

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE N/A	PAGE OF PAGES 1 9
2. AMENDMENT/MODIFICATION NO. 0005	3. EFFECTIVE DATE May 10, 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	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE	
8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP: Code)			<input type="checkbox"/>	9A. AMENDMENT OF SOLICITATION NO. RFP-13-100-SOL-00008
			<input checked="" type="checkbox"/>	9B. DATED (SEE ITEM 11) April 1, 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.

<input type="checkbox"/>	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 Attachment 2 of Section J and Section L of the 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)	
15B. CONTRACTOR/OFFEROR		16B. UNITED STATES OF AMERICA	
15C. DATE SIGNED		16C. DATE SIGNED	
_____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)	

1. On page 60 of the RFP, the Quality Metrics Appendix to the technical proposal in Section L.2.2. is hereby deleted in its entirety and replaced with the following:

The offeror shall provide the following Quality Metrics for the past four reporting periods (e.g. quarter, fiscal year, calendar year, etc.) for all active clinical studies:

- Update subject recruitment (numbers screened, numbers enrolled and drop-outs per clinical site).
- Contractor staff stability for CRAs, Project Manager, Regulatory and other personnel.
- Clinical study Trip Report timeliness.
- Queries as a measure of whether the clinical study PMs and CRAs are in control of their studies.

2. On page 107 of the RFP, Attachment 2, “Sample Request for Task Order Response 0002,” is hereby amended to add the following the section entitled “Base Period: Preparedness:”

“Option Period: Preparedness:

Continuation of activities as detailed in “Base Period: Preparedness” above, through Years 3, 4, and 5.”

3. On page 107 of the RFP, Attachment 2, “Sample Request for Task Order Response 0002,” is hereby amended to replace “Option Period: Response” with “Option: Response.”

This is illustrated as follows:

Option ~~Period~~: Response

Execute the plan to treat the first patient with the first dose within 24 hours of the unilateral execution of this option.

4. Item 17, “Vendor Management”, of Attachment 2B, Table 1 is hereby amended to delete the “X” under the “CRO” column for each of the three rows and inserting an “X” under the “BARDA” column for each of the three rows.

The relevant portion of the chart is updated as follows. The chart remains otherwise unchanged:

Activities	BARDA	CRO
17. Vendor Management		
Central laboratory: Select central laboratory, establish contract and make payments, manage central laboratory, develop laboratory database specs and visit specific laboratory requisitions, resolve all central laboratory lab issues with the sites; transfer central lab data to study database	X	✗
Interactive Voice Response System (IVRS)	X	✗
Select IVRS vendor, establish contracts and make payments, Manage IVRS contractor, develop IVRS database specifications and system menu, develop site IVRS manual; authorize subject eligibility verification and treatment assignment; transfer IVRS data to study database	X	✗
Vendor management sub-total		

5. Questions received.

QUESTIONS & ANSWERS

1. In RFP Amendment 0004 issued 5/2/13, BARDA has updated RFP Section L.2.2. – Appendices to Technical Proposal – with added Quality Metrics for “the past year for all active clinical studies.” Please provide clarification to the following items:
 - a. All active clinical studies: Given page limitations and because across all disciplines, we have a very large number of active clinical studies, we assume BARDA desires information for studies on infectious diseases, or chemical, biological, radiological, or nuclear clinical studies for the past calendar year. Please confirm.
ANSWER: Quality Metrics for all active clinical studies may be provided. Please limit your response to 50 examples, if available, with an emphasis on infectious disease, chemical, biological, radiological or nuclear clinical studies.
 - b. “Contractor staff availability (over each quarter)....” Because we track this type of staff stability and turnover on a calendar year basis (and not quarterly), we assume that metrics for the last calendar year will be acceptable for this item - Please confirm.
ANSWER: Calendar year information is acceptable. The RFP has been amended to require the past four reporting periods.
 - c. Regarding the items requested in the update to Section L.2.2 (subject recruitment; staff stability; trip report guidelines; and queries): please confirm that these items also DO NOT count against the 50-page Appendix page limit for the Technical Proposal.
ANSWER: These items identified in the question do not count against the 50 page Appendix page limit for the Technical Proposal.
2. Amendment 0004, answer #43 states that the list of sites should be a technical proposal “Attachment” that “does not contribute to the page count.” We presume this means an Appendix to the technical proposal, and that it DOES NOT count against the 50-page Appendix page limit. Please confirm.
ANSWER: The list of technical sites attachment specified in answer 43 of Amendment 0004 does not contribute to the 50-page Appendix page limit.
3. Should commitment letters from sites be included as part of this Appendix listing of the sites (or another location in the Technical or Business proposal)?
ANSWER: If you need to submit commitment letters they may be included in the Appendix listing of the Technical proposal (in the uncounted portion).
4. Can offerors add other Appendices if needed, as long as when added to the other items subject to the limit (e.g. those on RFP pg. 60), the 50-page maximum is not exceeded?
ANSWER: Yes, Offerors may add appendices if needed as long as the other items subject to the limit do not exceed the 50-page limit.
5. Amendment 0003 answer #28 states that the Small Disadvantaged Business Participation Plan information must be included in the Small Business Subcontracting Plan. However, the Small Business Subcontracting Plans are not applicable (and submission does not occur) for small businesses under the given solicitation, while the Small Disadvantaged Business Participation Plan, in our experience, IS required, irrespective of whether a firm is large or small. (This is stated in RFP Section L.13, pg. 68, top paragraph). Please confirm if BARDA is requesting the Small Disadvantaged Business Participation Plan for small businesses. If so, should it be as a separate attachment to the Business Proposal, and NOT part of the page limitation?

ANSWER: Correct. All Offerors are responsible for submitting information regarding of the extent of Small Disadvantaged Business Participation regardless of whether a Small Business Subcontracting Plan is required. If an Offeror is exempt from submitting a Small Business Subcontracting Plan, Attachment 4 should contain only information pertaining to Small Disadvantaged Business Participation.

6. If the government will be doing the PK testing will they ship the sample kits to the sites?

ANSWER: For Sample RTOR0002 , kits will not be shipped – assume standard blood tubes from the sites will be used.

7. It is stated that contractor should submit a cost proposal for the IDIQ but the RFP does not state any pricing assumptions to do. The government reference section L.3.4 but that refers to Other Administrative Data which does not provide any pricing perimeters. Please clarify what we are to be providing as cost for the IDIQ.

ANSWER: This issue was addressed under Amendment 003 with revision to Section L.3.2.

8. Should the EVM plan be submitted for both Sample Tasks 001 and 002?

ANSWER: This is addressed under Amendment 003, Question #56. As stated therein, Sample ROTRs 0001 and 0002 have been modified to be Cost Plus Fixed Fee and EVMS management plans are required. EVMS management plans are required by Task Orders that exceed the limits defined in HHSAR 334.203.

9. Due to our large institutional size we would like to provide the government with targeted metrics information. Can the contractor provide metrics on areas of interest or phases base on our current portfolio?

ANSWER: As stated in the answer in Question 1.a. above: Quality Metrics for all active clinical studies may be provided. Please limit your response to 50 examples, if available, with an emphasis on infectious disease, chemical, biological, radiological or nuclear clinical studies.

10. Per the instructions for the technical proposal Components (L.2.1.1), Section 5.A. (pg. 59) Objective 1 should discuss “organizational experience,” “issues or obstacles,” and “risk management”. Therefore, it appears that our approach to fulfilling Objective 1 should not be discussed here, but only in Section 4. (Section 4 calls for “technical approach/method”, and how the project is “to be organized, staffed, and managed”.) Please, confirm or clarify.

ANSWER: Section 4 shall provide an overarching, comprehensive statement of work describing how the Offeror proposes to address all of the requirements of this Request for Proposal Statement of Objectives. Section 5.A. shall expand upon the specific activities related to Objective 1 and Objective 2.

11. As opposed to Objective 1 - the instructions at Section 5.A.Objective 2 (pg. 59) indicate that the response should contain our approach to fulfilling Objective 2 (e.g. the “method”, 1st line). Therefore, it seems that:

- a. For Objective 2 BARDA is not requesting information on experience/issues/obstacles/risk management (which are requested for Objective 1). Please confirm or clarify.

ANSWER: Objective 2, as described in C.3.2., includes all aspects of Objective 1. As appropriate, Offerors are expected to address similarities/differences between the technical approaches for these Objectives, however a redundant activity list is not required.

- b. For Objective 2, Section 4 and Section 5 seem to be asking for the same (or similar) information. Please confirm or clarify.

ANSWER: Section 4 shall provide an overarching, comprehensive statement of work describing how the Offeror proposes to address all of the requirements of this Request for Proposal Statement of Objectives. Section 5.A. shall expand upon the specific activities related to Objective 1 and Objective 2.

- 12. Related to the above, the title “Technical Plan/Approach” for 5.A. appears to be misnamed, since what this refers to seems to be called for in Section 4? Please clarify.

ANSWER: Section 4 should provide an overarching, comprehensive statement of work describing how the Offeror proposes to address all of the requirements of this Request for Proposal Statement of Objectives. Section 5.A. should expand upon the specific activities related to Objective 1 and Objective 2.

- 13. Amendment 0004, pg. 31, Question 90 / Attachment #2, pg. 116, Table 2B, under 17 – Vendor Management. The response to question 90 states that, for Sample RTOR 0002, the contractor is not responsible for sample analysis. In Attachment #2, page 116, Table 2B, under 17 – Vendor Management, it appears that the contractor is expected to select, contract with, pay, etc. a central laboratory vendor.

- a. What is the purpose of the central laboratory vendor for Sample RTOR 0002?
- b. What sample analyses would the central laboratory perform?
- c. Should Offerors provide costs for a central laboratory vendor in the budget for Sample RTOR 002?
- d. If yes, what costs should be included?

ANSWER: This is in response to questions a, b, c & d above. For Sample RTOR 2, a central laboratory vendor is not required. This Amendment to the RFP changes Attachment 2B, Table 1 to make each of the Vendor Management tasks the responsibility of BARDA rather than the Offeror.

- 14. Reference: Amendment 0004, pg. 30, Question 88 / Attachment #2 on pg. 116, Table 2B under 17 – Vendor Management

Question: The response to question 88 states that an IVR system is not required for Sample RTOR 0002. In Attachment #2 on page 116, Table 2B under 17 – Vendor Management, it seems that the contractor is expected to select, contract with, pay, etc. an IVRS vendor.

- a. What is the purpose of the IVRS vendor in Sample RTOR 0002?

ANSWER: For Sample RTOR 0002, an IVR system is not required. This amendment revised Attachment #2 to make each of the Vendor Management tasks the responsibility of BARDA rather than the Offeror.

- b. Should Offerors provide costs for an IVRS vendor in the budget for Sample RTOR 002?
ANSWER: For Sample RTOR 0002, an IVR system is not required. This amendment revises Attachment #2 to make each of the Vendor Management tasks the responsibility of BARDA rather than the Offeror.
- c. If yes, what costs should be included?

ANSWER: For Sample RTOR 0002, an IVR system is not required so costs are not required.

15. The response to question 90 (Amendment 0004) states that the contractor is not responsible for sample analysis and the response to question 91 states that CRO is not responsible for shipping live viral samples in Sample RTOR 0002.

- a. What should the CRO assume about the disposition of samples collected in the clinical trial?
- b. Will clinical sites be responsible for processing and storing samples on site, and if so, how long should CRO assume samples will be stored?
- c. Or will samples be provided to BARDA for processing, shipping, and analysis?

ANSWER: The answer for all three questions above (a, b, & c) on the Sample RTOR 0002, the Offeror is not responsible for processing and storing samples on site.

16. Reference: Amendment 0004, pg. 31, Question 90 / Amendment 0003, pg. 31, Question 102
The response to question 90 states that the contractor is not responsible for sample analysis in Sample RTOR 0002.

- a. Does this include hematology and chemistry analyses, which Amendment 003 (page 31, response to question 102) states should be done by the clinical sites?
- b. Please clarify whether contractor will be responsible for analysis of hematology and chemistry samples.

ANSWER: The answer for questions a and b above on Sample RTOR 0002, the Offeror is not responsible for analysis of hematology and chemistry samples.

17. Since the contractor is not responsible for analyses of samples or for shipping live viral samples for Sample RTOR 0002 (responses to questions 90 and 91 in Amendment 4), what assumptions should the CRO make about who will process specimens; which specimens, if any, contractor is expected to ship and to where; and when and how laboratory results will be received by the sites?

ANSWER: For Sample RTOR 0002, the Offeror is not responsible for processing, shipping and analysis of samples. Consequently, the Offeror need not make any assumptions about who will process specimens; which specimens, if any, it is expected to ship and to where; and when and how laboratory results will be received by the sites.

18. For RTOR0001: On pg. 81, the target for enrollment of the first subject is January 2014, with other deliverable due dates occurring sooner (e.g. the final protocol in December 2013, and draft 30 days prior – per pg. 96). But with the estimated contract award date in September 2013 per the FedBiz notice, with a similar (or later) task start date, there is insufficient time for these pre-study activities to occur. So - can we assume a task start date on or around the contract award date (e.g. October 1, 2013) - even if this means these initial deliverables occur 2-3 months later than in the RFP?

ANSWER: The Sample RTORs are included for evaluation purposes only. No Task Order w award will result from Offerors' Sample RTOR responses. The information provided is hypothetical in nature.

19. For TOR0002: Page 107 states that the Base Period is for “Preparedness”, and the Options are for “Response”. In other locations, the RFP and Q&As state that the base period is 24 months (2 yr.) duration (e.g. pgs. 106, 110, Mod 0003 Q&A#97, the Attachment 14 Excel Sheet). However, on pg. 124, “Period of Performance” states that the “preparedness phase” may require up to 365 days (1 year), and that each subsequent year is a “Readiness” year. Q&A#97 also refers to an “Option to Respond” and an “Option to Continue Preparedness.” We recognize per Mod 0003 Q&A#89, that real world circumstances may necessitate at Response at any time in actuality. But – for proposal timeline and costing purposes – please clarify what should be proposed for each of the following periods:

- Should the 2-year base period consist of “preparedness” activities only?

ANSWER: For Sample RTOR 0002, the Government contemplates options for continued preparedness in years 3, 4 and 5. In addition, a separate option to respond to an emergency through execution of the protocol will be exercised as needed, and may occur during the two year base period. The current amendment to the RFP amends page 107 of the RFP to clarify the distinction between the options to extend preparedness activities and the response option.

- Should the 1st Option (yr. 3) be the “Response” (i.e. the conduct of the clinical trial)?

ANSWER: No. Because the Government cannot anticipate when an emergency event necessitating the exercise of the option to respond, Offerors shall propose preparedness work in years 1 through 5. Offerors must additionally propose a response option to be exercised by the Government as needed to respond to an emergency.

- Should the 2nd and 3rd Options (yrs. 4 and 5) be for continued preparedness?

ANSWER: Yes. Offerors shall propose preparedness work in years 1 through 5, as well as a response option to be exercised by the Government as needed to respond to an emergency. The current amendment to the RFP amends page 107 of the RFP to clarify the distinction between the options to extend preparedness activities and the response option.

20. Based on these and previous questions, would BARDA consider another nominal extension of the due date?

ANSWER: AMCG does not anticipate extending the due date for proposals.

21. RFP requirement: L.1 states that “The proposal must be signed by an official authorized to bind the Offeror(s) organization and must stipulate that it is predicated upon all the terms and conditions of this RFP.” Is government using the standard format for this? ‘Attachment 5, Protection of Human Subjects’, is the only document that captures institutional signature/approval. Should we use this page as the institutional signature page?

ANSWER: The offeror must complete the ‘Offer’ section of Page 1 of the RFP (i.e. the Standard Form 33). The form under Protection of Human Subjects is not appropriate.

22. Is it USG’s intention to issue RTORs to all awardees where the Tasks are substantively “whole studies” (i.e., a complete set of activities as per Attachment 1B) like those of the sRTORs in the RFP?

ANSWER: The strategic objective of the Medical Countermeasures Clinical Studies Network to provide a clinical study core services may be achieved through the issuance of future RTORs detailing a requirement for a “whole study”, or for any component of clinical development operations and activities.

23. Does the USG expect to issue RTORs to the Awardees for selective activities, and then award, for example, a Data Management task to Awardee1, a Pharmacovigilance task to Awardee2, etc.?

ANSWER: The strategic objective of the Medical Countermeasures Clinical Studies Network to provide a clinical study core services may be achieved through the issuance of future RTORs detailing a requirement for a “whole study”, or for any component of clinical development operations and activities.