

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE PAGE OF PAGES
1 66

2. AMENDMENT/MODIFICATION NO. Amendment No. 0003	3. EFFECTIVE DATE 04/08/2015	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY HHS\OS\ASPR\AMCG WASHINGTON, DC 20201	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	<input checked="" type="checkbox"/>	9A. AMENDMENT OF SOLICITATION NO. 15-100-SOL-00014
	<input checked="" type="checkbox"/>	9B. DATED (SEE ITEM 11) 03/16/2015
	<input type="checkbox"/>	10A. MODIFICATION OF CONTRACT/ORDER NO.
	<input type="checkbox"/>	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 extended, 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 1 copies 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 DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your 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 date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

CHECK ONE	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"/>	
<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 _____ copies to the issuing office.

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

Section J is changed by adding Attachment No. 8 "Pre-Proposal Conference Materials" and inserting Page Nos. 2 - 66 of this Amendment in that Attachment.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
15B. CONTRACTOR/OFFEROR	16B. UNITED STATES OF AMERICA
15C. DATE SIGNED	16C. DATE SIGNED
(Signature of person authorized to sign)	(Signature of Contracting Officer)

Attachment No. 8
Pre-Proposal Conference Materials



United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response



Advanced Development of More Effective/Universal Influenza Vaccines

Solicitation 15-100-SOL-00014

Pre-Proposal Conference

HHS/ASPR/BARDA

April 6, 2015



Agenda



- Welcome – Kyle Roberts
- Introductions/BARDA Influenza Vaccine Program – Dr. Robin Robinson
- Solicitation Technical Overview and Key Sections – Dr. Rick Bright
- Response to Submitted Technical Questions – Dr. Rick Bright
- Solicitation Contractual Overview and Key Elements – Kyle Roberts
- Solicitation Timeline – Kyle Roberts
- Business Evaluation – Kyle Roberts
- Business Questions and Answers – Kyle Roberts
- Small Business – Dwight Deneal
- Organizational Conflict of Interest – Michael Goulding
- Closing – Kyle Roberts



Universal Vaccine Program



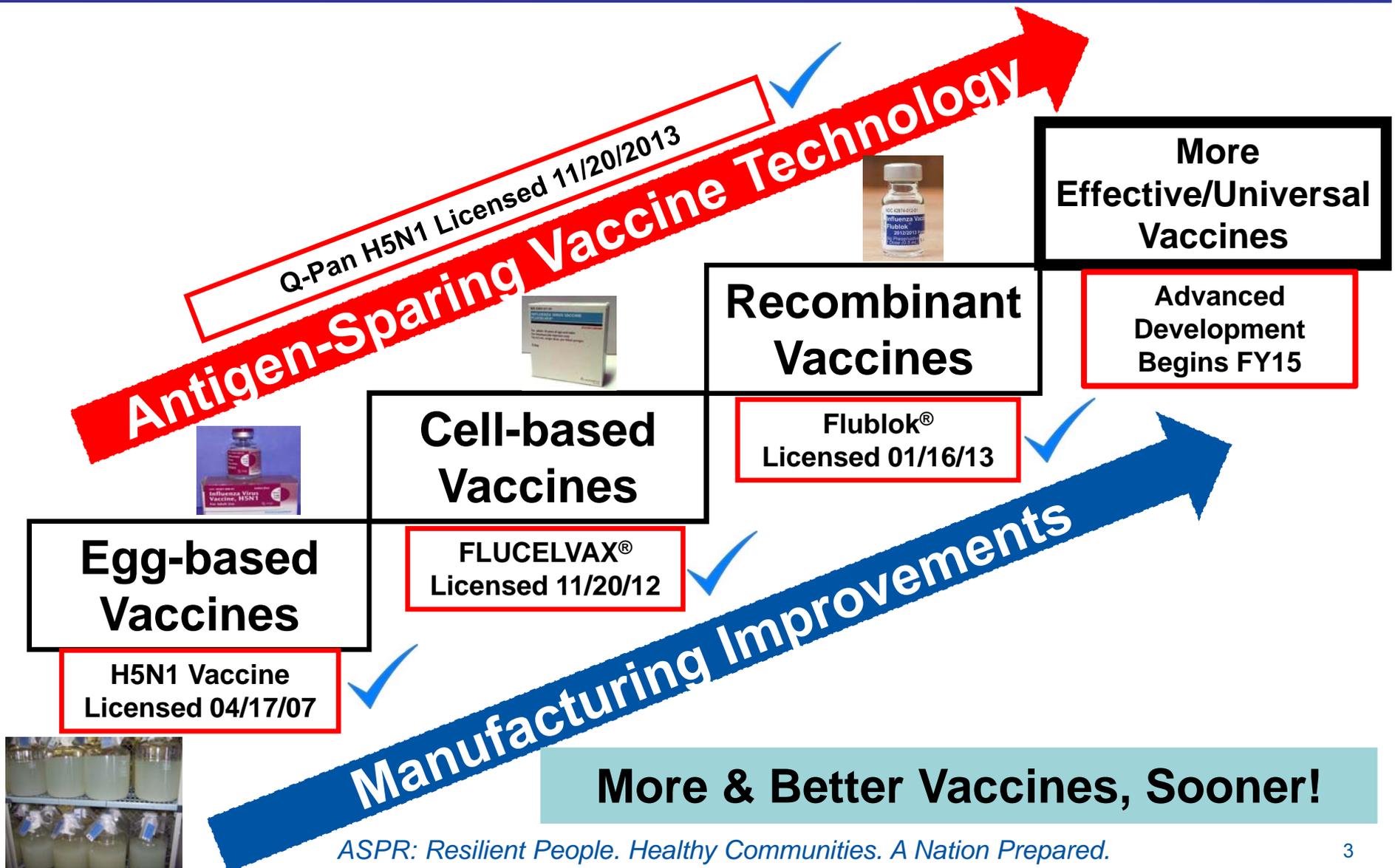
Making Progress Toward Universal Influenza Vaccines

Robin Robinson, PhD
Director

Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness & Response

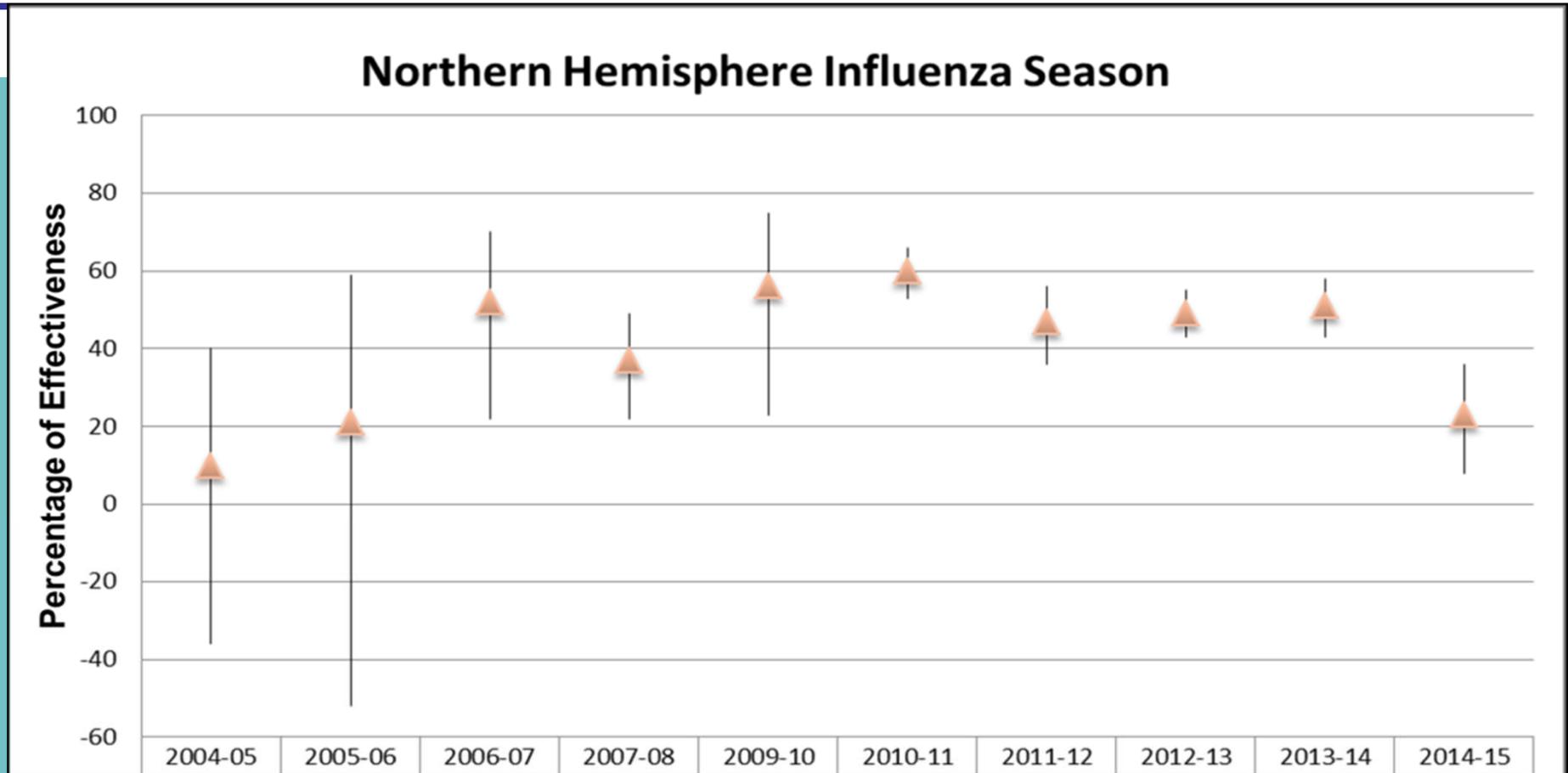


BARDA is Achieving National Pandemic Influenza Vaccine Goals

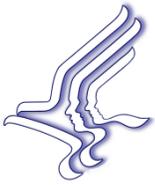




Limitations of Current Influenza Vaccines

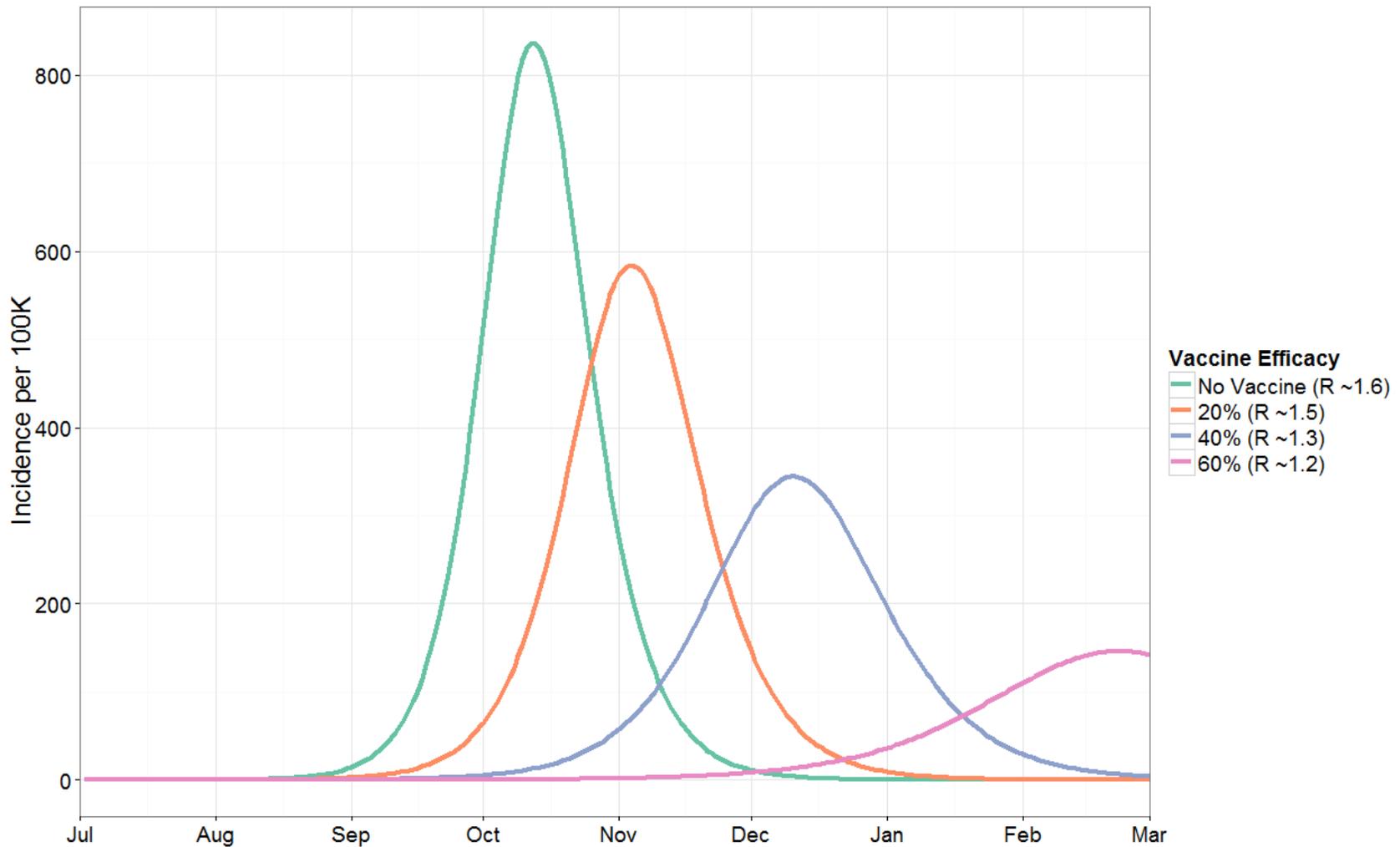


There is a need for improved, more effective influenza vaccines



Universal Influenza Vaccine

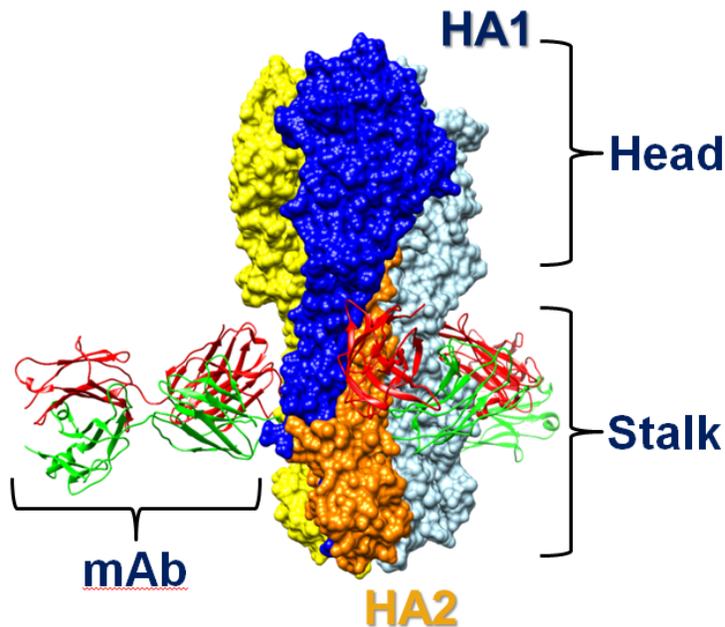
40% of population protected in advance





What is a More Effective/Universal Influenza Vaccine?

- A vaccine that provides safe, **more effective** and **long-lasting** immunity against a **broad** spectrum of divergent influenza viruses in all ages and people in high risk groups

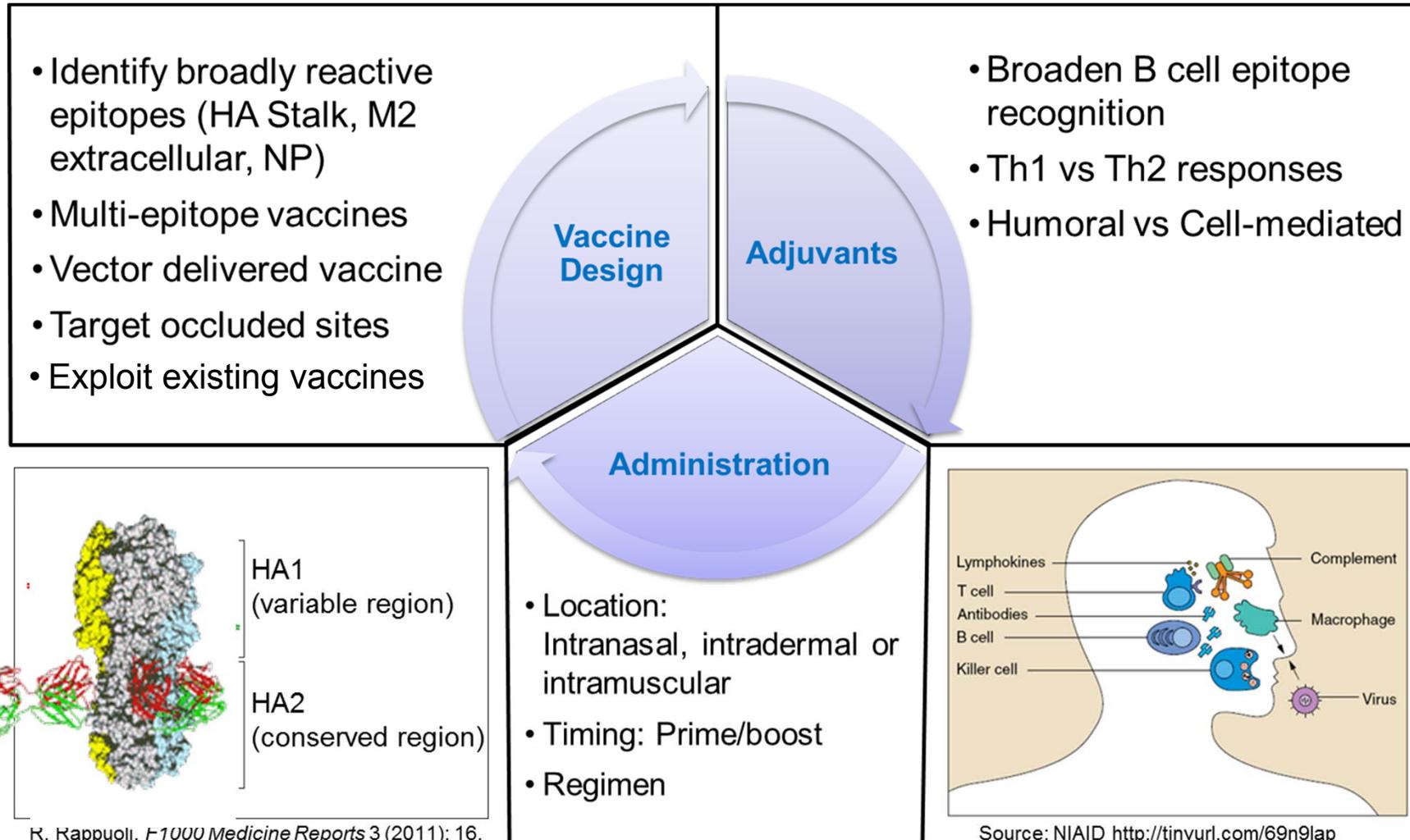


- **Prime** for emergence of a pandemic influenza virus
- Improve vaccine effectiveness
- Reduce the need for annual vaccination



Transformative Approach: Bringing it all together

More Effective/Universal Influenza Vaccines





Developmental Challenges for More Effective/Universal Vaccines



- **New science**
 - New/alternate regulatory pathways
 - New markers of immunity
 - Alternate production/analytical methods
 - New antigen/adjuvant combinations
 - Large scale or adaptive clinical programs
- **New partnerships**
 - Public/private partnerships
 - New consortiums/collaborations/Mergers & Acquisitions
- **Funding**
 - Up to \$1B per candidate from discovery to licensure



Ultimate Goal

“An Influenza Vaccine for Life”





Next Step



Advanced Development of More Effective/Universal Influenza Vaccines

Solicitation 15-100-SOL-00014

Rick Bright, PhD
Director, Influenza Division
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness & Response



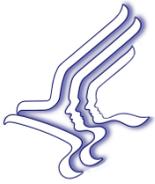
Mandatory Criteria

1. Evidence of Greater Cross-reactive Immune Responses to the Proposed Influenza Vaccine Candidate

- The Offeror must provide proof-of-concept data from *in vitro* and relevant animal studies supporting the ability of the candidate vaccine intended for clinical development to elicit greater cross-reactive immune responses compared to U.S.-licensed influenza vaccines against antigenically diverse influenza A viruses. For example, candidate vaccine will show cross-clade immunity within a subtype (e.g. H5 or H3) and/or cross-subtype immunity (e.g. against both H1 and H5 viruses).

2. Demonstration of Advanced Development of the Proposed Influenza Vaccine Candidate

- 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.



Mandatory Criteria (continued)

3. Plans for U.S. Vaccine Product Licensure

- It is essential that efforts funded as a result of this RFP shall lead towards U.S. licensure of the proposed influenza vaccine. The Offeror must demonstrate this commitment by documenting an active/in-effect investigational new drug (IND) submission to the U.S. Food and Drug Administration for the influenza vaccine candidate.

4. U.S. Vaccine Manufacturing Capability

- 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.



More Effective/Universal Influenza Vaccine: Target Product Profile

Property/Vaccine	Desired Primary Characteristics
Breadth of Protection	<i>Protects against antigenically divergent influenza A viruses and viruses from both influenza B virus lineages</i>
Efficacy	<i>Shows 20% or greater efficacy above a licensed influenza vaccine comparator as measured by clinical endpoints or surrogate endpoints (e.g. seroprotection or seroconversion rates) predicative of clinical benefit</i>
Duration of Immunity	<i>Protects for two years or more against influenza A subtypes and influenza B lineages</i>
Priming Immunity	<i>Primes for baseline immunity such that a single dose of pandemic influenza vaccine will boost immune response to protective levels against the pandemic influenza virus</i>
Safety	<i>Comparable to licensed vaccines</i>



Technical Evaluation Criteria

- Proposal completeness and quality will be evaluated in terms of risk and likelihood of successful completion of the project
- Merit and confidence (equal in value) ratings are assigned to below factors by evaluators

Evaluation Factors:

- I. Target Product Profile (*weighted higher than all others combined*)
Sub-factors (*weighted equally*): Breadth of protection, efficacy, duration of immunity, priming immunity, safety
- II. Technical Methodology and Approach (*II and III weighted equally and of higher importance than IV-VI*)
- III. Development Plan
- IV. Facilities (*IV-VI considered of equal importance*)
- V. Organizational Experience
- VI. Personnel



Questions received

- Over 75 questions were received
 - 25% of the questions were used to improve and clarify the RFP therefore not addressed within this conference
 - 5% of the questions were deemed to be specific to future contract negotiations
 - 70% of the questions will be used to guide our discussions today
- Of the questions that were in the 70%:
 - 11 were related to Mandatory Criteria
 - 7 were related to Statement of Objectives
 - 19 were related to the Target Product Profile
 - 4 related to Milestones and Deliverables



United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response



Responses to submitted technical questions



General Questions

General Comment to clinical trials questions:

Clinical protocol designs, including appropriate Phase (2 or 3) will be discussed during contract administration and does not need to be addressed at this conference. However, BARDA expects that all Offerors will wait the courtesy 30 day period for CBER comments and address appropriate comments to BARDA's satisfaction **prior** to initiation of clinical study.

Question 1:

Would BARDA consider extension of timelines beyond the estimated period of performance?

Response 1:

The base period of performance is up to four years with an option period of performance for up to five additional years. BARDA believes that 5-10 years should be adequate to support development towards licensure of a vaccine candidate with a relative maturity of TRL6 that meets the mandatory criteria at the inception of the award. Any determinations for extension need to be made on a case-by-case basis within the constraints of contracting law.

Question 2:

Could BARDA provide specific guidance on manufacturing strategies in the context of vaccine bulk/dose pre-pandemic stockpiling? Would product be kept in a stockpile for use?

Response 2

This RFP is not for the procurement of vaccine stockpiles; this is an advanced development contract to facilitate licensure of universal vaccines.



Topic 1: Mandatory Criteria

Question 3:

How is the “proposed influenza candidate vaccine” defined?

Response 3

Mandatory criteria defines the candidate as the “vaccine intended for clinical development,” that is, the Offeror must demonstrate that the required evidence exists for the vaccine they intend to develop and pursue for licensure regardless of whether offerors are:

- Considering first or second generation vaccines
- Considering combination of vaccines
- Have a platform technology for an unrelated indication which can be used to support this work

Question 4:

Can the mandatory criteria be relaxed?

Response 4

No. BARDA supports advanced development at the TRL 6 level and above. Per the Mandatory Eligibility Criteria #2, the required clinical data is documented by a final clinical study report to the FDA and should be appended to the proposal. Summary and/or interim data results are not sufficient.



Topic 1: Mandatory Criteria

Question 5:

Do vaccines need to address both influenza A and B?

Response 5

The mandatory criteria specifies cross-reactive (cross-clade or cross-subtype) immune responses to influenza A only.

Question 6:

Does all manufacturing for this vaccine need to be domestic, or just commercial manufacturing?

Response 6

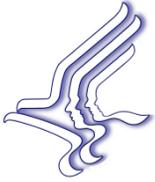
The mandatory criteria does not specify that all manufacturing needs to be domestic, only that the Offeror must submit evidence of domestic manufacturing capability (alone or with partners) for this vaccine.

Question 7:

How much support will BARDA provide to advance discussions with CBER regarding regulatory pathway and how much support will FDA provide regarding regulatory science and strategy?

Response 7

The Offeror will be expected to advance all discussions with CBER in the context of their regulatory submissions. BARDA will provide regulatory assistance as we do with all of our industry partners. BARDA will interact with CBER as appropriate within the constraints of a funding agency. FDA's guidance/advice/support to the Offeror will be determined by the FDA independent of BARDA.



Topic 2: Statement of Objectives

Question 8:

Will novel mechanisms of action be considered?

Response 8

Yes. The SOO is not prescriptive in stating how the vaccine will elicit long-lasting, broad spectrum, protective immunity, only that it should do this. Both well-known and novel mechanisms will be considered based on the RFP evaluation criteria.

Question 9:

Is there a desired threshold to rapid onset of immunity?

Response 9

The Target Product Profile does not specify a threshold to rapid onset. Demonstration of rapid onset under “Priming Immunity” will be evaluated favorably.

Question 10:

What is the primary indication and other desired indications of use for this universal vaccine?

Response 10

BARDA requires that the Offeror meet the attributes of the TPP to the extent possible. BARDA anticipates that Offerors will seek an indication for protection against disease caused by seasonal and pandemic influenza. The Offeror will be expected to discuss appropriate indications with CBER within the context of their regulatory submissions.



Topic 3: Target Product Profile

Question 11:

Will BARDA consider two TPPs - one for seasonal and one for pandemic?

Response 11

BARDA envisions a single TPP to be sufficient for both seasonal and pandemic. A vaccine that successfully fulfills the attributes of the current TPP shall be sufficiently cross-protective against both seasonal and pandemic strains.

Question 12:

Does BARDA consider all primary attributes of the TPP to be equally important? What is the importance of secondary attributes for the TPP?

Response 12

All primary attributes of the TPP are equally important - this has been explicitly articulated in Section M – Evaluation Factors for Award of the RFP. Secondary attributes will be taken into consideration as part of the evaluation under technical approach and development plan.

Question 13:

Could an incremental approach be taken if certain TPP attributes are not met within the estimated period of performance?

Response 13

An incremental approach may be considered in a case-by-case basis during the period of performance.



Topic 3: Target Product Profile

Question 14:

There were several questions related to 80% efficacy, including variability of % efficacy in different age populations , as well as variability of % efficacy from season to season.

Response 14

The new TPP states “Shows 20% or greater efficacy above a licensed influenza vaccine comparator...” This 20% increase is a point estimate and not the lower bound of a confidence interval. BARDA acknowledges there is age-related and season-specific variables with currently licensed influenza vaccines that may impact overall efficacy. However, we envision a transformative vaccine that will be able to transcend these issues. This is our target and what the Offeror should strive towards.

Question 15:

How does BARDA envision establishing efficacy via surrogate endpoints as it is unclear if existing correlates accurately predict clinical efficacy?

Response 15

BARDA will not be establishing efficacy via surrogate endpoints – this will be the Offeror’s responsibility. Determination of regulatory path to licensure will be data driven. Currently the only surrogate accepted by CBER is hemagglutination inhibition. In the absence of a validated surrogate, it is likely that the Offeror will need to utilize clinical endpoint efficacy to support a traditional approval pathway. This is something that Offerors will need to engage CBER to discuss as part of their regulatory interactions. BARDA will assist where appropriate.



Topic 3: Target Product Profile

Question 16:

There were several questions related to virus panel testing.

Response 16

The Offerors will be required to demonstrate cross-reactivity of clinical samples to a CDC panel of representative viruses using a functional assay relevant to the candidate vaccine's proposed mechanism of action.

Question 17:

What are the performance parameters for Breadth of Protection?

Response 17

BARDA envisions a universal vaccine should cover both Group 1 and 2 Influenza A viruses, as well as both B lineages.

Question 18:

Would BARDA consider a proposal with infant immunization as a necessary component of vaccine strategy?

Response 18

BARDA always strives to support MCM development for all special populations including infants. We welcome any proposal with infant immunization as a component of vaccine development. While this component may not be required as part of the proposal, it will be considered favorably and will be a vital part of the advanced development pathway that BARDA will discuss with all successful Offerors post- award.



Topic 4: Milestones & Deliverables

Question 19:

What support will BARDA and FDA provide to advance development of new assays and new correlates?

Response 19

New assays and new correlates are product-specific and will require Offeror to take the lead on the development of such assays intended to support licensure of its vaccine. BARDA will provide SME support to the extent that resources allow, as appropriate. FDA's level of support will be determined by the FDA independent of BARDA.

Question 20:

Will an efficacy study be required during the base period?

Response 20

This question can only be answered on a case-by-case basis; in general, however, any Phase 3 studies will likely not occur during the base period as the level of evidence required to proceed into a phase 3 study is substantial, and will need decision gate(s) for further evaluation/consideration for exercising option period of performance. Any discussions on **specifics** for protocol design (such as endpoints and comparators) for an efficacy study is deferred until after contract award as this will necessarily need to consider the attributes of the vaccine, itself, and cannot be generalized at this point.



Additional Q&A

Question 21:

Additional clarity is needed on the active IND requirement. Do we need to have a specific IND for the universal Flu vaccine for this RFP or if an existing Flu vaccine IND can be expanded for this need?

Response 21:

The universal influenza vaccine candidate intended for advanced development must have its own active/in-effect IND with the U.S. FDA.



Solicitation Timeline: Pre-Submission



- RFP issued 3/16/2015
- Pre-Proposal Conference 4/06/2015
- Amendments (potential Q&A's/RFP changes) various dates
- Proposals Due **5/15/2015**
- Anticipated Award Date **9/2015**



Thank you for your interest!



- Any additional questions must be submitted in writing to the contracting office (ASPR AMCG)
- Select questions and responses will be made public through solicitation amendments
- No deadline extensions will be granted



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Advanced Development of More Effective/Universal Influenza Vaccines Business Presentation

Solicitation 15-100-SOL-00014

S. Kyle Roberts

Section Chief, Influenza and Emerging Diseases

Office of Acquisition Management Contracts and Grants

Office of the Assistant Secretary for Preparedness and Response

Pre-Proposal Conference

BARDA/ASPR/OS/HHS

April 6, 2015



Note

This presentation and verbal discussions that occur during this meeting are not intended to change the requirements of the RFP. Changes to the RFP must be documented in writing and posted to the Federal Business Opportunities website for this solicitation.

All official solicitation documents are posted on www.FedBizOpps.gov.

The solicitation and all amendments to the solicitation documents are posted on that website under BARDA_Universal_Influenza_Synopsis for the Solicitation number 15-100-SOL-00014.

Please take note of amendments to the RFP.



United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response



RFP Review



Solicitation Key Elements



- Proposals are due May 15th, 2015, 5:00PM (ET)
 - Proposal delivery
- Mandatory Minimum Criteria
- Oral Presentations
- Full and open competition
- Teaming and subcontracting arrangements are permitted
- Period of Performance
 - Base + Option Periods
- USG reserves right to issue multiple awards
- All updates, amendments, etc. will be available online at www.fedbizopps.gov



Requests for Proposals Comments



- Be certain to read the entire RFP

- Ask questions on anything that is unclear or requires further clarification

- Direct written questions to the appropriate individuals.
 - Contract Specialist (matthew.mccord@hhs.gov)
 - Contracting Officer (kevin.nilles@hhs.gov)



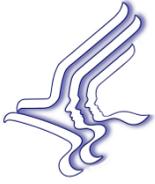
RFP vs. BAA

- This Solicitation is an RFP, Not a BAA
 - FAR Part 15 Procedures
 - Evaluation
 - Competitive Range, if needed
 - Exchanges, if needed
 - Source Selection

 - No Areas of Interest (SOO Only)

 - No Whitepaper (Proposal Only)

 - No Categories of Proposals



Post-Submission Activities

- Mandatory Criteria Evaluation
- Oral Presentation
- Technical and Business Evaluation Panels
- Contracting Officer Competitive Range Determination
- Pre-award Debriefing for Offerors not in the competitive range
- Discussions/Negotiations (if necessary)
- Site Visits (if necessary)
- Request and Receive Final Proposal Revisions
- Evaluation of Final Proposal Revisions
- Brief Source Selection Authority
- Award Determination
- Draft Contracts
- Contract Award
- Post-Award Debriefing



Business Proposal Clarifications

- Costs unallowable unless authorized by Contracting Officer (B.4.):
 - Certain types of subcontracts;
 - Foreign travel costs;
 - Food for meals; light refreshments; or beverages
 - etc...

- Small Business Plan:
 - Required for contracts (task orders) in excess of \$650K
 - Not required for small businesses (defined by NAICS code)



Business Evaluation

The basis of evaluation may include the use of various cost/price realism analysis techniques to ensure a fair and reasonable price such as, but not limited to:

- Comparison of proposed prices received in response to the solicitation.
- Comparison of proposed prices with resources proposed.
- Obtaining information/reports from DCAA or other outside agencies, and the Independent Government Cost Estimate.
- Review and analysis of cost and pricing data as well as other cost and pricing data submitted



RFP Questions



Please submit questions 10 calendar days prior to solicitation closing date (*i.e.* May 5). However, we will make our best effort to answer questions received after this date until the solicitation closes (*i.e.* May 15).

Submit questions to: matthew.mccord@hhs.gov



United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response



Question & Response Review



Business Questions & Answers

- We would appreciate your feedback whether an excel based EVM engine and Project based scheduling would meet the expectations in robustness which are expected for an EVM Tier 2 implementation.
 - **Response: Microsoft Excel and Project are generally not recommended at Tier 2. A more robust EVM engine such as Deltek Cobra or MPM is recommended for Tier 2. However, note the Government does not offer preference to any particular software provider.**



Business Questions & Answers

- Can you provide an idea of the budget allowed for an award?
 - **Response: An Offeror should propose the realistic and reasonable costs necessary to implement its technical approach to performing the SOO.**

- Is there a page limitation for the business proposal?
 - **Response: There is no page limit for the business proposal.**

- When does the government intend to award contracts?
 - **Response: The Government intends to make award(s) in Fiscal Year 2015.**



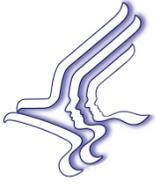
Business Questions & Answers

- In the past we have submitted a limited scope white paper for preliminary screening. However, unless we skipped some important information, in the present solicitation we could not find such a requirement, except for the deadline for a full submission. This permits offerors 60 days to submit a full-scale proposal, was this the original intent of BARDA?
 - **Response: That is correct: a white paper is not requested. A full proposal is required.**



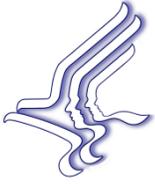
Business Questions & Answers

- Article B.2., section C. Fee: would it possible to know the fixed fee rate (“equal to ___% of actual costs incurred each invoicing period”)?
 - **Response: The fixed fee is proposed by the offeror. The percentage of fixed fee to be invoiced each invoicing period will be equal to the percentage that the fixed fee represents of the total estimated cost. For example, a \$50 fixed fee on a contract estimated to cost \$1,000 would be invoiced at a rate of 5% of costs incurred for that invoicing period.**



Business Questions & Answers

- **ARTICLE B.3. ADVANCE UNDERSTANDINGS, h.**
Establishment of Indirect Cost Rate: would it be possible to know indirect costs' temporary billing rates?
 - **Response: These rates are typically established and approved by the cognizant government auditor. If a potential offeror does not already possess such rates, new rates must be proposed by the offeror and will be evaluated and approved before any resultant award.**



Business Questions & Answers



- **ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS, section b. Travel Costs: will there be a revised amount for Total expenditures for travel, now set at 0\$?**
 - **Response: This figure will be updated based on the travel costs included in a successful proposal.**



Solicitation 15-100-SOL-00014 Pre-Proposal Conference



Small Business Discussion



Ethics/Conflicts of Interest



Michael Goulding, Esq.
Deputy Associate General Counsel
Procurement, Fiscal, Information Law Branch
General Law Division
Office of the General Counsel
U.S. Department of Health & Human Services



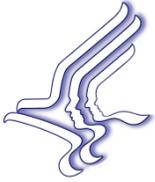
General Standards of Conduct

- **“Government business shall be conducted in a manner above reproach and, except as authorized by statute or regulation, with complete impartiality and with preferential treatment for none.** Transactions relating to the expenditure of public funds require the highest degree of public trust and an impeccable standard of conduct. **The general rule is to avoid strictly any conflict of interest or even the appearance of a conflict of interest in Government-contractor relationships.”** FAR 3.101-1 (emphasis added).



Organizational Conflicts of Interest

- Conflicts of interest involving contractors and their work on behalf of the Government are referred to as "organizational conflicts of interest" ("OCI") and are governed by FAR 9.5.
- An OCI may result when factors create an actual or potential conflict of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential conflict of interest on a future acquisition. In the latter case, some restrictions on future activities of the contractor may be required. FAR 9.502(c).



Organizational Conflicts of Interest Potential OCIs



- An OCI arises when, because of other activities or relationships with other persons:
 - a person is unable or potentially unable to render impartial assistance or advice to the Government; or
 - the person's objectivity in performing the contract work is or might be otherwise impaired; or
 - a person has an unfair competitive advantage. FAR 2.101.



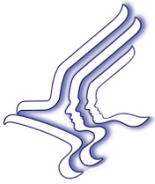
Organizational Conflicts of Interest Potential OCIs



- Impaired Objectivity Cases:

Generally arise in situations where a firm's work under one Government contract could entail the firm evaluating itself through either assessment of its own performance under another contract, or evaluation of its own and/or competitors' proposals in a procurement process. The concern here is the firm's ability to render impartial advice.

- Government Contractors are not prohibited from evaluating their own offers for products or services, or those of a competitor, *provided that proper safeguards are in place* to ensure objectivity to protect the Government's interests. FAR 9.505-3.
- Former employees of contractors are also not prohibited from evaluating the offers of their former employers provided that *appropriate safeguards are in place*.



Organizational Conflicts of Interest Potential OCIs



- Unfair Competitive Advantage Cases:

Unequal access to information cases arise in situations where a firm has access to nonpublic information as part of its performance of a Government contract and where that information may provide the firm a competitive advantage in a later competition for a Government contract. The concern in such situations is generally limited to the risk of the firm gaining an unfair competitive advantage in the later competition. FAR 9.505-4.

Biased ground rules cases arise in situations where a firm, as part of its performance of a Government contract, has in some sense set the ground rules for another government contract by, for example, writing the statement of work or the specifications for that other contract. The primary concern in such situations is one of unfair competitive advantage in that the firm could skew the competition for the other contract, intentionally or not, in its favor. FAR 9.505-1, 9.505-2.



Organizational Conflicts of Interest Potential OCIs



- Contractors may also obtain proprietary and source selection information by acquiring the services of marketing consultants.
- If used in connection with an acquisition, may give the contractor an unfair competitive advantage.
- Contractors should make inquiries of marketing consultants to ensure that the marketing consultant has provided no unfair competitive advantage. FAR 9.505-4(c).
- **IMPORTANT:** A contractor may be free of conflicts, but by using a third party to assist responding to a solicitation, may unwittingly expose itself to an OCI



Organizational Conflicts of Interest Contracting Officer Responsibilities



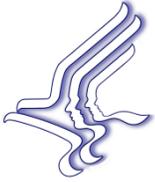
- Identify and evaluate potential conflicts of interest as early in the acquisition process as possible. FAR 9.504.
- Make a reasonable determination that no consideration of a potential OCI is required
OR
- Perform a reasonable, documented assessment that identifies and evaluates the potential OCI that may arise due to the contractor's past or ongoing relationships or activities.
- If there are areas of contract performance that create significant conflicts or potential conflicts, the contracting officer should establish and document a course of action that will effectively **avoid, neutralize or mitigate the conflict** (following the procedures in FAR 9.504-9.506).
- If the conflict cannot be mitigated, neutralized or avoided, the CO can: (1) amend the solicitation to remove the conflict; (2) amend the solicitation to impose restraint on the contractor's eligibility for future contracts or subcontracts; (3) exclude the contractor from competition; or (4) obtain a waiver of the OCI requirements of FAR Subpart 9.5 from the agency head.



Organizational Conflicts of Interest Contractor Do's and Don'ts



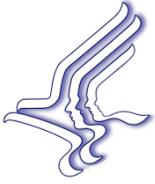
- DO be proactive by:
 - Assisting the CO by identifying potential conflicts as early as possible.
 - Explaining whether or not the potential conflict requires avoidance, neutralization or mitigation.
 - Providing the CO with a proposed mitigation plan if necessary.
 - Being responsive to questions from the CO and HHS legal counsel.
- DON'T be reactive by waiting for the CO to identify the potential conflict.



Procurement Integrity Act



- Governs the Fairness of Procurement Process, Including:
 - Who May Have Access to Proposal Evaluations
 - Disclosure of Bid/Proposal Information
 - Restrictions on Future Employment Discussions



Procurement Integrity Act **ASPR**

ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

41 U.S.C. 2101-2107 (FAR 3.104)

- No person or other entity may disclose contractor *bid or proposal information or source selection information* to any person other than a person authorized, in accordance with applicable agency regulations or procedures, by agency head or the contracting officer to receive such information.
- No person shall, other than as provided by law, knowingly obtain contractor bid or proposal information or source selection information before the award of a Federal agency procurement contract to which the information relates.
- This “ban” applies to everyone (*i.e.*, not just federal employees.)



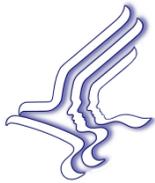
Procurement Integrity Act **ASPR**

ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

Definitions

Bid and Proposal Information includes:

- Cost or pricing data.
- Indirect costs and direct labor rates.
- Proprietary information about manufacturing processes, operations, or techniques marked by the contractor in accordance with applicable law or regulation.
- Information marked by the contractor as “contractor bid or proposal information” in accordance with applicable law or regulation.
- Information or data marked by offeror which indicates data that offeror does not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes.



Procurement Integrity Act **ASPR**

ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

Definitions

Source Selection Information includes:

- Bid prices submitted in response to an agency invitation for bids, or lists of those bid prices before bid opening.
- Proposed costs or prices submitted in response to an agency solicitation, or lists of those proposed costs or prices.
- Source selection plans.
- Technical evaluation plans.
- Technical evaluations or proposals.



Procurement Integrity Act **ASPR**

ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

Definitions (cont.)

Source Selection Information also includes:

- Cost or price evaluations of proposals.
- Competitive range determinations that identify proposals that have a reasonable chance of being selected for award of a contract.
- Rankings of bids, proposals, or competitors.
- Reports and evaluations of source selection panels, boards, or advisory councils.
- Other information marked as “Source Selection Information – See FAR 2.101 and 3.104” based on a case-by-case determination by the head of the agency or the contracting officer, that its disclosure would jeopardize the integrity or successful completion of the Federal agency procurement to which the information relates.



Procurement Integrity Act **ASPR**

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PREPAREDNESS AND RESPONSE

Violations

Even a Suspected Violation May Stop The Procurement (See FAR 3.104-7)

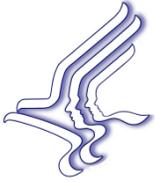
- Violations and “Possible Violations” Must Be Reported to the HCA
- Other Penalties (41 U.S.C. 2105)
 - Criminal Penalties (Up to 5 Years In Prison)
 - Civil Penalties (For Individuals - \$50K Per Violation)
 - Administrative Penalties (Cancellation, Rescission, Debarment, and Suspension.)



Procurement Integrity Act Other Related Prohibitions



- The offer or acceptance of a bribe or gratuity is prohibited by 18 U.S.C. 201.
- The acceptance of a gift, under certain circumstances, is prohibited by 5 U.S.C. 7353 and 5 C.F.R. part 2635.
- A federal employee must be recused if he or she is seeking employment with the industry offeror or another company that makes a directly competing product.
- An offeror who engages in employment discussion with a government official participating personally and substantially in that federal agency procurement (in excess of the simplified acquisition threshold), knowing that the government official has not disqualified himself or herself from further participation is subject to criminal, civil or administrative penalties.



Procurement Integrity Act

Industry Do's and Don'ts



- DON'T solicit/accept bid and proposal information or source selection information (unless authorized to do so).
- DON'T give gifts to government employees involved in a procurement in which your company is an offeror.
- AVOID making offers of employment to government employees involved in a procurement in which your company is an offeror.
- DON'T continue employment negotiations with a government employee if the employee fails to disqualify himself or herself from participation in the procurement.
- DO, if your company improperly receives bid and proposal or source selection information: (1) limit its dissemination/reproduction within the company; (2) track its dissemination/reproduction; (3) immediately notify the cognizant contracting officer or if unknown, the agency HCA; (4) provide a full description of its handling while in your company's possession.



Solicitation 15-100-SOL-00014 Pre-Proposal Conference



Closing Remarks