic, device, vaccine)

ANSWER:

The mandatory criteria is hereby amended to remove the requirement for the identity of the sponsor.

The study title may be redacted to remove the identity of the clinical material being evaluated. The study title and IND number are required. These data elements will be cross-referenced with internal USG resources or external resources. NOTE: Only one study is required to meet the mandatory criteria.

(4) QUESTION:

The current version of the RFP includes the following language (in relevant part):

L.2.1.1. Technical Proposal – Components

(5) Section 5: Technical Evaluation Criteria (p.59-60)

E. Sample Request for Task Order Response 0001

"The Offeror shall submit an Integrated Project Plan that outlines key, critical path milestones, with —go/no go decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, regulatory submissions, and storage and delivery of product."

F. Sample Request for Task Order Response 0002

"The Offeror shall submit an Integrated Project Plan that outlines key, critical path milestones, with —go/no go decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, regulatory submissions, and storage and delivery of product."

Please clarify the intent and scope of the government's request concerning these Integrated Project Plans? Such plans are typically developed and are under the control of the Sponsor of holder of the IND/BLA rather than within the scope of services provided by CRO, SMO or sites involved in managing clinical studies.

In order to comply with this request for an IPP for the influenza vaccine and smallpox therapeutic products, offerors will require extensive information concerning these products' current development state, and product profile (or TPP).

ANSWER:

E. "Sample Request for Task Order Response 0001" fully describes the USG intent and scope for the Integrated Project Plan. Offerors are encouraged to address this requirement to the best of their ability.

F. "Sample Request for Task Order Response 0002" is hereby amended to remove 'manufacturing' and 'storage and delivery of product'. Offerors are encouraged to address the remaining aspect – regulatory submission milestones – to the best of their ability.

Additional information concerning the products' will not be provided.

(5) **QUESTION:**

Regarding the following sections:

**ATTACHMENT #3
DISCLOSURE OF LOBBYING ACTIVITIES, WITH INSTRUCTIONS**

**ATTACHMENT #4
SMALL BUSINESS SUBCONTRACTING PLAN**

**ATTACHMENT #10
CONTRACT PERFORMANCE EVALUATION REPORT**

**ATTACHMENT #12
SUMMARY OF RELATED ACTIVITIES**

For each of these, can you please clarify whether they shall be included in 1) Technical proposal, 2) Business proposal or 3) both, and whether the associated documents are to be included in the page count for the corresponding section?

ANSWER:

Each of the said attachments should be included in the Business Proposal. These attachments do NOT count against the corresponding page limit.