

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE N/A	PAGE 1	OF 3	PAGES
2. AMENDMENT/MODIFICATION NO. 0006	3. EFFECTIVE DATE 05/06/2015	4. REQUISITION/PURCHASE REQ. NO. N/A	5. PROJECT NO. (If applicable)		
6. ISSUED BY HHS/OS/ASPR/AMCG 330 Independence Avenue, S.W., Room G640 Washington, D.C. 20201		7. ADMINISTERED BY (If other than Item 6)		CODE	
8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP Code)		<input type="checkbox"/>	9A. AMENDMENT OF SOLICITATION NO. 15-100-SOL-00014		
		<input checked="" type="checkbox"/>	9B. DATED (SEE ITEM 11) 03/16/2015		
			10A. MODIFICATION OF CONTRACT/ORDER NO.		
			10B. DATED (SEE ITEM 13)		
CODE	FACILITY CODE				

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

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

12. ACCOUNTING AND APPROPRIATION DATA (If required)

N/A

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

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

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

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

PURPOSE OF AMENDMENT:

- (1) Extends due date for Organizational Conflict of Interest (OCI) notification and representation; and
- (2) Provides further responses to questions received.

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) Kevin Nilles 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)	

The following section of the RFP is hereby amended and restated:

SECTION L – INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

ARTICLE L.11. Organizational Conflict of Interest Notification and Representation

- (a) An actual or potential Organizational Conflict of Interest (OCI) may arise when an offeror obtains an unfair competitive advantage by acquiring the services of a marketing consultant that possesses unequal access to information or set the ground rules for a solicitation. See FAR Subpart 9.5, Organizational and Consultant Conflicts of Interest, for more information.
- (b) Each prospective offeror intending to respond to this solicitation shall make a representation and disclosure pursuant to subparagraphs (1) and (2), respectively, of this paragraph via email [\[kevin.nilles@hhs.gov\]](mailto:kevin.nilles@hhs.gov) & [\[matthew.mccord@hhs.gov\]](mailto:matthew.mccord@hhs.gov) on or before **3:00PM ET on May 13, 2015**.
 - (1) Representation. The offeror [] did [] did not have contact with a “marketing consultant,” as FAR 9.501 defines that term, relating to this solicitation, whether or not that contact resulted in a definitive consulting agreement.
 - (2) Disclosure. If the offeror did have contact with a marketing consultant relating to this solicitation, the offeror shall provide a disclosure statement describing all relevant facts concerning its contact(s). The disclosure statement shall include the date of the contact; the names of the persons involved in the contact; details about the contact, including a summary of the information discussed; whether the contact resulted in a definitive consulting agreement, and if so, a copy of that agreement; along with other information that is necessary for a true and accurate representation of the contact and the business relationship with the consultant and/or marketing consulting firm. That disclosure statement shall also include a description of actions that the offeror has taken or proposes to take, to avoid, mitigate, or neutralize an actual or potential conflict of interest that may arise from its contact(s).
- (c) Offerors responding to this solicitation shall assist and provide relevant information to the Contracting Officer in identifying, evaluating, and resolving an actual or potential OCI.
- (d) If the Contracting Officer determines that an actual or potential conflict exists, the offeror shall not receive an award unless the conflict can be avoided, neutralized, or mitigated.
- (e) Any offeror failing to provide a representation, full disclosure, or other required information shall not be eligible for award. Nondisclosure or misrepresentation of any relevant information may also result in disqualification from award, termination of a resultant contract for default, or debarment from Government contracts, as well as other legal action as the law or a resultant contract permits.

The following section of the RFP is hereby added:

SECTION J – LIST OF ATTACHMENTS

Attachment #9 – QUESTIONS & RESPONSES

1. Is a vaccine with Phase I safety data and preclinical animal effectiveness data with respect to prevention of influenza A disease responsive to this RFP?

Response: A human phase 1 safety study is not responsive unless it is also a dose-ranging study. Mandatory criteria #2 requires “completion of a phase 1 dose ranging clinical study...”

2. Will there be continuations of this RFP in future rounds?

Response: Depending on funds availability and ongoing programmatic requirements, it is possible that future RFPs for similar requirements may occur.

3. Will BARDA consider an extension to the submission date at this time, to May 30, 2015?

Response: At this point, BARDA will not be granting an extension beyond the May 15th date. If a prospective offeror cannot propose in time for this solicitation, that prospective offeror should consider submitting under the current or future Broad Agency Announcement.

4. For Mandatory criteria #2 "Demonstration of Advanced Development of the Proposed Influenza Vaccine Candidate", it is stated:

The Offeror must demonstrate significant progress towards advanced development of the proposed influenza vaccine candidate by completion of a Phase 1 dose-ranging clinical study that shows the vaccine candidate is well tolerated and able to induce cross-reactive immune responses to a range of antigenically divergent influenza viruses. This is to be documented by submission of a final clinical study report for the Phase 1 study, as well as any supportive clinical data.

How BARDA would like to have the final study report for Phase 1 if we are not allowed to have appendices in the Mandatory Criteria volume? Should we include it in the Technical volume and refer to it in the Mandatory criteria volume?

Response: The final study report for Phase 1 may be included in the Technical proposal appendices and referenced in the Mandatory Criteria volume.