

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE N/A	PAGE OF PAGES 1 31
2. AMENDMENT/MODIFICATION NO. 0004	3. EFFECTIVE DATE May 2, 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)				()	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.

()	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.

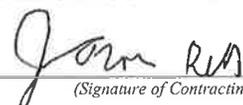
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

PURPOSE OF AMENDMENT:

- (1) Extend the proposal due date.**
- (2) Update Sections F, H, J, L and M of the RFP.**
- (3) 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	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY  (Signature of Contracting Officer)	5/2/13

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

SECTION A - SOLICITATION/CONTRACT FORM

[...]

SOLICITATION

9. Sealed offers in original and 0 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in See Block 7 until 12:00 PM local time ~~May 16~~ ^(Hour) ~~May 21, 2013~~ ^(Date)
CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

SECTION F – DELIVERIES OF PERFORMANCE

F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.3.2.1. Safety Reports

See SECTION H.2.4.

~~Serious Adverse Events (SAEs) that are designated as possibly or probably associated with the administration of the drug/use of the product or Suspected Unexpected Serious Adverse Reaction (SUSARs) shall be reported by e-mail and phone calls to the COR and CO within 24 hours of knowledge of the event. Essential information including the SAE descriptive narrative and initial/follow-up information received from the investigative site including the subject number, the onset and resolution of the event, the investigator's assessment of severity, if any medical intervention was used to resolve the event or its intensity and if the drug was discontinued should be included in the communication.~~

~~Protocol deviations that impact patient safety should be reported within no more than 24 hours from Contractor knowledge of the event.~~

F.3.2.3. Quarterly Technical Progress Reports

~~Quality Metrics: For active clinical studies (not exclusively those funded by BARDA):~~

- ~~• Update subject recruitment (numbers screened, numbers enrolled and drop-outs per clinical site).~~
- ~~• Contractor staff stability (over each quarter) 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.~~

[NOTE: This language moved in similar form to SECTION L.2.2., Appendices to Technical Proposal. See page 4 of this Amendment.]

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.2. CLINICAL RESEARCH

H.2.3. BARDA Protocol Review Process Before Patient Enrollment Begins

[...]

6. Plans for data and safety monitoring (~~see B above~~) and monitoring of the clinical study site, pharmacy, and laboratory.

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES

L.1. PACKAGING AND DELIVERY OF PROPOSAL:

PACKAGING AND DELIVERY OF PROPOSAL: Proposals must be submitted in Adobe PDF, Microsoft Word, Microsoft Excel, and Microsoft Project 2007 electronic format as appropriate and sent via e-mail to MCM-CSN@hhs.gov no later than ~~May 16~~ May 21, 2013 – 12 pm ET. Facsimile proposals are **not** authorized.

L.2. TECHNICAL PROPOSAL

L.2.1. Technical Proposal Instructions

Offerors shall prepare their technical proposal submissions to respond to the requirements listed in SECTION C, and shall provide an index that cross-links the proposal with SECTION C and Evaluation Factors in SECTION M. ~~This index does not count towards the Technical Proposal page limitation.~~

L.2.1.1. Technical Proposal – Components

E. Sample Request for Task Order Response 0001

Describe in detail the Offeror's plan to prepare for and execute a clinical study described, in the timeframe indicated. 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. ~~NOTE: The rolled up Gantt showing high-level task organization should be included in the technical proposal. The full MS Project 2007 or compatible format Gantt chart should be provided as an appendix to the Technical Proposal and does not count towards the Technical Proposal page limitation.~~ 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 0001 shall be limited to 15 pages and shall be included in the Offeror’s business proposal as described in SECTION L.3.

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. **NOTE: The rolled up Gantt showing high-level task organization should be included in the technical proposal. The full MS Project 2007 or compatible format Gantt chart should be provided as an appendix to the Technical Proposal and does not count towards the Technical Proposal page limitation.** 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.

L.2.2. Appendices to Technical Proposal

The offeror shall provide the following **Quality Metrics** for the past year for all active clinical studies:

- Update subject recruitment (numbers screened, numbers enrolled and drop-outs per clinical site).
- Contractor staff stability (over each quarter) 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.

L.3. BUSINESS PROPOSAL
L.3.4. Other Administrative Data

[...]

(3) The proposal must identify any former HHS employee(s) to be utilized on this project by providing the individual's name when employed by HHS, where employed, and the capacity in which employed. **NOTE: Only former HHS employee(s) who were employed at the Department of Health & Human Services within the past 5 years need to be identified.**

(4) The Offeror must demonstrate that it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. In addition to the submission of financial statements, this includes submission of information regarding available line of credit, bonding capability, and available plant and facilities for contract performance. (If assistance from outside sources is required, indicate the amount required and the anticipated source(s).) **NOTE: Financial statements may be added as an appendix to the Business Proposal and thus, not be counted against the 50 page limit for the Business Proposal.**

[...]

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.

For purposes of satisfying this Mandatory Criteria, “offeror” is defined as the “Prime Contractor” under a standard Prime Contractor sub relationship or, in the alternative, a member of a formal partnership or a formal joint venture (JV) arrangement under FAR 9.601(1). If an offeror proposes a contractor teaming arrangement per FAR 9.601(1), that proposal must clearly specify that arrangement, and also demonstrate that either the formal partnership or the formal JV satisfies the mandatory criteria. If an offeror proposes a contractor teaming arrangement per FAR 9.601(2), the Prime Contractor designated in the teaming arrangement must meet the mandatory criteria on its own merits (i.e. not based on Subcontractor’s merit).

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.

SECTION J – LIST OF ATTACHMENTS

ATTACHMENT #1

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0001

Attachment 1B – Pricing Schedule/CLIN Structure

Table 1. Cost and Price Schedule:

[...]

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Equipment Costs	Travel Costs	Other Direct Costs	Other Indirect Costs	Pass-through Costs Subcontractor and Consultant Costs	Fixed Fee	Total
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[...]

7. Investigational product (IP) management												
Packaging, labeling, storage and distribution		X	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:												

[...]

11. Project management and training									
Create Project Management and Monitoring Plan		X							
Project management		X							
Monthly project status reports		X							
BARDA/CRO team teleconferences: weekly during study start-up and enrollment and bi-weekly thereafter		X							
CRO internal teleconferences and meetings		X							
CRO team training		X							
Project management and training sub-total:									
GRAND TOTAL:									

Attachment 1E – Submission Instructions

“Volume 2 – Price Submission”

[...]

b) The respondent shall include a price response substantially equivalent to the tables in Attachment 1B.

[...]

~~e) 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, including any indirect or overhead rates applicable. The fully burdened hourly rates will be incorporated into any resultant contract awards under B.5. Advance Understandings, and must be used for budgeting task orders and reimbursement of labor costs.—~~

ATTACHMENT #2

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0002

Protocol Summary

[...]

Number of CRF pages per subject	Approximately 32
Randomization	There is no randomization schema; all eligible patients will receive the investigational drug.
Unique CRF Pages per subject	8 Pages

Attachment 2B – Pricing Schedule/CLIN Structure

Table 1. Cost and Price Schedule:

[...]

Activities	BARDA	CRO	Direct Labor	Fringe Rate	Material Costs	Equipment Costs	Travel Costs	Other Direct Costs	Other Indirect Costs	Pass-through Costs Subcontractor and Consultant Costs	Fixed Fee	Total
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[...]

12. Study and Protocol Planning												
Clinical Protocol and ICF template		X		X								
Site Procedures Manual Preparation and distribution to sites				X								
Investigator Brochure preparation		X										
Investigator Brochure distribution to sites				X								
Study Protocol and Planning Sub Total:												
13. Regulatory activities:												
Preparation and collection of investigator regulatory document packages				X								
Trial Master File Preparation and Maintenance				X								

Central/National IRB submission & Approval	✘	X							
Regulatory activities Sub-Total									
14. Site Initiation									
Site identification and screening	✘	X							
Pre-study site qualifications visits		X							
Site selection	✘	X							
Investigator contract template development, distribution, budget negotiation, and contract establishment with sites		X							
Investigator meeting planning, attendance and conduct. Include pass through costs for meeting planner, if used, and assume 2 attendees per site, up to 8 contractor attendees and 4 HHS/ BARDA attendees and guests		X							
Site Initiation Visits		X							
Study Initiation Sub Total									
15. Site Monitoring and Management									
Interim monitoring visits		X							
Study site management		X							
Close out visits		X							
Manage investigator payments		X							
Site Monitoring and Management Sub Total									
16. Investigational product (IP) management									
Packaging, labeling, storage and	X								

distribution									
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	✘							
Retrieval or on-site disposal of IP		X							
IP management sub-total:									
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		X							

study database									
Vendor management sub-total									
18. Pharmacovigilance									
Development pharmacovigilance plan	✘	X							
Development of the 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							
Pharmacovigilance sub-total									
19. Data Management									
Develop data management plan		X							
Finalize the development of CRF	✘	X							
Develop CRF completion instructions and monitoring guidelines		X							
Design database, prepare edit specifications		X							
Data/CRF review, query resolution to database lock		X							
Coding of baseline medical conditions, AEs, SAEs and concomitant medications		X							
Central laboratory data downloads		X							
AE/SAE listings and reconciliation		X							

with the Pharmacovigilance database									
Final database audit		X							
Data management sub-total									

[...]

22. Project management and training									
Project management & project management Plan (to include readiness & response strategy)		X							
Monthly project status reports		X							
BARDA/CRO team teleconferences: weekly during study start-up and enrollment and bi-weekly thereafter		X							
CRO internal teleconferences and meetings		X							
CRO team training		X							
Project management and training sub-total:									
GRAND TOTAL:									

ATTACHMENT #1

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0001

Attachment 1B – Pricing Schedule/CLIN Structure

Table 2 Summary of project activities and costs:

ACTIVITIES	Labor Costs	Pass-Through Costs
1. Study and protocol planning		
2. Regulatory activities		
3. Study initiation		
4. Site monitoring and management		
5. Investigational product management		
6. Vendor management		
7. Pharmacovigilance		
8. Data management		
9. Biostatistics		
10. Clinical study report		
11. Project management and training		
Totals		
Fringe/Overhead/G&A		
GRAND TOTAL		

ATTACHMENT #2

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0002

Attachment 2B – Pricing Schedule/CLIN Structure

Table 2 Summary of project activities and costs:

ACTIVITIES	Labor Costs	Pass-Through Costs
12. Study and protocol planning		
13. Regulatory activities		
14. Study initiation		
15. Site monitoring and management		
16. Investigational product management		
17. Vendor management		
18. Pharmacovigilance		
19. Data management		
20. Biostatistics		

21. Clinical study report		
22. Project management and training		
Totals		
Fringe/Overhead/G&A		
GRAND TOTAL		

ATTACHMENT #2

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0002

[...]

Cost/Price Proposal: Contractors are required to provide a cost/price proposal. Cost/price proposal must include a completed Attachment **2A2B**. Proposals should address the Offeror's technical approach, skill mix and hours, hourly rates, estimated travel, Other Direct Costs (ODCs), and total price.

ATTACHMENT #1

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0001

Attachment 1C – Statement of Work

[...]

Deliverables & Schedule

Delivery #	Deliverable Title	Format	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
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ATTACHMENT #2

SAMPLE REQUEST FOR TASK ORDER RESPONSE 0002

Attachment 2C – Statement of Work

[...]

~~**Government-Furnished Equipment (GFE)/ Government-Furnished Information (GFI)**
Successful awardees are anticipated to use H5N1 antigen formulated with adjuvant produced by HHS under prior contracts to complete the objectives of this task order. The USG retains all rights to the material and information associated with that material.~~

Attachment 2E – Submission Instructions

“Volume 2 – Price Submission”

[...]

f) The respondent shall include a price response substantially equivalent to the tables in Attachment 2B.

[...]

~~j) 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, including any indirect or overhead rates applicable. The fully burdened hourly rates will be incorporated into any resultant contract awards under B.5. Advance Understandings, and must be used for budgeting task orders and reimbursement of labor costs.—~~

(End of Changes to the text of the RFP)

QUESTIONS & ANSWERS

1. The PDF file under Amendment 4 is named for Amendment 3 and the internal cover page is Amendment 3 but there is also another Amendment 3 listed on the website. Please clarify the number of amendments and relevant attachments for each amendment.

ANSWER: The Amendment with a formal cover sheet (Standard Form 30), executed by Contracting Officer 4/22/13 and labeled Amendment/Modification 0003 is the official Amendment 3. A signed Standard Form 30 is required to officially amend a solicitation. The FedBizOpps system inadvertently labeled the Pre-Proposal Conference slides as “Amendment 3.” That is incorrect and is not an official Amendment to the RFP. Furthermore, the current document is Amendment #0004 to the RFP.

2. Will the Technical Proposal be reviewed in its totality in order to determine whether the Mandatory Minimum Criteria in Section L is satisfied?

ANSWER: No. The Mandatory Evaluation Criteria described in Section L.2.1.1.(3) of the RFP should be presented as a stand-alone section and will be evaluated on its independent merit. Proposals failing to successfully satisfy the criteria in this section will not be evaluated further.

3. Please clarify the answer to the question 1 in Amendment 4 [sic] at page 13 regarding the mandatory criteria for eligibility. What does “prime level” mean in terms of a teaming arrangement and a consummated prime contract with HHS? The FAR anticipates that only a single entity may serve as a prime contractor, and thus, that single entity would assume full legal responsibility for all aspects of performance of the contract. Even if that prime has entered into teaming arrangement with one or more other entities, only a single prime contractor is typically the signatory to the contract. Does the RFP require that the single entity that signs the contract/serves as the prime contractor must meet the Mandatory Criteria on its own? Or alternatively, does the RFP permit the prime contractor to enter into a teaming arrangement with one or more Clinical Research Organizations (CRO) that satisfy the Mandatory Criteria, with such entities serving as first tier subcontractors under any final prime contract (as the earlier response to questions suggests)? Please clarify.

ANSWER: Please see clarification to Section M.1.2. in the current RFP.

4. Amendment to previous response provided in Amendment #3 (in red):

QUESTION: 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. Please see clarification to Section M.1.2. in the current RFP.

5. Please confirm The Material(s) Matrix on page 103 is intended for a listing of estimated Direct costs for materials?

ANSWER: Both the “Material(s) Matrix” in Attachment 1E and Attachment 2E were deleted by the previous amendment to the RFP.

6. Which appendices do not count against the page limit for the Technical Proposal?

ANSWER: Section J attachments 3, 4, 5, 6, 9, 12, 13 and 14 do not count against the Technical Proposal page limit. The quality metrics appendix to the Technical Proposal, added by this amendment to the RFP, also does not count towards the Technical Proposal page limit.

7. The industry standard for Clinical Research is to provide such services on a fixed-price (or fixed-unit) basis. In the USG setting, these services are frequently provided (including to BARDA, as a subcontractor to a BARDA prime contractor) under FAR Part 12 procedures. In light of this, what are BARDA expectations for evaluating contractors whose subcontractors are providing clinical research services on a commercial basis (e.g. fixed price, in accordance with FAR Part 12)?

ANSWER: The prime contractor may select whatever contract type it feels is the most appropriate for its subcontracts. However, the USG reserves the right to review subcontract for appropriateness, prior to approval.

8. May the CRO use its own small business plan vs. HHS plan? If so, the CRO would still be willing to submit status reports electronically.

ANSWER: An Offeror should use a plan substantively and in a format similar to the HHS plan. It may be tailored to an Offeror's specific situation.

9. On pg. 33, under Section H.2.3, the paragraph after item 7 references a Contract Officer Authorization (COA) Letter. Please clarify – is this COA the authorization to begin enrollment at the clinical site?

ANSWER: Correct.

10. Pg. 110 where it says “Additional Information”- Timeline: “24 hours from execution of the option to execute the study to First Patient First Dose” - what action by BARDA would indicate this 24 hour turn around?

ANSWER: BARDA will execute the option established in the Task Order award base period.

11. On pgs. 79 and 81 – it specifies that Task Order 0001 will be firm fixed price. However, on pg. 82, under “Cost/Price Proposal” it lists components that are more indicative of a cost-reimbursement structure, including for example, “provisional billing rates” which are used in CPFF contracts. Please confirm the type of task order envisioned. Our experience is that these types of tasks are typically cost-reimbursement, due to the uncertainties inherent in clinical studies. To that point, Task Order 0002 will be a “Mixed Cost Reimbursement/Firm Fixed Price” task (pg. 106.) Please confirm why this task order is envisioned to be a different type.

ANSWER: This has been updated by a previous amendment.

12. Would you confirm that the financial statement we have to include with the Business Volume (L.3.4.(4)) will not count against the page limit? These financial statements, which are prepared by outside accountants, are lengthy and we don't edit or reduce them when submitting them with proposals.

ANSWER: The current amendment modifies the RFP to clarify financial statements are not counted against the page limit.

13. In Attachment 1B number 10 it mentions investigational product (IP) management; however throughout the proposal and task orders there is no mention of BARDA's requirements for investigational product management. Can you please clarify the responsibilities of the CRO for investigational product management?

ANSWER: See previous amendment to the RFP.

14. On pg. 101 – Volume 2, item c: it says “See Attachment 7.” But, Attachment 7 is the invoicing instructions. Please clarify.

ANSWER: The labor/pricing matrix(es) requirements were removed by the previous amendment. Please see Section J - Attachment #14.

15. On pg. 101 – item e – states that the labor rates to be proposed shall be fully burdened rates, inclusive of all indirect costs (which would be indicative of a time and materials (T&M) type contract. Yet, the various pricing tables split out the direct labor costs from indirect costs. Please confirm.

ANSWER: The referenced table (Item E) has been removed by the amendment. However, in the base portion of the contract, the labor rates requested are to be unburdened.

16. Will BARDA be providing any form of indemnification to successful offerors under the resultant contract or awarded task orders?

ANSWER: As a general rule, the United States Government doesn't indemnify contractors, however, under unusual circumstances it may be allowable (see PREP Act <https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx>).)

In addition to the individual sample task order cost proposals, in the business proposal do we need to provide an additional cost proposal for the overarching ID/IQ vehicle or will the ceiling of \$600 million be utilized for the ID/IQ award/awards?

ANSWER: The Business Proposal instructions in Part L were clarified by the previous amendment.

17. Can the Government provide a comprehensive list of all anticipated labor categories that could be utilized under this ID/IQ? Offerors can then provide labor rates for all labor categories to the Government which will aid the Government in cost/price evaluation.

ANSWER: The labor categories are to be proposed at the discretion of the Offeror.

18. Section L.3.4 (3) (Other Administrative Data) says the proposal must identify any former HHS employee(s) to be utilized on this project. Do we need to include every former HHS/NIH employee utilized on the project or just the people that worked for HHS in the recent past?

ANSWER: Please see clarification to Section L.3.4 (3) of the RFP.

19. In both Sample Task ROTR 0001 and 0002 in Attachments 1B and 2B there is an identical Table 1 (beginning at pages 86 and 114 respectively) which has column headings including Direct Labor, Fringe Rate, Material Costs, Other Direct Costs, Other Indirect Costs, Pass Through Costs,

and Total. Now that the Government has specified that both sample task orders will be CPFF and has provided spreadsheets with multiple tabs that will capture this information, does the Government need the information to be displayed in these tables in the listed format, or can we simply provide the total estimated cost for each horizontally listed study activity?

If the answer is that the current format is needed, are there some columns, such as Fringe Rate and Other Indirect Costs which can be eliminated as the detailed pricing spreadsheets we're now using will contain this information.

If the answer is that the current format is needed, we note that these tables do not provide a column for Fixed Fee. Should we add this column or include Fixed Fee within another column as appropriate? Can offerors modify or add columns as needed?

ANSWER: The referenced tables have been clarified by this amendment to the RFP in order to align with the Excel templates provided in the previous amendment.

20. On Page 11 of the modification released this week (labeled as Modification 0003), the changes to Section L.3.2 indicate the business proposal "shall not exceed 50 pages (not including information required located in Section J – List of Attachments ...)" On Page 10 of this modification, Attachment #14 has been added to Section J (the two Microsoft Excel files). We read this as meaning that the pricing detail spreadsheets added to Section J will not be counted against the 50 page limit (also consistent with the Government's answer to #24). Please confirm?

ANSWER: Confirmed.

Also, please confirm that none of the attachments listed in Section J will count against either Task Order page limit if needed for a Task Order response (including Attachment #14).

ANSWER: Confirmed.

21. Page 8 of the modification released this week indicates that the Table 3 – Cost Centers is still required for submission. Given the requirements for detailed pricing in the new Attachment #14 spreadsheets, would the Government please clarify the types of information it expects to see in Table 3 of each ROTR and whether this is different than the information that would go in Attachment #14? For instance, the example given for each Table 3 is the unit cost of pathology slides. It seems like this same information will be captured in the detailed spreadsheets on a tab for materials or supplies.

ANSWER: This table has been removed via this Amendment to the RFP.

22. Page 12 of the modification released this week states that Offerors should "Discuss any additional direct labor (new hires) that will be required during the performance period and any financial risks that could be anticipated." Did the Government mean that we should list any new categories of personnel that might need to be hired? If no, how can offerors predict individual new personnel that might need to be hired without having some standard assumptions in the RFP as to the number of studies we might perform at any given time? Can you elaborate on what is needed here?

ANSWER: This should list the Offeror's relevant personnel and is left to the discretion of the offeror. This may be framed in general terms.

23. In both Sample Task ROTR 0001 and 0002 in Attachments 1B and 2B there is an identical Table 2 (beginning on pages 90 and 119 respectively). This appears to require a summarized or condensed version of the Table 1 which precedes it. Columns for Materials and Other Direct Costs are missing, however. Does the Government want summarized information related to these categories and can we revise this table as needed?

ANSWER: Table 2 under Attachments 1B and 2B are removed in this amendment to the RFP.

24. Page 124 of RFP, TO#2 (smallpox), states that "... awardees are anticipated to use H5N1 antigen" This information appears to be copied from TO#1. Will BARDA provide information on Government- furnished product for TO#2?

ANSWER: Addressed in the current amendment to the RFP.

25. In Section L.2.1., it is stated that "As part of the technical proposal, the Offeror's will be required to submit a cross reference between the RFP and technical proposal to assist the government in their review." Is the cross reference matrix part of the 75-page limit?

ANSWER: Addressed in the current amendment to the RFP.

26. Question 47 and the subsequent response in Amendment 003 dated April 22, 2013 states: "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. Per the current amendment to the RFP, Gantt charts may be included in an appendix and do not count toward the Technical Proposal page limitation.

- a. The current RFP page requirements for the Technical Proposal are 75 for the Technical Proposal and 50 pages for the Appendices. Our understanding is that there is no appendix in the Technical Proposal whose page count does not count toward the page limitation. Can the Government confirm that the fully expanded GANTT chart should be included as the last Appendix of the Technical proposal for which there would be no page limit associated with it AND that all other Appendices would fall within the 50 page limit?

ANSWER: This is addressed in the current amendment to the RFP.

27. In Sample Task ROTR 002, there is limited information about the specifications for the study (compared to ROTR 001 page 81 Study Parameters). What additional information can you provide on the number of subjects expected, SAEs, number of unique CRFs, anticipated study duration, anticipated tables, listings and figures, and other similar specs?

ANSWER: Additional information related to the specifications of sample RTOR 0002 are provided in these answers to questions provided with this amendment to the RFP.

28. Will BARDA be providing any form of indemnification to successful offerors under the resultant contract or awarded task orders?

ANSWER: This will be addressed for each future Task Order.

29. In Section L.2.1., it is stated that "As part of the technical proposal, the Offeror's will be required to submit a cross reference between the RFP and technical proposal to assist the government in their review." Is the cross reference matrix part of the 75-page limit?

ANSWER: The cross reference matrix is not part of the 75 page limit. See the current amendment to the RFP.

30. Section B1 page 3 of the RFP states that the MCM CSN will complement the academic institution-based model established by NIAID.

Can the Government define if they expect there will be opportunities for collaboration between the two networks.

ANSWER; Collaboration, if any, will be established and managed by BARDA.

31. If the Government expects potential collaboration, is there a model that the Government expects to apply. If so, what will that model be?

ANSWER: The Government will establish and manage potential collaborations.

32. Section H.2.3 page 32, #6 References “(see B above).” Can the Government specify the location of this “See B above” reference within the RFP?

ANSWER: The reference to “(see B above)” is deleted from the RFP per the current amendment.

33. In Attachment 1A Page 86, are qualification visits expected to be applied to 100% of the sites? Can the Offeror price according to their SOP for performing Qualification Visits, where if there were recent related trials performed at the site, a qualification visit may be waived?

ANSWER: As long as the recent trials have Quality metrics that can be shared with the Government, yes, a qualification visit can be waived (assuming the metrics prove proficiency).

34. Should the offeror's be prepared to transfer or work with clinical samples at an appropriate BSL containment facility?

ANSWER: As appropriate, Offerors should be prepared to transfer or work with clinical samples at an appropriate BSL containment facility. This will be addressed for each future RTOR.

35. If the Offeror has not completed a clinical study under an FDA IND application under the offeror's name are they still eligible. We have worked on several FDA protocols where the IND was held by the Pharma/Device company but never our company's name.

ANSWER: Yes, the Offeror is eligible as long as the clinical study satisfies the requirements of Section M.1.2.

36. Must a contractor propose to provide cost-type services in order to be responsive this solicitation?

ANSWER: Yes.

37. If the contractor must bid on all task orders, it is permissible that the clinical research elements of a task order that are commercial in nature be provided as a fixed-price item, even under a full or partial “cost-type” task order?

ANSWER: Offerors are expected to propose terms that are most advantageous to the Government, including fixed-price and/or cost-type elements within the Task Order response.

38. Should the CRO anticipate the need to undertake IND-related submission activities? If applicable, will ex-US Regulatory Agency submission scope of work (regulatory authorities application) be defined from the start or may evolve depending on the studies?

ANSWER: BARDA will define the scope of work if ex-USA regulatory submission work is required in future RTORs.

39. May the CRO's SOPs and CRO site contract templates be used consistently throughout the work and for all countries?

ANSWER: BARDA reserves the right to review CRO SOPs for acceptance to be used as templates.

40. In section L.3.2 and elsewhere, the RFP makes clear that the business proposal portions of the Sample Task Orders are to be included in the page count of the Business Proposal. Is the same true for the Technical Proposal page count, i.e. are the 40 pages of technical discussions of the Sample Task Orders to be included in the 75 pages of the Technical Proposal?

ANSWER: Yes, technical discussions of the Sample Task Orders are to be included in the 75 pages of the Technical Proposal.

41. On pg. 11, at Section C.3.1.1.c – referencing regulatory and other documents: does this include preparation of the original IND and all subsequent amendments? Will the INDs have a full CMC section or will they cross reference the developer's master file or IND?

ANSWER: In collaboration with the CRO, BARDA and/or the developer will prepare the IND and subsequent amendments. BARDA anticipates being responsible for the CMC section of any IND used in response to this solicitation.

42. On pg. 11, Section C.3.1.1.e - are the subcontracts referenced those subcontracts for the sites participating in the study mentioned in that same section at item 1d above ("protocol specific clinical site"), or is it for other subcontracts that the CRO may require to conduct the study as noted in item 5 on pg. 12 that references "identification and contractual agreements with clinical research vendors"?

ANSWER It is anticipated that to successfully execute the clinical study task order, subcontracts with clinical sites and clinical research vendors will be required. This item anticipates that establishment of those subcontracts will be a core capability required to successfully execute the clinical study task order.

43. It is noted on pg. 71 in Section in M.1.3.2 that "explicit identification of internal/external resources is required"; however, on pg. 12, item 8b references "having current access to a network of sites." Would BARDA prefer a sample list of sites or an encompassing comprehensive list of sites? We are asking this question with an interest to deliver what is required, while cognizant of the proposal page limits.

ANSWER: An comprehensive list of sites that are applicable to this solicitation is desired as an Attachment to the technical proposal that does not contribute to the page count.

44. On pg. 13, under C.3.2.1. Preparedness – would BARDA prefer a discussion focused on the process or does BARDA want to understand the specific vendors for preparedness?

ANSWER: A discussion focused on the process is appropriate in response to C.3.2.1. Specific vendors would be appropriate for the response to Sample RTOR 0002.

45. On pg. 14, under C.3.2.2. it says "the Contractor shall provide a dedicated project team" - does this mean that all the staff are to be 100% dedicated to the project?

ANSWER: "Dedicated" in this context was intended to imply a commitment to the project. Dedicated was not intended to require a 100% effort, unless it was appropriate. Key personnel will be established for each Task Order and will require a contract modification

to change.

46. On pgs. 30-31, Section H.2.1 – Safety and Monitoring Issues – lists requirements that would appear not to apply to the Contractor (CRO), but rather to the specific subcontracted sites. For example, the first paragraph on pg. 31 mentions IRB approval and the FWA number – which we presume would pertain to the sites, and not the overall CRO. Please clarify.

ANSWER: It would be the CRO responsibility to ascertain that IRB approval and FWA has been obtained by a site.

47. On pg. 33, under Section H.2.4 - Required Time-Sensitive Notification – the timelines for reporting the AEs to the COR are not consistent. For example, item 4 (which specifies that the reports should be sent to the COR and FDA “concurrently”) – is inconsistent with items 1, 2, and 3, which specify COR notification “within 24 hours” of FDA notification. Also, these items 1, 2, and 3 are inconsistent with pg. 19 at Section F.3.2.1 – for safety reporting to the COR. Please clarify.

ANSWER: The current amendment updates Section F.3.2.1. of the RFP to reference H.2.4. the RFP.

48. On pg. 33, under the same section – items 1, 2, and 3 have the contractor reporting to the FDA instead of reporting to the sponsor prior to reporting to the FDA. Is BARDA going to assign a Government medical reviewer to participate in the SAE review prior to FDA notification?

ANSWER: BARDA will communicate with the FDA. The government may assign a government medical reviewer to participate in the SAE review. Offerors should anticipate provision of this service.

49. On pg. 57, Section L.2.1 – specifies the 75 page limit for the technical proposal. Are the 20 page limit responses to the Task Order 1 and 20 page limit response to the Task Order 2 part of the 75 pages of the technical proposal, or are they in addition to the 75 pages?

ANSWER: Technical proposal responses to sample RTOR0001 and sample RTOR0002 are included in the 75 page limit.

50. On pg. 60 under Section L.2.2 - Appendices to Technical Proposal - Please clarify the statement: “the Offeror shall provide the contact information of their U.S. Government partners in conduct of any research or other work that will be completed at a U.S. Government facility or using U.S. Government personnel during the course of the contract. The Offeror shall indicate whether the listed U.S. Government partners have been notified of the Offeror’s intentions to respond to this RFP.” For example, please clarify “U.S. Government partners” and “using” U.S. Government personnel – does this mean our Federal clients, and if so, what is the rationale for this requirement?

ANSWER: The identity and contact information for U.S. Government partners, including federal clients, will be used to collect past performance information and to ensure there is no duplication of effort.

51. On pg. 80, in the first paragraph under “Notice to All MCM CSN Contractors” – the RFP states “The budget proposal should be prepared and submitted to show the tasks outlined in Table 1, Attachment 2, and Attachment 3. It appears that Attachment 2 is the 2nd RTOR (pg. 105) and Attachment 3 isn’t a cost document, as it is a disclosure of lobbying activities (pg. 132). Please clarify. There is a similar comment on pg. 106 (third paragraph, second sentence) under “Notice to All MCM CSN Contractors” where it states: “The budget proposal should be prepared and submitted to show the tasks outline in Table 1, Attachment 2 and Attachment 3.” Is Table 1 the

same table as Attachment 2B – Pricing Schedule/CLIN Structure? Attachment 3 is a disclosure of lobbying activities. Please clarify.

ANSWER: This is addressed in a previous amendment.

52. On pg. 81, Table 1 includes “central randomization/IVRS”. Does BARDA require an IVRS, or would web-based randomization be acceptable (considering that sites increasingly prefer web over voice systems, that web-based systems are less costly, and that it is easier to integrate them with the study database)?

ANSWER: Randomization may be Interactive Voice Response System (IVRS) or web-based.

53. On pg. 96 (in Attachment 1C): Deliverables and Schedules table, Deliverable #8, 4th column: is the Medical Monitor noted here a Contractor or a BARDA function?

ANSWER: Items #6 and 8 on Page 96 are deleted per the current amendment. The medical monitor referred to here is the contractor’s medical monitor.

54. For both studies – would ex-US sites be considered acceptable?

ANSWER: Ex-US sites are not acceptable in response to sample RTOR 0001 or sample RTOR 0002.

55. The RFP encourages cross referencing between the overall SOO and the SOWs of both task orders: is there a preference for where in the proposal the rationale and detail is provided?

ANSWER: Cross-referencing is at the discretion of the Offeror. Offerors are anticipated to provide three Statements of Work relating to the Base Contract, and the two task orders.

56. Please clarify: is the Microsoft Project File to be provided as a separate file, and does it count as part of the page count?

ANSWER: The Microsoft Project File does not count towards the page limitation.

57. On pg. 97, #10 states that the proposed clinical sites shall be provided within 10 days of executed task orders for the response to task order 1. Should offerors include the rationale for choosing these sites or list the sites specifically?

ANSWER: The Offerors are to include a list of the specific sites and the rationale for choosing those sites.

58. Please confirm: are the site costs to be part of the CRO’s costs (are they to be included in the Contractor’s cost proposal)? We know that the Contractor will negotiate the contracts, but do we include the costs in this proposal?

ANSWER: The total cost should include the appropriate subcontractor costs of the sites, and should be included in the Offeror’s total cost proposal.

59. On pg. 11, 3d it says the CRO will “assist with study related materials and instructions...” Please expand on how the CRO will assist in the development of the memory aid.

ANSWER: The CRO will prepare the initial draft of study related materials and instructions to be reviewed and approved by BARDA.

60. On pg. 115 (in Attachment 2B) – Packaging Labeling, Storage, and Distributing – please confirm that this includes shipment up to the location where the IP will be dispensed/administered to the subjects, i.e. that the Contractor will have no involvement in the process apart from providing

input to the process design.

ANSWER: CRO will not be responsible for manage IP distribution and related documentation. The modified table of responsibilities is included in this amendment.

61. Are the 20 page limitations for the technical proposals for RTOR 0001 and 0002 (total = 40 pages) included in the 75 page limitation for the overall technical proposal?

ANSWER: Yes.

62. On page 59 of 156, section L.2.2.(5).E states “The Offeror shall submit a Gantt chart presented electronically as an integrated project plan in Microsoft Project 2007 format.” Is the Government requesting that the Gantt chart be embedded into the technical proposal or would they like the Microsoft Project 2007 Gantt chart be a separate attachment included in the proposal submission?

ANSWER: A separate attachment in Microsoft Project 2007 format is acceptable.

63. If an IND/IDE is required then will BARDA be the sponsor of the IND/IDE or is this dependent upon the needs of each individual product/trial? Should we consider USAMMDA?

ANSWER: The sponsor of the IND/IDE will depend on the needs of each individual product or trial and specified in the Task Order.

64. Regardless of IND/IDE sponsor is it BARDA’s expectation that the contractor will prepare and manage the IND/IDE submission process, i.e. production of necessary documents, attendance/leading meetings with FDA, filing the IND/IDE, etc.

ANSWER: BARDA will manage the IND/IDE process. The contractor may assist in the production of necessary documents. The specific requirements of the contractor will be established in future RTORs.

65. In Attachment 1B (page 86) and Attachment 2B (page 114), where the table indicates shared responsibility between BARDA and the CRO for an activity, can the Government provide guidance on how the Offeror should price the activity when there is not a full understanding of the scope of the specific activity the Offeror will perform (as opposed to the activities that BARDA will perform).

ANSWER: This is addressed in a previous amendment.

66. On pg. 22, in Section F.3.2.3 - Quality Metrics states: “For active clinical studies (not exclusively those funded by BARDA)” - does BARDA intend to award studies that are being funded by other agencies? Please clarify.

ANSWER: No and this amendment to the RFP removes the phrase ‘not exclusively those funded by BARDA’ and moves this section to L.2.1.1 Technical Proposal Components.

67. In addition to the individual sample task order cost proposals, in the business proposal do we need to provide an additional cost proposal for the overarching ID/IQ vehicle?

ANSWER: Yes, a cost proposal for the base IDIQ contract is required. See L.3.4.

68. On page 106 it states that Task Order 002 is Mixed Cost Reimbursement/Firm Fixed Price; however, on page 110 it is noted as a Firm Fixed Price. Which is correct?

ANSWER: This is addressed in a previous amendment.

69. How long is the contract duration/performance period for Task 002? On pages 106 and 110, it is stated as 24 months with three 12 month option periods; however, page 124 states that “the preparedness phase may require up to 365 calendar days after the award. Each subsequent year will be considered a Readiness year and will be structured as a contract option.”

ANSWER: This is addressed in a previous amendment.

70. The first page of Attachment #1 for Task Order Response 0002 (pg. 78) includes a list of attachments. According to the checkboxes, Attachment 1B – Pricing Schedule/CLIN structure is not supposed to be included. However, this Attachment does appear starting on page 86 and includes two tables, Table 1 and Table 2. Further, this Attachment is referenced in Attachment 1E on page 101 under Volume 2 – Price Submission, item (a).

Items b), c), and d) on page 101 instruct that the tables in Attachment 1E be used for the price response. These tables, when compared to the ones in Attachment 1B, utilize different categories of cost/price. For instance, Table 1 under Attachment 1B includes pass-through costs, which do not appear in Table 2 under Attachment 1E. Further, Table 2 under Attachment 1E allows for fee, but this item does not appear in Attachment 1B. Therefore, the total price calculated by each set of tables would not equal.

a. Assuming that both sets of tables are required in order to show both breakdown of price by task as well as breakdown by labor role, how should the offeror reconcile the differences in the tables?

ANSWER: This is addressed in the current amendment to the RFP.

b. Also, if Attachment 1B is to be used, please clarify the differences between the following terms: Materials costs, Other Direct Costs, and Pass-Through costs.

ANSWER: This is addressed in the current amendment to the RFP.

c. In addition, item e) on page 101 states that the “hourly rates proposed for each labor category shall be fully burdened rates, including any indirect or overhead rates applicable.” However, all of the tables request that overhead, fringe, and profit on these rates be separately represented. Please clarify.

ANSWER: Item e) has been modified to remove the sentence requiring fully burdened rates. This is addressed in the current amendment to the RFP.

d. For Table 3 – Cost Centers in Attachment 1E, please clarify if this table is meant to provide a breakdown of the base year materials costs in the Material(s) Matrix that appears below. Further, please clarify how the term “Materials” is to be interpreted given the omission of the term “pass-through costs” in this attachment. (Please see question 7b above.)

ANSWER: This table has been removed per prior amendment to the RFP.

71. In Attachment 2C – Statement of Work for Sample Request for Task Order Response 0002, the following is specified as Government-Furnished Equipment (GFE) / Government-Furnished Information (GFI): “ ... use H5N1 antigen formulated with adjuvant produced by HHS under prior contracts ...”. Sample Task Order 2 specifies clinical trials in response to orthopoxvirus

infections and the use of H5N1 antigen does not seem to be relevant. Please advise on appropriate GFE/GFI.

ANSWER: Sample RTOR002 is modified in this amendment to remove the section describing GFE/GFI.

72. RTOR 0002: Will BARDA or the contractor be responsible for identifying and selecting the protocol team members? Will BARDA or the contractor be responsible for writing the draft protocol?

ANSWER: Please clarify the function of the protocol team.

CLARIFICATION FROM CONTRACTOR:

We define a protocol team as a small group of technical/scientific experts who, together, design a clinical research protocol. Depending on the protocol/investigational product, it may include:

- *disease area researcher(s) (e.g., infectious disease physicians with special expertise in smallpox, influenza, or anthrax, etc.);*
- *laboratory specialist(s) (e.g., virologist, pharmacologist, immunologist);*
- *biostatistician;*
- *medical officer/expert representative from BARDA;*
- *representative from pharmaceutical company developing the investigational product;*
- *medical writer (if contractor is expected to write the protocol, this position would be provided by contractor)*

Our question is whether the contractor would design and write the protocol and, if so, would the contractor select/provide the members of the team (except of course the BARDA and pharma reps).

ANSWER: For sample RTOR 0002, BARDA will provide the clinical research protocol.

73. A small business subcontracting is required for both Sample Task 0001 and Sample Task 0002 but can we combine them into one subcontracting plan?

ANSWER: No, these need to be stand-alone subcontracting plans.

74. Are we still to submit Attachment 1B-Pricing Schedule/CLIN Structure, Table 1 with the cost proposal?

ANSWER: Yes.

75. One more question, the Excel spreadsheet (attachment 14) that is to be submitted for the cost proposal does not include a LABOR-PERCENT EFFORT and TRAVEL tab. Is there a reason why these two tabs are not included?

ANSWER: Please complete in the Excel spreadsheet as provided. Any additional information is welcome to be provided at the Offeror's discretion, but not required.

Questions related to ROTR 0001:

76. For Sample ROTR 0001, are offerors required to include the costs/price for the actual conduct of the sample trial (i.e., the investigator costs for the 6 sites)?

ANSWER: For sample RTOR 0001, yes, Offerors are required to include the costs/price for the actual conduct of the sample trial.

If yes, where within the cost and price schedule should this be included?

ANSWER: In the spreadsheet provided in Amendment #3, the total subcontractor cost should be reported. Supporting documentation should be included in the business proposal.

77. In Sample ROTR 0001 Table 2 on pages 90-91 contains only two columns (Labor Costs and Pass Through Costs). Please confirm whether the column for Labor Costs is just supposed to contain:

- i. The prime contractor's direct labor costs or fully burdened labor costs? And if it is supposed to include fully burdened labor costs should this include profit?
- ii. Subcontractor labor costs?

ANSWER: This is addressed in the current amendment to the RFP.

78. In both Sample Task ROTR 0001 and 0002 there is a Table 3 (pages 103 and 130 respectively). Please confirm what is to be included in this table and whether it is only to be used in capturing direct costs?

ANSWER: This is addressed in a previous amendment.

79. Will the information in each Table 3 then be consolidated into the Other Direct Cost section of the respective Table 2 pricing?

ANSWER: This is addressed in a previous amendment.

80. In both Sample Task ROTR 0001 and 0002 in Attachments 1B and 2B there is an identical Table 1 (beginning at pages 86 and 114 respectively). In addition, each has a Table 2 in Attachments 1E and 2E (pages 102 and 129 respectively). For each sample Task Order, are Offerors supposed to include both a completed Table 1 (from Attachments 1B and 2B) as well as a completed Table 2 (from Attachments 1E and 2E)?

ANSWER: Yes. Table 2 in attachment 1E and 2E has been replaced by a previous amendment.

Or should the activities listed in the left column of each Table 1 become the WBS section headers for the pricing in each Table 2?

ANSWER: Offeror may choose to use the activities described in Table 1 as their WBS headings.

81. Similarly, each sample task order has a Table 2 in Attachments 1B and 2B (pages 90 and 119 respectively), which appears to require summarized pricing by project activities. Do Offerors need to include a completed Table 2 from Attachments 1B and 2B in addition to the pricing required in Attachments 1E and 2E?

ANSWER: No, table 2 in Attachments 1B and 2B has been removed per the current amendment to the RFP.

82. If Offerors are required to complete Table 1 and/or Table 2 from Attachments 1B and 2B of both sample tasks, neither contains a column for profit or fee. Does the Government want Offerors to list their profit or fee in the cost/pricing information provided in these tables? If so, where should we list it? Should we add a column or lump it with indirect costs?

ANSWER: This is addressed in the current amendment to the RFP.

Questions related to ROTR 0002:

83. P. 106/156 states that it is a mixed cost reimbursement/FFP type task order contract while page 110 states it is a FFP type contract. Please clarify the type of contract BARDA would award for this kind of task order. If a mixed CR/FFP is anticipated, please specify which costs would be CR and which would be FFP.

ANSWER: This has been updated by a previous amendment.

84. On pages 107 and 110, there is reference to a 72 hour table-top exercise. Please clarify whether the table-top exercise is expected to last a total of 72 hours or expected to test a compressed timeframe of 72 hours of execution; and whether this includes the debrief; or whether the table-top exercise is expected to gap test the execution of the initial 72 hours of the response option period.

ANSWER: For sample RTOR 0002, Offerors are expected to propose the exercise parameters, durations and objectives.

85. Is the contractor expected to conduct the orthopoxvirus immunoglobulin testing and the PK testing; or will conducting these laboratory assays be the responsibility of BARDA?

ANSWER: For sample RTOR 0002, the contractor is not responsible for conducting the orthopox immunoglobulin testing and PK testing.

86. Please clarify the anticipated types of security restraints and releasability constraints and how task order performance will be affected.

ANSWER: For sample RTOR 0002, no response.

87. Regarding the instructions for Sample ROTR 0002 in the paragraph labeled Cost/Price Proposal on page 110, did the Government intend to reference Attachment 2A (page 112), which is just additional terms and conditions?

ANSWER: For sample RTOR 0002, the current amendment to the RFP changes this reference from '2A' to '2B'.

88. Sample Task Order 2, page 110 states that there will be no randomization schema and that all eligible patients will receive the investigational drug. Table 2B on page 116 states that the CRO will be responsible for pricing the IVR system. Can the Government confirm that it does require an IVR for this task and specify the scope of activities required by the IVR?

ANSWER: For sample RTOR 0002, an IVR system is not required.

89. Page 110 Sample Task Order 2. Can the Government define the number of unique CRF pages per subject?

ANSWER: For sample RTOR 0002, eight (8) unique CRF pages are required.

90. For task order 2, is HHS going to specify the location of the facility for sample analysis?
ANSWER: For sample RTOR 0002, the contractor is not responsible for sample analysis.
91. For task order 2, is the CRO responsible for shipping live viral samples and are there restrictions on who can receive them?
ANSWER: For sample RTOR 0002, the CRO is not responsible for shipping live viral samples.
92. Page 124 of RFP, TO#2 (smallpox), states that "... awardees are anticipated to use H5N1 antigen" This information appears to be copied from TO#1. Will BARDA provide information on Government- furnished product for TO#2?
ANSWER: Addressed in the current amendment to the RFP.
93. In Section L.2.1., it is stated that "As part of the technical proposal, the Offeror's will be required to submit a cross reference between the RFP and technical proposal to assist the government in their review." Is the cross reference matrix part of the 75-page limit?
ANSWER: Addressed in the current amendment to the RFP.
94. Question 47 and the subsequent response in Amendment 003 dated April 22, 2013 states: "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. Per the current amendment to the RFP, Gantt charts to be included in an appendix which does not count toward the page limitation.
95. The current RFP page requirements for the Technical Proposal are 75 for the Technical Proposal and 50 pages for the Appendices. Our understanding is that there is no appendix in the Technical Proposal whose page count does not count toward the page limitation. Can the Government confirm that the fully expanded GANTT chart should be included as the last Appendix of the Technical proposal for which there would be no page limit associated with it AND that all other Appendices would fall within the 50 page limit?
ANSWER: Addressed in the current amendment to the RFP.
96. In Sample Task ROTR 002, there is limited information about the specifications for the study (compared to ROTR 001 page 81 Study Parameters). What additional information can you provide on the number of subjects expected, SAEs, number of unique CRFs, anticipated study duration, anticipated tables, listings and figures, and other similar specs?
ANSWER: Additional information is provided in the answers to other questions in this amendment.