

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			I. CONTRACT ID CODE N/A	PAGE OF PAGES 1 31
2. AMENDMENT/MODIFICATION NO. 0003	3. EFFECTIVE DATE April 22, 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)		

8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP: Code)	(E)	9A. AMENDMENT OF SOLICITATION NO. RFP-13-100-SOL-00008
	X	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.

(E)	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 Sections B, I, J and 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 <i>(Signature of person authorized to sign)</i>	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY  <i>(Signature of Contracting Officer)</i>	16C. DATE SIGNED 4/22/13

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

SECTION B – Supplies or Service and Price / Cost

B.5. ADVANCE UNDERSTANDINGS

B.5.6. Cost Unallowable Unless Authorized by the Contracting Officer

~~This section prohibits or restricts the use of contract funds for the following, unless otherwise approved in advance by the Contracting Officer:~~

Notwithstanding the clauses and unless authorized in writing by the Contracting Officer, the cost of the following items or activities shall be unallowable as direct costs:

[...]

SECTION I – CONTRACT CLAUSES

I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

FAR	52.210-1	Apr 2011	Market Research
FAR	52.222-41	Nov 2007	Service Contract Act of 1965.

SECTION J – LIST OF ATTACHMENTS

ATTACHMENT #1 - SAMPLE REQUEST FOR TASK ORDER RESPONSE 0001

[...]

Study Design

Table 1: Study Description

STUDY PARAMETERS	
Number of subjects	400
Number of sites	6
Target first subject first visit	January 2014
Enrollment duration	2 weeks
Target last subject last visit	February 2015
Study close out, data clean up, analysis and report preparation	8 weeks

Total program duration	24 26 months
Number of unique CRF pages	15
Number of CRF pages per subject	55
Central randomization/IVRS	Yes
Central laboratory	Yes
Total number of SAE expected	25
Final analysis	
Number of tables	15
Number of listings	10
Number of figures	5

[...]

Contract Type

The Government contemplates award of the following contract type:

Cost Reimbursement [checked]
 Firm Fixed Price [unchecked]
 Mixed Cost Reimbursement/Firm Fixed Price

[...]

Contract Type(s): ~~Firm Fixed Price~~ Cost Plus Fixed Fee

Attachment 1B – Pricing Schedule/CLIN Structure
Table 1. Cost and Price Schedule:

[...]

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
5. Investigational product (IP) management									
Packaging, labeling, storage and distribution	✘	X							
Authorization of initial IP shipment to sites	X								
Manage IP distribution and related documentation		X							
Verify IP documentation at sites, including dispensing records		X							
Perform IP accountability audits	X	X							
Retrieval or on-site disposal of IP		X							
IP management sub-total:									

[...]

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Other Direct Costs	Other Indirect Costs	Pass through Costs	Total
7. Pharmacovigilance									
Development pharmacovigilance plan and safety database		X							
Provide 24 hour medical monitoring to all sites for all medical issues		X							
Collect information on SAEs from sites		X							
Prepare SAE narratives		X							
Submit expedited safety reports to regulatory authorities and sites		X							
Data Safety Monitoring Board		X							
Pharmacovigilance sub-total									

Attachment 1C – Statement of Work

Appendix A: Schedule of Procedures/Evaluations

Study Visit	Screen* 0	1		2	3		4	5	6	7	
Study Day	-28 to -1	0	2*	8	21	V3+2*	V3 +8	V3+28	208	365	Early Termination
Procedure											
Informed Consent	X										
Review Eligibility Criteria	X	X			X						
Review Health Status				X	X		X	X		X	X
Vital Signs (Temp, Pulse, BP)	X	X			X						
Medical History	X	X									
Targeted Physical Examination, as indicated	X	X		X	X		X	X			X
Urinary pregnancy test	X [†]	X [†]			X [†]						
Assessment of lymph nodes	X	X		X	X		X	X			
Concomitant Medications	X	X	X	X	X	X	X	X			X
Blood for safety labs ¹	X			X			X				
Blood for Antibody Assays ²		X		X	X		X	X	X	X	X
Randomization		X									
Vaccination		X			X						
Distribute Memory Aid and Study Related Materials		X			X						
Review Memory Aid			X	X		X	X				
SAE Assessment		X	X	X	X	X	X	X	X	X	X
AE Assessment		X	X	X	X	X	X	X			X

¹ Safety labs include general chemistry and hematology: Electrolytes, SGPT, SGOT, albumin, total protein, creatinine, BUN, WBC with differential, RBC, platelets, HgB, HCT, PT, PTT.

² Antibody assays include Hemagglutination Inhibition Assay and microneutralization.

Deliverables & Schedule

Delivery #	Deliverable Title	Format³	Timeframe for submission
1	Draft protocol	MS Word	30 days prior to submission to CBER
2	Draft IND Submission package	MS Word	30 days prior to submission to CBER
3	Final protocol	Adobe Acrobat	Due: December 2013
4	Final IND Submission package	Adobe Acrobat	Due: December 2013
5	Interim report including a safety and immunogenicity for all subjects through Day 42 visit	Adobe Acrobat	30 days after all subjects complete Day 42 visit
6	SAEs	Email, telephone	Within 24 hours of SAE notification to CRO
7	Enrollment updates	MS PowerPoint	Weekly while enrollment is ongoing
8	Safety information specifically any several local or systemic reactions, Grade 3 or Grade 4 laboratory values	MS Word	Within 5 days of notification to the medical monitor
9	Investigator Brochure	Adobe Acrobat	Due: With the final protocol
10	Proposed Clinical Sites	Adobe Acrobat	Within 10 days of executed Task Order
11	Final Clinical Study Report	Adobe Acrobat	Within 3 months of database lock

³ As specified, or compatible products with similar capabilities

Attachment 1E – Submission Instructions

“Volume 2 – Price Submission”

~~c) The response shall include the labor/pricing matrix(ces) for the base period and the option periods using the format included in Table 2 below. In Table 2 respondent shall list all labor categories proposed for each major Section of the SOO/SOW by WBS number and title as proposed by the respondent. The labor/pricing matrix(ces) should include labor categories as identified in the Master Contract Section J, the number of full-time equivalents (FTEs), the number of total hours per labor category, and the total dollar value. The respondent shall include a comparison between the labor categories/hourly rates proposed in this task order to your Labor/Pricing Matrix(ces) in the Master contract (See attachment 7).~~

The response shall include a submitted Excel spreadsheet which can be obtained per the instructions in SECTION J - Attachment #14. Modify the spreadsheet as-needed to present the figures in an appropriate manner.

The excel spreadsheet can be submitted as a separate Excel document or as a pdf. This portion of the submission instructions (e.g. font size, file format, etc.) supersede any other formatting/submission instructions included in this RFP.

“Table 2 – Labor/Price Matrix” is hereby deleted and replaced with the following text:

PLEASE SEE SECTION J – LIST OF ATTACHMENTS, Attachment #14 of the RFP for instructions.

The “Material(s) Matrix” table/chart (under Table3 – Cost Centers) is hereby deleted. Submission of this table/chart is no longer required for this RFP. Table3 – Cost Centers is still required for submission.

ATTACHMENT #2

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0002

[...]

Contract Type

The Government contemplates award of the following contract type:

Cost Reimbursement
[checked]

Firm Fixed Price

Mixed Cost Reimbursement/Firm
Fixed Price [unchecked]

[...]

Contract Type(s): ~~Firm Fixed Price~~ **Cost Plus Fixed Fee**

[...]

Attachment 2E – Submission Instructions

“Volume 2 – Price Submission”

~~h) The response shall include the labor/pricing matrix(ces) for the base period and the option periods using the format included in Table 2 below. In Table 2 respondent shall list all labor categories proposed for each major Section of the SOO/SOW by WBS number and title as proposed by the respondent. The labor/pricing matrix(ces) should include labor categories as identified in the Master Contract Section J, the number of full time equivalents (FTEs), the number of total hours per labor category, and the total dollar value. The respondent shall include a comparison between the labor categories/hourly rates proposed in this task order to your Labor/Pricing Matrix(ces) in the Master contract (See attachment 7).~~

~~The response shall include a submitted excel spreadsheet which can be obtained per the instructions in SECTION J - Attachment #14. Modify the spreadsheet as-needed to present the figures in an appropriate manner.~~

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“Table 2 – Labor/Price Matrix” is hereby deleted and replaced with the following text:

PLEASE SEE SECTION J – LIST OF ATTACHMENTS, Attachment #14 of the RFP for instructions.

The “Material(s) Matrix” table/chart (under Table3 – Cost Centers) is hereby deleted. Submission of this table/chart is no longer required for this RFP. Table3 – Cost Centers is still required for submission.

ATTACHMENT #14 IS HEREBY ADDED TO SECTION J – LIST OF ATTACHMENTS

ATTACHMENT #14

Please see two (2) Microsoft Excel files included separately in this attachment to FedBizOpps.gov. One of the templates is for use with ATTACHMENT #1 – Sample RTOR 0001 and the other for ATTACHMENT #2 – Sample RTOR 0002. It is permissible for Offeror to tailor the templates to best represent the company’s proposed costs, so long as they remain substantively the same.

If you have trouble accessing the file, please email mcm-csn@hhs.gov.

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.3. BUSINESS PROPOSAL

L.3.2. Business Proposal Instructions

The business proposal shall not exceed 50 pages (~~not including information required located in SECTION J – List of Attachments, cover page, or table of contents).and shall reflect all cost information per objective as delineated in the SOO.~~

The business proposal shall include the business portion of the Offeror’s response to Sample Request for Task Order Response 0001 and Sample Request for Task Order Response 0002. The sample ROTR business proposals shall not exceed 15 pages each (~~which ARE included in the 50 page total~~).

[...]

(6) Past performance information

Offerors shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors.

The Offeror shall provide a list of the last five (5) contracts completed during the past three years and all **government** contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

- (a) Name of Contracting Organization
- (b) Contract Number
- (c) Total Contract Value
- (d) Description of Requirement
- (e) Contracting Officer’s name and telephone number
- (f) Program Manager’s name and telephone number

(7) Direct Labor Information

~~Offerors shall define general Direct Labor categories that the Offeror anticipates will be required to successfully accomplish the objectives defined in the SOO. Offerors shall also submit unburdened labor rates for each category, which may be represented as a range, as needed.~~

~~Offeror should also provide the proposed annual escalation rate for each of the five years this IDIQ contract could potentially last (assuming all options were exercised by the Government). Discuss your proposed rate as compared to historical experience and include when and how escalation will be calculated/implemented.~~

Discuss any additional direct labor (new hires) that will be required during the performance period and any financial risks that could be anticipated.

L.3.4. Other Administrative Data

[...]

(2) The proposal must list any current commitments with the Government relating to the work or services contemplated by this RFP as well as ANY proposal submitted to any government solicitation which is pending. Furthermore, proposal must indicate whether these commitments will or will not interfere with the completion of work and services as contemplated under this proposal.

[...]

(6) Offeror must provide the most recent pending/established indirect rate agreement with this proposal, if applicable. If no rates have been established, Offeror must provide rationale for the proposed rates.

(End of Changes to the text of the RFP)

QUESTIONS & ANSWERS #2

1. Does the mandatory criterion apply at the team level or at the prime level? Does the prime itself have to meet the mandatory criteria?

ANSWER: The mandatory criteria will apply at the prime level. In a teaming arrangement where there is more than one prime level offeror, any of the prime level offerors could satisfy the criteria.

2. With regard to an offeror that may have a teaming arrangement, is it the government's intention to make an award only to those offerors whose prime contractor of the team performs the majority (> 50%) of the work associated with each potential task order?

ANSWER: There is no percentage requirement for work completed by a prime contractor as this is full-and-open competition. However, note that FAR Clause 52.215-23 Limitations on Pass-Through Charges is always applicable.

3. Please clarify whether clause HHSAR 352.234-3 will be inserted into any resultant contract award and clarify whether a validated and accepted EVMS as further detailed in HHSAR 352.234-3 is a requirement of the solicitation.

ANSWER: It is not anticipated at this time that HHSAR 352.234-3 will be included in a resultant award. Contractors may be required to have EVMS capabilities for work under resulting Task Orders with dollar values in excess of FAR, HHSAR, and ASPR thresholds. These guidelines would be well-defined at the time a sample task order is issued.

4. Please clarify if a certified, electronic EVMS tool is required, and if so for what thresholds.

ANSWER: A certified electronic EVMS tool is not a requisite for award. However, if a task order is awarded in excess of the defined thresholds, a management plan will be required. Current EVMS capabilities will not be a considered in the evaluation of proposals under this RFP.

5. In the cost proposal, are we required to show fee on cost reimbursable task orders only?

ANSWER: Both RTOR 1 and RTOR 2 are cost-reimbursement, per the amendment to the RFP.

6. The business proposal instructions indicate the maximum length is 50 pages, including both sample task orders.

- a. Does this 50 page limit include the forms listed in paragraph L.3.1 on page 61?

ANSWER: The 50 page limit applies to the Business Proposal, but does NOT apply to Attachments in Section J of the RFP.

- b. Does the 50 page limit include spreadsheets which reflect the required detailed pricing?

ANSWER: Yes.

- c. Does the 50 page limit include the small business subcontracting plan?

ANSWER: No. The 50 page limit applies to the Business Proposal, but does NOT apply to Attachments in Section J of the RFP.

- d. Please confirm that the title page and table of contents do not count against the 50 page limit?

ANSWER: Yes.

- e. Please confirm that the cover page and table of contents for the business volume of each Sample Task Order does not count against the separate 15 page Task Order limits?

ANSWER: Confirmed. The title page and table of contents of the Sample Request for Task Order Responses business proposals do not count against the 15 page limits.

- f. The Business Proposal instructions in section L.3.2 on page 61 indicate that the business portions of the Sample Task Order responses should be included within the Business Proposal. The instructions for each Sample Task Order indicate that each Sample Task Order should have a separate Volume II-Price Submission. Does the Government prefer that we imbed the business portion of each Sample Task Order within the main Business Volume or would you prefer that both Sample Task Order business volumes be segregated as attachments or appendices to the main Business Volume (the entire package being subject to the 50 page limit)?

ANSWER: The page limit for the portion of the Business Proposal related to the base contract is 50 pages. Included in that 50 pages, the page limit for the Sample Request for Task Order Response 0001 business proposal is 15 pages and the page limit for the Sample Request for Task Order Response 0002 business proposal is 15 pages. Therefore, 50 page limit for the entire Business Proposal.

Please present the RTOR document segregated as attachments or appendices to the main Business Proposal.

- g. For the pricing tables and charts required for Sample Task Orders 1 and 2, may we use font as small as 8 point.

ANSWER: Yes, fold-outs used for charts, tables may not exceed 11" x 17"; no smaller than 8 point font.

7. Regarding the CLIN tables in sections B.4.1 and B.4.2, please confirm whether we are required to provide a value in place of the TBD in each table (e.g., by adding the value of the two sample task orders) or whether the Government will assign overall base contract ceiling values at the time of award?

ANSWER: Offerors are not required to provide a value in place of the TBD in the tables in sections B.4.1 and B.4.2.

- a. If we are to provide a value in place of the TBD designation, are we to list a single, all-encompassing price or break them out as described in the * footnote under each table (by labor costs, facility costs, and all other costs)?

ANSWER: This table will be updated prior to a contract award for any resulting award.

8. Regarding Section B.5.6 on RFP page 7:

- a. Subsection (g) indicates that costs incurred in the performance of any cost-reimbursement type subcontracts (including consulting agreements) are unallowable unless approved in advance by the contracting officer.

- i. Does the government believe it unlikely that it will approve cost reimbursement type subcontracts in general?

ANSWER: No, this is not unlikely. The nature of the activities required in the task order will dictate the contract type.

- ii. Are Time and Material (T&M) consulting agreements (essentially standard fixed price per labor hour agreements) allowable without pre-approval?

ANSWER: No, because Time & Material contracts have cost-reimbursement components, they are treated as cost-reimbursement contracts and therefore require prior written authorization.

- b. Subsection (h) indicates costs incurred in the performance of a fixed-price subcontract that exceeds \$150,000 are unallowable unless approved in advance by the contracting officer.

- i. Does the government believe it unlikely that it will approve fixed-price subcontracts in excess of \$150,000 in general?

ANSWER: No, it is fully anticipated that fixed price subcontracts in excess of \$150,000 may be approved, however they will always require prior written authorization from the contracting officer (see FAR 44.2).

9. Will costs for subject recruitment or subject remuneration be allowable as part of an approved protocol?

ANSWER: It is anticipated that costs of this nature could be allowable as part of an approved protocol. However, direct costs will only be reimbursed if they satisfy the standards set forth in FAR Part 31.

10. Regarding Section L.3.4(2) on page 65 – The RFP indicates the business proposal must list any current commitments with the Government “relating to **the work or services** and indicate whether these commitments will or will not interfere with the completion of work and services as contemplated under this proposal” (emphasis added). Please clarify what is meant by “the work or services?” Does this mean we are to list all current contracts with any Government entity? Or commitments that are in some way related to the work or services contemplated under this RFP?

ANSWER: Correct, Offerors must list other commitments with the Government related to the work contemplated under this RFP.

11. HHSAR Clause 352.231-70 is included in the RFP. It indicates that “an individual’s direct salary is the annual compensation that the Contractor pays for an individual’s direct effort (costs) under the contract” (emphasis added). If a prime contractor or subcontractor employee has a normal gross annual salary of \$200,000 (which would exceed Executive Level II if the employee worked full-time for a year under the contract) and only works 100 hours on the contract during a given

year, their compensation for the direct effort under the contract will equal approximately \$9,615 ($\$200,000/2080 = \$96.15 * 100 = \$9,615$). Please confirm that in this situation there would be no violation of 352.231-70, because the compensation paid for the direct effort under the contract is far below the Executive Level II threshold?

ANSWER: Confirmed.

12. Regarding Section M.2.1 Base Contract Business Proposal Evaluation on page 75 – The RFP indicates: “The Offeror’s business proposal and proposed cost/pricing shall be evaluated separately and then the overall analysis of the business proposal will be evaluated to reach the best overall value to the Government.” Sections M.2.2 and M.2.3 proceed to talk separately about the Sample ROTR Business Proposal Evaluations. Please confirm that the only specific costs/prices to be submitted relate to the two Sample ROTRs and that there is no separate specific costs/prices as part of the basic business proposal?

ANSWER: The RFP has been clarified via amendment, see L.3. Business Proposal Instructions. Offerors shall submit labor categories and rates under the general portion of the RFP in addition to the costs requested in the Sample RTOR’s.

13. For Table 2 – Labor/Price Matrix on page 102, please confirm the “Standard Hourly Rate” column is intended to be the Direct Labor cost and not a fully burdened cost?

ANSWER: The “Labor/Price Matrix” has been removed from this RFP and replaced with the excel budget found in Section J – List of Attachments (Attachment #14). This spreadsheet clearly delineates labor costs from any applicable rates.

14. Please confirm that Certified Cost or Pricing data will not be required as part of this RFP proposal submission?

ANSWER: Confirmed. Certified Cost or Pricing data is not required.

15. With regard to Sample ROTR 0002, the Contract Type information provided at the top of page 106 indicates that Sample ROTR 0002 is a mixed type task order (both fixed price and cost reimbursement). Please clarify which aspects of Sample ROTR 0002 are intended to be fixed price and which are cost reimbursement. Or should Sample ROTR 0002 be exclusively firm fixed priced? (Please note that page 110 lists Sample ROTR 0002 as being solely firm fixed price).

ANSWER: Sample ROTR 0002 is now a cost reimbursement task order. The RFP has been modified to reflect this.

- a. Table 1 for Sample ROTR 0002 on page 129 lists only a single CLIN. If this contains both FFP and Cost Reimbursement activities, will a second CLIN be needed?

Answer: N/A

16. Tables 1 and 2 of Attachments 1B and 2B require Offerors to list Pass through Costs. The RFP also contains FAR Clause 52.215-23 Limitations on Pass-Through Charges. Can the Government provide clarification as to what is considered a pass-through charge? If our normal accounting practice is to charge only our G&A indirect rate plus appropriate Fee on subcontractor costs, would any of that be considered a pass-through cost?

ANSWER: The “Labor/Price Matrix” has been removed from this RFP and replaced with

the excel budget found in Section J – List of Attachments (Attachment #14). This spreadsheet clearly delineates labor costs from any applicable rates.

17. The RFP includes the Service Contract Act. Please provide the applicable Wage Determination for use in pricing the Sample Task Orders.

ANSWER: The Service Contract Act is not applicable to this solicitation. The solicitation is hereby amended to remove FAR 52.222-41, Service Contract Act of 1965, and FAR 52.222-43, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts).

18. Regarding RFP Attachment #11 on page 150, are Offerors supposed to send this Past Performance Questionnaire to current or former customers? If so, how many customers need to complete the questionnaire?

ANSWER: No. Attachment #11 and Attachment #12 are for informational purposes only.

19. Clinical sites typically request various types of equipment to manage studies, including laptops, centrifuges, freezers, and so forth depending on the requirements of the study. Can these expenses be built in to the site fees so that the site is actually paying for the equipment out of its fee, and thus not violating section B.5.6?

ANSWER: The stipulation referenced in B.5.6. has been reworded via amendment to the RFP. However, note that if a fee is paid to the contractor can be used at the contractor's discretion.

20. Does Section B.5.6.e prohibition on travel to attend general scientific meetings/conferences and Section B.5.6.f include study investigator meetings?

ANSWER: No, the requirements set forth by B.5.6.e. would not exclude study investigator meetings related to the work under a task order. B.5.6.e. only prohibits travel to attend general scientific meetings and conferences without prior approval from the Contracting Officer. As a study investigator meeting related to the work under an awarded task order is NOT a general scientific meeting/conference, prior approval would not be needed.

21. On pages 3 and 4 of Amendment 1 for Attachments #1 and #2, would you clarify whether the Sample Task Order **Volume II – Price Submission** can be submitted in 1) MS Word **or** Adobe Acrobat, and Price Data in Excel, or 2) if Volume II for Attachments #1 and #2 may **only** be submitted in MS Word and Price Data in Excel?

ANSWER: Volume II – Price Submission for Sample ROTR 0001 and Sample ROTR 0002 may be submitted in MS Word or Adobe Acrobat, with price data in Excel.

- a. Packaging and Delivery of Proposal instructions in the RFP indicate that “*Proposals must be submitted in Adobe PDF, Microsoft Word, Microsoft Excel, and Microsoft Project 2007 electronic format as appropriate*” does this mean that the Technical and Business Proposals are to be submitted in both Adobe PDF and Microsoft Word or one or the other?

ANSWER: Either is acceptable.

22. a. Please provide clarification on section B.5.3 Fulfilling Minimum Order Requirements. Does this mean that a contractor only must propose to fill one task order in the base period and can

claim \$400,000.00 even if the contractor is not awarded a contract?

ANSWER: Successful Offerors that win contracts under this solicitation will be required to respond to all future ROTRs as described in Section G.4. Such Contractors will be entitled to \$400,000.00 at the end of the base period of performance if they have satisfied all of their obligations under the base contract and have not won work under any task orders during that time. Contractors that are awarded a task order in an amount less than \$400,000.00 will receive payment for the balance of the minimum ordering amount at the end of the base period. For example, a Contractor that performed \$300,000.00 worth of work under task orders in the base period of the contract would be entitled to payment in the amount of \$100,000.00 at the end of the base period.

b. Similarly, does this section also mean that if option periods are exercised for the contract, each contractor is entitled to \$200,000.00 total even if they have only received a task order for a value less than \$200,000.00?

ANSWER: Contractors that win work in an amount less than \$200,000.00 will receive payment for the balance of the minimum ordering amount at the end of the relevant option period. For example, a Contractor that performed \$100,000.00 worth of work under task orders in the relevant option period of the contract would be entitled to payment in the amount of \$100,000.00 at the end of that option period (i.e. totaling the \$200,000.00 minimum guarantee for an option period).

23. On pg. 4, at Section B.2, RFP says that one or more IDIQ contracts will be awarded. Can BARDA provide further information on how many awards are actually contemplated? Also, will some of these awards be for small businesses (and if so how many), to facilitate achievement of small business goals?

ANSWER: The anticipated number of contract awards is dependent on the quality of proposals received. This solicitation is full and open competition.

24. Section L.3.2 (Business Proposal Instructions) indicates that the business proposal shall not exceed 50 pages and that the business proposal for each sample Task Order cannot exceed 15 pages each. Are the remaining 20 pages reserved for all of the business proposal attachments and appendices? For example, do the Offeror's Points of Contact form, Disclosure of Lobbying Activities form, and completed Representations and Certifications count towards the 50 page limit?

ANSWER: The Business Proposal is limited to 50 pages total. Included in the Business Proposal are Sample RTOR 001 and Sample RTOR 002. The Sample ROTR 0001 business proposal is limited to 15 pages. The Sample ROTR 0002 business proposal is limited to 15 pages. Documents required which are located in SECTION J – LIST OF ATTACHMENTS, as well as the cover page and table of contents do not count against the 50 page limit.

25. For the completion and submission of Attachment #11 entitled Past Performance Questionnaire, is the government looking for the feedback of an NIH project officer of a current federal project? Also, how many Past Performance Questionnaires should we have completed?

ANSWER: See the business proposal instructions at Sections L.3.2.(6) and the method of

evaluation of past performance in Section M.2.4. Attachment #11 and Attachment #12 forms are included for informational purposes only.

26. The Payment Information Form is included as Attachment #13 on Page 156 of 156 of the RFP; however, the Business Proposal Instructions do not mention this form. Should this form be included as a business proposal appendix document?

Answer: This only needs to be completed if the offeror is not registered to do business with the government.

27. Are bidders to include a Small Business Plan for the sample task order if the dollar threshold requirement is met? If so, please confirm if the page limit remains at a 15 page maximum for each task order business proposal.

Answer: Yes. Please note that the page limits do NOT apply to attachments located in Section J of the RFP.

28. Are bidders to include extent of Small Disadvantaged Business participation plans with the qualifying sample task orders? If so, please confirm if the page limit remains at a 15 page maximum for each task order business proposal.

ANSWER: Information relating to the extent of Small Disadvantaged Business participation must be included in the Small Business Subcontracting Plan (Attachment #4 located in Section J).

29. Page 61 of the rfp – L.3.2 Business Proposal Instructions states: “The business proposal...shall reflect all cost information per objective as delineated in the SOO.” Please confirm if bidders are only required at this time to provide costing for the following: 1) sample task order 0001 2) sample task order 0002

ANSWER: This section has been clarified via RFP amendment.

30. Page 82 of the rfp – Cost/Price Proposal states: “Cost/price proposal must include a completed Attachment 2” Can you confirm if the instructions should have read Attachment 1B?

ANSWER: Confirmed. This has been updated in the RFP. Furthermore, the RTOR 002 instructions have been updated to reference “Attachment 2B.”

31. Since sample task order is firm fixed price are bidders able to present the budget in an alternative format to attachment 1B?

ANSWER: The sample request for task orders have been changed to cost-reimbursement type.

32. Are the labor rates submitted to the business proposal for purposes of evaluating costs or are they anticipated to be the only labor rates used throughout the life of the contract?

ANSWER: They are for purposes of evaluating costs. While these rates are not binding, they must be proposed in good-faith and may be used as a benchmark for future evaluations.

33. Can you provide clarification regarding the labor category rates you appear to want in the general portion of the business proposal when it appears that Task Order will be FFP or CPFF? T&M labor categories would generally not be applicable to FFP or CPFF tasks/contracts. If we have fully loaded hourly rates in that how will we bill the government?

ANSWER: The RFP has been amended to provide clarification on the labor rates we are requesting. CPFF task orders are anticipated under this RFP, which require disclosure of unburdened labor rates. While these proposed rates will not be binding, however they must be proposed in good-faith and may be used as a benchmark for future proposals.

34. For fixed price RTORs will BARDA allow interim billing or only at completion?

ANSWER: Interim billing will be allowed.

35. Does a small business subcontracting plan need to be submitted for both Task Orders?

ANSWER: Yes.

36. Minimum ordering amount/year will each awarded contractor be guaranteed this amount?

ANSWER: Successful Offerors that win contracts under this solicitation will be required to respond to all future ROTRs as described in Section G.4. Such Contractors will be entitled to \$400,000.00 at the end of the base period of performance if they have satisfied all of their obligations under the base contract and have not won work under any task orders during that time. Contractors that are awarded task orders in an amount less than \$400,000.00 will receive payment for the balance of the minimum ordering amount at the end of the base period. For example, a Contractor that performed \$300,000.00 worth of work under task orders in the base period of the contract would be entitled to payment in the amount of \$100,000.00 at the end of the base period.

37. Are both Task Orders considered cost reimbursement now?

Answer: Yes.

38. Assurance of Compliance for Human subjects – is this required at the prime level or is sub level sufficient?

ANSWER: HHSAR 352.270-4 will be included in any resultant award. Assurance of Compliance for Humans will be enforced according to the terms set forth in the regulation (included below):

Notice to Offerors of Requirements of 45 CFR Part 46,
Protection of Human Subjects (January 2006)

(a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually

identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Government's Project Officer will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, the Project Officer will consult with OHRP.

(e) In accordance with 45 CFR Part 46, offerors being considered for award shall file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall ensure that: the rights and welfare of the human subjects involved are adequately protected; the risks to the subjects are reasonable in relation to both the potential benefits, if any, to the subjects and the importance of the knowledge to be gained; and informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP website (at http://www.hhs.gov/ohrp/assurances/assurances_index.html).

(f) Offerors may consult with OHRP for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

39. Please confirm Attachment 9 Risk Mitigation Plan / Matrix Template should be completed and included as the Risk Mitigation Plan in the Appendix of the Technical Proposal?

ANSWER: Yes, Attachment 9 Risk Mitigation Plan / Matrix Template should be completed and included as the Risk Mitigation Plan in the Appendix of the Technical Proposal.

40. The RFP notes that HHSAR 352.228-7 is applicable. Does BARDA request offerors to carry Clinical Trial Insurance and if so, shall offerors include this cost in their Sample Task Order 0001 and Sample Task Order 0002?

ANSWER: The requirement to carry Clinical Trial Insurance will be defined on a case-by-case basis. For purposes of this RFP response, the cost of Clinical Trial insurance should be included in Sample RTOR 0001 and 0002 proposal responses.

41. Per the RFP, QA support will be needed throughout both of the objective/task orders but what

about Investigator Site Audits? Does BARDA plan to conduct those themselves or do they intend for the contractor to do so?

ANSWER: As appropriate the contractor is expected to conduct site audits. BARDA reserves the right to attend, initiate or conduct site audits independently or in concert with the contractor. BARDA RQA does have the expertise to conduct an ISA but can also have a contractor conduct the ISA. In the latter case BARDA may be an observer.

42. Will this contract execute Emergency Use Authorization expanded access trials only in the Continental United States?

ANSWER: This contract anticipates the potential to execute Emergency Use Authorized trials only in the United States (including expanded access trials).

43. Please confirm if the page counts for the sample task order technical (20 page limit per) and business proposal (15 page limit per) are included in the total page count limit of 75 pages for the technical proposal and 50 pages for the business proposal.

ANSWER: Yes

44. To what extent do activities as described in section C.3.1 (Objective 1) have to be completed in a single protocol or single IND, and does each individual service need to be the sole responsibility of the offeror, or are previous teaming experiences acceptable?

ANSWER: Activities described in section C.3.1. (Objective 1) do not need to be completed in a single protocol or single IND. Previous teaming experiences are unacceptable.

45. Will the successful bidder be responsible for establishing subcontracts (per Section C.3.1 8a, page 12) with the clinical sites, or will they be responsible for establishing a site selection process?

ANSWER: A successful Offeror is responsible for establishing subcontracts with clinical sites and for establishing a site selection process.

46. Beginning on page 114, the numbering of the activities associated with Task 2 (i.e., the CLIN structure) differs from the summary (Table 2) on page 119. Please clarify.

ANSWER: Hereby. Renumber SRTOR 0002 Table 2 on pg 119 and remove site initiation exercise.

47. Given the page limits, will you accept a rolled up GANTT chart that as-is is within the page limit, but then fully expand it to evaluate it?

ANSWER: No. The RFP is hereby modified to permit Gantt charts to be included in an appendix whose page count does not count toward the page limitation.

48. What is the estimated number of non-emergency trials, by phase and by year, that are expected to be competed on this contract?

ANSWER: BARDA may conduct two (2) to five (5) non-emergency trials per year. The Phase of the studies will be specified in the RTOR. BARDA does not commit to conducting any studies, however B.5.1. specifies the Minimum Ordering Amount of \$400,000 for the base period, and \$200,000 for each subsequent option period.

49. Regarding Section G.4.2 and G.4.3:

- a. Section G.4.2 says all prime contractors will be provided an opportunity to bid for each Task Order, while the 4th paragraph of G.4.3 says that "... the Contracting Officer shall provide an ROTR to the contractors that receive contracts for the particular part for which responses are being solicited." Will offerors who are awarded a prime contract be

eligible to bid on all Task Order requests or will prime contractors be segregated into groups based on the Clinical Studies and Clinical Trial Response Readiness objectives? Please clarify?

ANSWER: In accordance with the procedures in FAR 16.505 'Fair Opportunity', all Offerors who are awarded a prime contract be eligible to bid on all Task Order requests.

- b. What does the requirement to “respond” to all RTORs mean in Section G.4.3? Has the contractor “responded” by notifying the Contracting Offeror in writing that it is not capable of performing the services as required in this section?

ANSWER: A response to an RTOR may simply be a statement that the Offeror is not capable of providing the requested service.

50. Are academic medical centers permitted to be part of the MCM network if the CRO routinely uses these types of sites?

ANSWER: Academic medical centers that meet the requirements established in the RFP would be acceptable.

- a. Assuming the answer is yes, is BARDA interested in utilizing a site consortium with commercial and academic sites managed by a CRO for this effort? For example, for ROTR 001, is it acceptable to include 1 academic site and 5 commercial sites that met all requirements?

ANSWER: This would be acceptable.

51. Will the Contractor be required to submit the CSR electronically or via paper?

ANSWER: All reports to the government will be electronic.

52. Will BARDA provide a protocol template to be utilized for any study requiring protocol development?

ANSWER: Yes.

53. What % of projected trials would not be conducted under an IND?

ANSWER: We currently do not any information regarding this question.

54. Does the Government have a preferred vendor for safety database services?

ANSWER: No

55. What National IRBs would likely be utilized?

ANSWER: This will be defined in any future task order requiring the use of a National IRB.

56. Regarding Section C.5.1, is the Contractor required to submit an EVMS management plan for ROTR 001 and ROTR 002 as part of the fixed price proposal response?

ANSWER: 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 the HHSAR (HHSAR 334.203).

57. Regarding Attachment 2, does the Government expect site costs such as recruitment, enrollment, remuneration, visit fees, supplies, etc to be included? If so, where would those costs fit in Attachment 2?

ANSWER: The government expects site costs such as recruitment, enrollment, remuneration, visit fees, and supplies to be included in Attachment 2B under 14. Site Initiation.

58. On page 95 of 156 (Number 1 of Exclusion Criteria) in the RFP, a description of the vaccine composition is included. However, the adjuvant is simply described as squalene-based. Since squalene itself is not an adjuvant, can you be more specific about the composition of the actual adjuvant or give its designation such as MF59 or AS03?

ANSWER: Assume the adjuvant is a generic oil in water emulsion, however Offerors are not anticipated to be responsible for activities requiring information on the composition of the adjuvant.

59. Can the Government clarify whether the RFP requires that the pricing provided for Sample Tasks 1 and 2 should (or should not) include per patient reimbursement to the site(s).

ANSWER: Yes, it should.

- a. Appendix A, page 96. If the answer above is that the pricing should include per patient reimbursement costs as part of this proposal response, can the Government define the type of safety labs and antibody assays required for Sample Task 1?

ANSWER: For Sample RTOR 0001, safety labs are general chemistry and hematology: Electrolytes, SGPT, SGOT, albumin, total protein, Creatinine, BUN. WBC with differential, RBC, platelets, HgB, HCT, PT, PTT. Antibody assays include Hemagglutination Inhibition Assay and microneutralization. Page 96 is hereby modified to include this list of safety labs and antibody assays.

60. If the service listed in C.3.1 on page 11 is not listed in either of the sample Task Order pricing schedules on page 87 or 114, should the Offeror assume that the service will not be provided for the Sample Task?

ANSWER: Offerors are expected to provide the ensemble of services required to complete the objectives of the Sample Task Orders given the information provided, even when they are not explicitly identified.

61. Can the Government further clarify item 5 on page 12, where it defines the service as identification and contractual agreement with a vendor to support remote data entry?

- a. What are the potential circumstances where remote data entry may be relevant?

ANSWER: No additional information on this topic is available.

62. Page 12, Section 8a. The RFP states that the Offeror must have current access to a network of sites available to perform clinical studies. Does the Government require a description of the site network?

- a. If so, can the Government define the specific information/capabilities/experience it is interested in to understand the Offeror's site network capabilities?

ANSWER: The government requires a description of the site network. The description should include the therapeutic areas and the Phase of studies the sites have conducted as well as the site personnel available to work on the studies.

63. Section C7, page 16. Can the Government confirm whether or not it would like the template for the QC/QA monitoring plan submitted with the RFP response?

ANSWER: Yes.

64. For the purposes of defining the approach and price for clinical monitoring, is the Government willing to consider Risk Based Monitoring Approach or does it require 100% source verification?

ANSWER: The government is willing to consider less than 100% source verification. Please provide a plan for a Risk Based Monitoring Approach.

65. Section M 1.3.2 d page 72. Can the Government confirm that it would like the actual quality management metrics from the Offeror's experience or is it the defined targeted metrics that the Government is interested in?

ANSWER: BARDA would like to review the actual quality management metrics from the Offeror's experience.

66. Section M 1.3.5 page 73. Can the Government provide a more specific definition of the request for "quantitative details" requested to be included in the Technical Approach for Sample Tasks?

ANSWER: No further information will be provided for this topic.

67. Attachment 1B, page 86. When providing pricing information, should the Offeror assume that the protocol is already developed, as on page 80 the RFP states that the design has already been discussed with the FDA?

ANSWER: Yes.

68. Attachment 1B page 86. Is this table a complete list of all activities to be performed for the trial or is this a tool to assess comparative pricing?

ANSWER: The table is a guide for pricing.

- a. For example, the table does not list any activities related to independent auditing or preparation of the IND package.

69. Attachment 1B page 87. Does management of investigator payments include contracting with investigators?

ANSWER: Yes.

70. In Section G9 regarding Key Personnel on page 29, should the key personnel identified for this contract include the program director, project manager, medical monitor, data management project manager, and biostatistician as defined on page 80 of the RFP related to Sample Task Order 01, or is the list on page 80 just related to Sample Task Order 01 and not necessarily tied to the overall contract Key personnel?

ANSWER: For the technical proposal to the base contract, top level management positions are sufficient. It is anticipated that responses to the Sample RTOR will require additional highly qualified personnel who should be identified as key to those responses. Key personnel

for Task Orders are anticipated to include the program director, project manager, medical monitor, data management project manager and biostatistician.

71. For both Sample Tasks Orders 1 and 2, the RFP states that the Offeror is to provide 24 hour medical monitoring and there is no pricing requested for development and management of either an SMC or DSMB. Does this mean that the Government does not intend to use either an SMC or DSMB in the sample tasks?

ANSWER: The government will stipulate whether a SMC or DSMB is required for a study in the task order. Sample RTOR 0001 does require a DSMB. Sample RTOR 0002 does not require a DSMB.

72. The RFP uses the phrase "key personnel" in many locations without specifying the positions of interest, and the RFP also makes clear that the qualifications of key personnel should be provided. Since highly qualified personnel working on each task order will change based on the nature of the task order, can an offeror assume that the identification of top level management positions for the technical and business sides of the proposal is sufficient for key personnel? If not, could more guidance be provided by BARDA on the nature of key personnel.

ANSWER: For the technical proposal to the base contract, top level management positions are sufficient. It is anticipated that responses to the sample Task Orders will require additional highly qualified personnel who should be identified as key to those responses. Key personnel for Task orders are anticipated to include the program director, project manager, medical monitor, data management project manager, and biostatistician.

Questions pertaining to RTOR 0001:

73. Attachment 1 clearly outlines the study design as a randomized, placebo controlled trial, please confirm if study vaccines and adjuvant will be administered in a double blind manner.

ANSWER: Yes

74. Attachment 1 clearly outlines the study design as a randomized, placebo controlled trial, please confirm if study vaccines and adjuvant will be administered in a double blind manner.

ANSWER: Yes

75. Please confirm if secondary packaging and labeling into kits will be required by the CRO.

ANSWER: For sample RTOR0001, secondary packaging and labeling into kits will be required of the CRO.

76. The deliverables schedule on page 96 outlines final IND submission package in Dec 2013, please confirm if CRO will be expected to prepare an IND as this task is not included in regulatory activity (Attachment 1B, Section 2, Table 1).

ANSWER: For sample RTOR 0001, HHS will prepare and submit the IND package.

77. In RTOR 1, how is the vaccine + adjuvant packaged – pre-filled syringe containing antigen & adjuvant; separate single-use antigen & adjuvant components that must be combined prior to administration; multi-use pre-mixed vials containing antigen + adjuvant; or multi-use separate vials of antigen & adjuvant that must be combined prior to administration? What are the dimensions of the smallest unit package of vaccine and how many vaccine doses does this represent?

ANSWER: For sample RTOR 0001, separate, multi-dose vials of antigen & adjuvant that must be combined prior to administration are required. Each vial will contain 5 antigen doses or 5 adjuvant doses. The smallest unit package of vaccine will be twelve (12) five (5) mL vials. Package dimensions are as follows:

Components	Dimensions	Contents	Comment
Package	2.5" x 1.125" x 1.125"	10 doses	Providers receive increments of 10 packages
Master Carton	12.5"x 6.5" x 5.625"	100 packages (1,000 doses)	Provider can store as master carton or as packages

78. In Attachment 1, Attachment 1B – Pricing Schedule/CLIN Structure, page 86 of 156, there is no mention of DSMB or Safety Review Committee (SRC). Is either the DSMB or SRC to be included in the costs for Objective 1 Clinical Studies? If yes, which committee?

ANSWER: For sample RTOR0001, Yes. Pricing Schedule/CLIN Structure, item 7 on Pharmacovigilance on page 88 is hereby amended to add a line item for Data Safety Monitoring Board. This item is the responsibility of the Offeror and should be included in the business and technical proposals.

79. An adjuvant is mentioned in the synopses along with A/H5N1 vaccine. Will cross-reporting to other sites for other studies be necessary for expedited reports?

ANSWER: For sample RTOR0001, all reports involving the safety and immunogenicity will be submitted to BARDA. BARDA will be responsible for optioning any clinical trial agreements with manufacturing which include cross-reporting. In sample RTOR 0001, cross-reporting is not required.

80. It is noted in Attachment 1B on page 88 that the contractor is to "Provide 24 hour medical monitoring to all sites for all medical issues". Our definition of medical monitoring includes answering medical inquiries from the sites (PIFs), review of alert labs (PADFs), quarterly review of listings (AEs, conmeds, and medical history) and coding review every six months. Please confirm which tasks listed above you would like the contractor to include in medical monitoring activities.

ANSWER: Please define all acronyms. Hereby

81. Page 81 states:

Site Visit

Site visits by HHS personnel are required post-award. See —Table 1: Scope of work and costs for each study activity in Attachment 2 for details.

Please clarify the reference to Attachment 2, Table 1 as well as the role and responsibility of

HHS personnel in the site visits.

ANSWER: BARDA representative(s) will visit (with or without a representative of the CRO) one or more clinical site(s) to assess the quality of the site(s) and observe CRO site start-up activities, or other currently unspecified reasons.

82. What is the duration of the contract for task order #1? In Table 1 (page 81) the total program duration is stated to be 24 months. On pages 79 and 81, the anticipated period of performance/contract duration are stated to be 26 months from date of task order award. Please clarify.

ANSWER: Table 1 on Page 81 is hereby amended to 26 months.

83. Table 1 on page 86/156 lists BARDA as responsible for Investigator Brochure preparation, while the Deliverables & Schedule table on page 96 lists the Investigator Brochure as a contract deliverable. Please clarify whether the contractor will be responsible for preparation of the Investigator Brochure

ANSWER: Page 96 is hereby amended to remove delivery of item 9, Investigator Brochure.

84. On page 87, Table 1 indicates that both BARDA and the CRO will have responsibility for packaging, labeling, storage and distribution of IP and that BARDA will be responsible for authorization of initial IP shipment to sites. Please clarify the respective roles and responsibilities of BARDA and the CRO in this regard.

ANSWER: For Sample RTOR0001, BARDA will provide the Investigational Product. The CRO will be responsible for the packaging, labeling, storage and distribution of the Investigational Product. Table 1 on Page 87 is hereby amended to remove the 'X' in the column demarking the responsibility of BARDA.

85. Regarding the Instructions to Offerors in Sample ROTR 0001 on page 82: The text in Red Font in the paragraph labeled Cost/Price Proposal indicates that the Cost/Price Proposal must include a completed Attachment 2. A similar comment is made in the Site Visit paragraph on page 81. Attachment #2, however, is the Sample Request for Task Order Response 0002 on page 105. Did the Government mean Attachment 1B or some other reference?

ANSWER: In red font on Page 82 the RFP is hereby amended to substitute 'Attachment 1B' for 'Attachment 2'.

- i. Similarly, page 80 of the proposal requests that costs for Sample RTOR 0001 be provided in Table 1, Attachment 2 and Attachment 3. We are unclear where Attachment 2 and 3 are located in the document – please clarify.

ANSWER: The RFP is hereby amended to substitute Attachment 1B and 1C for Attachment 2 and 3 respectively on page 80.

86. Regarding the Sample ROTR 0001 Volume 2 – Price Submission instructions on page 101:

- ii. Paragraph c) says “the labor/pricing matrix(ces) should include labor categories as identified in the Master Contract Section J, Section J of the RFP is the list of Attachments located on page 52. Please clarify what was meant here? Is there a specified list of labor categories we are supposed to use?

ANSWER: The RFP is hereby amended to delete the phrase 'as identified in the Master Contract Section J,' from the RFP on Page 101.

- iii. The last sentence of paragraph c) asks Offerors to compare “between the labor

categories/hourly rates proposed in the task order with the Labor/Pricing Matrix(ces) in the Master contract (See Attachment 7).” Attachment 7 of the RFP contains invoice/financing instructions. Please clarify what is intended here and how Offerors can compare labor categories/hourly rates when there is no official Labor/Pricing Matrix?

ANSWER: The RFP is hereby amended to delete the sentence “The respondent shall include a comparison between the labor categories/hourly rates proposed in this task order to you Labor/Pricing Matrix(ces) in the Master contract (See attachment 7).” from Page 101 item c).

- iv. In addition to the requirements in Paragraph c) regarding listing labor categories included in Table 2, Paragraph e) says:

“The Offeror shall provide all labor categories and labor rates for work under the prospective contract. The hourly rates proposed for each labor category shall be fully burdened rates ... The fully burdened rates will be incorporated into any resultant contract awards ... and must be used for budgeting task orders and reimbursement of labor costs.”

We understand this is a sample task, but why are Offerors being asked to price labor categories and fully burdened labor rates when this is a firm fixed price task order? Firm fixed price contracts are typically priced based on completion of milestones or priced based on regular incremental payments. The use of fully burdened labor categories is consistent with Time and Materials (T&M) contracts, not fixed price contracts. Please clarify the requirements for labor categories/fully burdened rates with regard to Sample ROTR 0001 and please clarify whether these requirements will affect future actual Task Order Requests?

ANSWER: Sample RTOR 0001 is hereby amended to a Cost Plus Fixed Fee type contract.

87. Please confirm that Offeror’s do not need to include the costs of any study drug or sponsor provided material related to Sample ROTR 0001.

ANSWER: Offeror’s do not need to include the costs of any study drug or sponsor provided material related to Sample RTOR 0001.

88. *Data Safety Monitoring Board (DSMB):*

- v. It is typical for a DSMB to be comprised of an odd number of members (either 3 or 5 total members is most common). Please provide the number of members you intend to have serving on this committee.

ANSWER: The Offeror’s design/discussion of this issue will be a factor in the technical assessment of their experience and qualifications to conduct the type of studies BARDA may be interested in. For Sample RTOR 0001, a DSMB with 3 members is required for sample RTOR 0001. For Sample RTOR 0002, a DSMB is not required.

- vi. How many data review meetings are anticipated during the study? How many of these meetings do you anticipate will be held face-to-face and how many via teleconference?

ANSWER: For Sample RTOR 0001, three scheduled teleconferences are required. For Sample RTOR 0002, zero review meetings are anticipated.

Questions pertaining to RTOR 0002:

89. Is it anticipated that response period will only occur after the 24 month base period has elapsed or could these overlap if tasks for preparedness have completed to an extent that it was possible to activate a response if outbreak situation occurred?

ANSWER: The response may occur at any time during the Task Order period of performance. The preparation and response components of Sample RTOR 0002 could overlap. If response is required during the preparation period, the timeline to response may be amended to suit the circumstance.

90. Is 24-hour response expected to cover 100% of all regions/states/cities in the USA only?

ANSWER: For Sample RTOR 0002, Yes. The 24 hours response is expected to fully cover all of the United States. There is no expectation of coverage outside of the U.S.

91. For “manage IP distribution” activity (Attachment 2B, Section 16, Table 1) there are two crosses indicating responsibility for HHS/BARDA and CRO. Please confirm if CRO will be responsible for setting up drug storage central depots and shipping to sites within 24 hours.

ANSWER: For Sample RTOR 0002, the storage, shipment and delivery of the product will be solely managed by HHS.

92. Will HHS/BARDA ship supplies in advance to a CRO-managed depot if needed, or will 24-hour response come from BARDA managed depot?

ANSWER: For Sample RTOR 0002, the storage, shipment and delivery of the product will be solely managed by HHS.

93. What is the likely product expiration date?

ANSWER: For Sample RTOR 0002, HHS will be accountable for the expiry of the investigational product delivered to the clinical site(s).

94. Are there any time points (e.g., between option periods) where interim analyses would be required?

ANSWER: This question is unclear, please clarify.

95. Is there a minimum or maximum patient number that would trigger study termination and/or reporting?

ANSWER: For Sample RTOR 0002, No. Collection of data from 200 patients are sufficient to complete enrollment. The number of patients will be determined based on the size of the emergent event. Hereby.

96. In section H.2.2, page 31 of 156, expectation is that all Phase III studies will have a DSMB. Attachment 2B, starting on page 114 of 156, does not include Data Safety Monitoring Board (DSMB) in the Activities for the Phase III study. Should the contractor response include DSMB activities and associated costs?

ANSWER: Sample RTOR 0002 is hereby amended to solely Cost Plus Fixed Fee.

97. Please clarify the duration of the base award for task order 2 and the number and duration of option periods.

ANSWER; The base award for Sample RTOR 0002 is 24 months. The duration of option periods in Sample RTOR 0002 is 12 months. The Option to Respond will only be executed in the case of a Public Health Medical Emergency. The Option to continue preparedness

will be exercised at the end of the base period, as warranted by performance and/or BARDA program needs.

98. Please clarify the scope of the table top exercise and subsequent gap analysis in terms of the scope of exercise inputs. For example, would this include modeling only those activities within the precise task 2 scope such as product delivery, patient eligibility, AE reporting, etc., or would it also include external impacts such as public response, media participation, coincident emergencies, etc.

ANSWER: For Sample RTOR 0002, the contractor is expected to gap test the aspects of preparedness for which the contractor is responsible such as collection of clinical data, as defined in Sample Request for Task Order Response 2, from sites treating patients during an emergency.

99. Please clarify the scope of the table top exercise participants. Would the exercise be limited to BARDA and the contractor(s), or would it also include distribution partners, site participants, the Food and Drug Administration and/or others?

ANSWER: For Sample RTOR 0002, the table top exercise will include participants from the contractor and BARDA.

100. On page 114, Table 1 indicates that both HHS/BARDA and the CRO will have responsibility for the clinical protocol and ICF template. Please clarify the respective roles and responsibilities of HHS/ BARDA and the CRO regarding the development of a final clinical protocol and ICF template.

ANSWER: For Sample RTOR 0002, HHS will develop protocol and ICF template for use during an emergency. The CRO is expected to ensure IRB approval of the protocol during the period of performance for preparedness.

101. On page 115, the table indicates that HHS/BARDA will be responsible for packaging, labeling, storage and distribution of investigational product as well as authorization of initial IP shipment to sites and that both HHS/ BARDA and the CRO will have responsibility for managing IP distribution and related documentation. Please clarify the respective roles and responsibilities of HHS/ BARDA and the CRO in this regard. For example, will HHS/BARDA or the CRO be responsible for shipping IP to the sites?

ANSWER: For Sample RTOR 0002, HHS will be responsible for packaging, labeling, storage and distribution of investigational product including shipping IP to the sites.

102. Will the contractor be responsible for conducting the hematology and chemistry laboratory analyses?

ANSWER: For Sample RTOR 0002, the hematology and chemistry laboratory analysis for Sample RTOR 0002 is expected to be done by the clinical sites treating the patients.

103. Do you anticipate 24/7 dosing?

ANSWER: For Sample RTOR 0002, Yes.