

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE	OF	PAGES
			N/A	1		11
2. AMENDMENT/MODIFICATION NO. 0004	3. EFFECTIVE DATE 04/22/2015	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.		
			<input checked="" type="checkbox"/>	15-100-SOL-00014		
				9B. DATED (SEE ITEM 11) 04/22/2015		
				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.
<input type="checkbox"/>	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).
<input type="checkbox"/>	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
<input type="checkbox"/>	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) Organizational Conflict of Interest (OCI) notification and representation;
- (2) Responses to questions received; and
- (3) OSDDBU preproposal conference presentation.

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 sections of the RFP are hereby added:

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 & matthew.mccord@hhs.gov] on or before **3:00PM ET on April 29, 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.

SECTION J – LIST OF ATTACHMENTS

Attachment #9 – QUESTIONS & RESPONSES

1. If we are using adjuvants to meet the criterion of 50M doses in 4 months for the pandemic plan, can they be manufactured outside the US?

Response: The Offeror must submit evidence of domestic manufacturing capability, either alone or in partnership with other manufacturers, or plans for technology transfer to a domestic production site.

2. Can adjuvant manufacturing outside the US with stockpiling in the US be acceptable?

Response: This universal influenza vaccine contract would not be a stockpiling contract, therefore this question is not applicable.

3. Since we already have an active IND for our proposed vaccine candidate, would it be acceptable to cross-refer to the existing IND for all CMC aspects of the product when we file an IND for the advanced development of a 'universal' flu vaccine candidate?

Response: Your universal influenza vaccine candidate will need to have its own active/in-effect IND with the appropriate language reflected in the General Investigational Plan. If the universal influenza vaccine candidate, itself, is already under a different IND and it is the exact process, a cross-reference may be appropriate. Your regulatory office should be able to determine this.

4. "BARDA requests that the Contractor shall provide DHHS for review and acceptance a Product Feasibility Plan (also referred to as a Pandemic Product Plan) for technology transfers and/or to establish a domestic capability to manufacture the proposed influenza vaccine." Question: If the proposed vaccine candidate contains a set of antigens, does it have to be the same for the Pandemic Product Plan or can it be adapted for the pandemic strain as long as the same process is used and doses are delivered as planned

Response: The Product Feasibility Plan is a post-award contract-defined milestone and not part of the evaluation factors for award (Section M).

Attachment #10 – OSDBU PRE-PROPOSAL CONFERENCE PRESENTATION



OSDBU

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION

Subcontracting Overview

Solicitation 15-100-SOL-00014 Universal Flu

Pre-Proposal Conference

Dwight D. Deneal, Small Business Specialist
Office of Small & Disadvantaged Business Utilization
U.S. Department of Health and Human Services



SMALL BUSINESSES ARE THE  OF THE ECONOMY

Small Business Act, 1953

“It is the Declared Policy of the Congress
...to insure that a fair proportion of the total purchases
and contracts or subcontracts for property and services
for the Government ...be placed with small business
enterprises...to maintain and strengthen the overall
economy of the Nation.”



U.S. Department of Health and Human Services

OSDBU

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION

SMALL BUSINESSES ARE THE  OF THE ECONOMY

RESPONSIBILITIES

The OSDBU Director and delegated staff are responsible for advocating, educating, facilitating to the maximum practicable use of all small businesses in the federal acquisition process (prime/subcontractor) and OSDBU Director reports directly to the Deputy Secretary (HHS/OS)

Responsibilities include:

- **Outreach Activities**
- **Advocacy**
- **Unification of the Business Process**



“Myth-Buster”
OSDBU is not SBA





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SMALL BUSINESS SUBCONTRACTING

- Prime contractors are required to utilize small business concerns, consistent with efficient performance on applicable federal procurements
- HHS FY 15 Subcontracting goals are included in applicable solicitations/contracts:

SB	SDB	WOSB	HUBZone	VOSB	SDVOSB
33%	5%	5%	3%	3%	3%





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SMALL BUSINESS SUBCONTRACTING

The Small Business Subcontracting Plan encourages the development of increased subcontracting opportunities.

Applicability (FAR 19.7)

Contracts or contract modifications > \$650,000 (\$1.5m for construction) that have subcontracting opportunities shall submit an acceptable subcontracting plan.

Exemptions (FAR 19.7)

- Small businesses
- Personal services contracts
- Contract performed outside the US
- Modifications that do not contain the clause at FAR 52.219-8





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Commercial Subcontracting Plan vs. Individual Subcontracting Plan (FAR 19.7)

Commercial Subcontracting Plan

- Applies to the entire production of commercial items sold by either the entire company or a portion of the company, e.g. segment, division, etc.

- Covers the offeror's fiscal year

Individual Subcontracting Plan

- Applies to a specific contract

- Includes goals that are based on the offeror's planned subcontracting in support of a specific contract

- Covers the entire contract period, including all options periods





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BEST PRACTICES

- Appoint a small business advocate(s) business unit within your respective Businesses and champion small business supplier diversification as a “bottom line” driver.
- Include opportunities for small business concerns in every Federal procurement
- Establish an automated mechanism for tracking all Small Business Subcontracting Plans within the organization
- Develop marketing materials on How to do business guides for small business suppliers
- Conduct Supplier Information Forms and
- Contact HHS OSDBU Points of Contact(s)





U.S. Department of Health and Human Services

OSDBU

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION

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OSDBU CONTACT

Dwight D. Deneal, Small Business Specialist
Supporting: Assistant Secretary for
Preparedness & Response (ASPR/AMCG)

Website: www.hhs.gov/smallbusiness

Phone: 202.692.4775

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