DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY: Office of the Assistant Secretary for Health/ National Vaccine Program Office

FUNDING OPPORTUNITY TITLE: Research, Monitoring and Outcomes Definitions for Vaccine Safety

ACTION: Notice

ANNOUNCEMENT TYPE: COMPETITIVE COOPERATIVE AGREEMENT

FUNDING OPPORTUNITY NUMBER: NV-VSR-15-0001

CFDA NUMBER: 93.344

CFDA PROGRAM: Research, Monitoring and Outcomes Definitions for Vaccine Safety

DATES: Applications are due April 15, 2015 by 5 p.m. ET. To receive consideration, applications must be received electronically via Grants.gov by the HHS Office of the Assistant Secretary for Health (HHS/OASH), Office of Grants Management (OGM) no later than this due date. Applications which do not meet the specified deadlines will be returned to the applicant unread. All applicants must submit electronically via Grants.gov unless they obtain a written exemption from this requirement 2 business days in advance of the deadline by the Director, HHS/OASH Office of Grants Management. To obtain an exemption, applicants must request one via email from the HHS/OASH Office of Grants Management, and provide details as to why they are technologically unable to submit electronically through Grants.gov portal. Requests should be submitted at least 4 business days prior to the application deadline to ensure the

request can be considered prior to 2 business days in advance of the deadline. If requesting an exemption, include the following in the e-mail request: the HHS/OASH announcement number; the organization's DUNS number; the name, address and telephone number of the organization; the name and telephone number of the Authorizing Official; the Grants.gov Tracking Number (GRANTXXXX) assigned to the submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to ogm.oash@hhs.gov. Note: failure to have an active System for Account Management (SAM) registration will not be grounds for receiving an exemption to the electronic submission requirement.

The HHS/OASH Office of Grants Management will only accept applications via alternate methods (hardcopy paper via US mail or other provider or PDF via email) from applicants obtaining prior written approval. The application must still be submitted by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via US mail or other service or PDF via email) with an approved written exemption will be accepted. *See* the heading "**APPLICATION and SUBMISSION INFORMATION**" for information on application submission mechanisms.

To ensure adequate time to successfully submit the application, HHS/OASH recommends that applicants register as early as possible in Grants.gov since the registration process can take up to one month. For information on registering for Grants.gov, refer to http://www.grants.gov or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Applicants are strongly encouraged to register multiple authorized organization representatives.

EXECUTIVE SUMMARY: HHS/ OASH/ National Vaccine Program Office announces the availability of funds for Fiscal Year (FY) 2015 **cooperative agreement awards** under the authority of section 1702(a) of the Public Health Service Act, as amended [42 U.S.C. 300u-1(a)]. This notice solicits applications for projects to conduct research on vaccine safety. The National Vaccine Program Office (NVPO) collaborates with federal partners to provide strategic direction for the coordination of the vaccine and immunization enterprise for the National Vaccine Plan (NVP) implementation http://www.hhs.gov/nvpo/vacc_plan/2010%20Plan/nationalvaccineplan.pdf. NVPO will partner with an organization to collaborate on a research project that will fall specifically under goal 2 of the NVP, and is intended to i) ensure a robust vaccine safety scientific system; ii) facilitate the timely integration of advances in manufacturing sciences and regulatory approaches to enhance product quality and patient safety; iii) enhance timely detection and verification of vaccine safety signals; iv) improve timeliness of the evaluation of vaccine safety signals; v) improve causality assessments of vaccines and related adverse events following immunizations (AEFI); vi) improve scientific knowledge about why and among whom vaccine adverse reactions occur; vii) improve clinical practice to prevent, identify and manage vaccine adverse reactions and; viii) enhance collaboration of vaccine safety activities. NVPO is looking to partner with an institution or organization to conduct pertinent research on these areas, specifically, but not limited to, determining the safety profile of new vaccines during the early development stage, developing or modifying existing vaccines to improve their safety, conducting applied research that will have a direct impact on the current vaccine safety monitoring system, conducting research that will

achieve consensus definitions of vaccine safety outcomes that could be utilized to collect consensus data in clinical research conducted globally.

The National Vaccine Program Office anticipates selecting and awarding two cooperative agreements of $250,000 each.

I. FUNDING OPPORTUNITY DESCRIPTION:

OASH/ National Vaccine Program Office (NVPO) provides strategic direction for the coordination of the vaccine and immunization enterprise through the National Vaccine Plan (NVP) implementation. NVPO specifically provides guidance and coordination for all vaccine safety systems, activities and research studies in the U.S. through the Immunization Safety Task Force (ISTF). While engaging vaccine safety stakeholders through the ISTF, NVPO is able to identify gaps in vaccine safety monitoring and research. NVPO has launched this pilot cooperative agreement program to partner with an organization to conduct research that will strengthen the current U.S. vaccine safety enterprise. The program's objective is to conduct research in vaccine safety related areas, specifically, but not limited to, determining the safety profile of new vaccines during the early development stage, developing or modifying existing vaccines to improve their safety, conducting applied research that will have a direct impact on the current vaccine safety monitoring system, conducting research that will achieve consensus definitions of vaccine safety outcomes that could be utilized to collect consensus data in clinical research conducted globally.

NVPO is particularly interested in projects related to researching, establishing or testing the vaccine safety profile of vaccines that are currently recommended for or are expected to be

routinely administered to pregnant women and/or newborns. Topics of research may cover establishing the safety of a vaccine in either the pregnant women, her newborn or both, at any stage of the vaccine development, testing and/or pre-clinical or clinical research and monitoring of vaccine safety. This pilot program encourages collaborative efforts with experts across fields to maximize the results and impact of the research project.

NVPO scientific staff will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- **Provide guidance and support in the design and development of the research project**
- **Serve as a resource to provide scientific/programmatic support during the accomplishment of the research by participating in the design of the activities, providing access to vaccine safety stakeholders and contributing with subject matter expertise**
- **Oversee the adequacy of adverse event following immunization research, monitoring and result analysis and reporting, and have regular communications with the principal investigator (PI) and study team**
- **Participate in the preparation of publications and public presentations of the data obtained under this Cooperative Agreement**

AUTHORITY: section 1702(a) of the Public Health Service Act, as amended [42 U.S.C. 300u-1(a)]

II. AWARD INFORMATION

The National Vaccine Program Office intends to make available approximately $ 500,000 for competing cooperative agreements. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner.

Grants will be funded in annual increments (budget periods) and are generally approved for a project period of up to one year. Funding for all approved budget periods beyond the first year of the grant is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, and adequate stewardship of Federal funds.

Award Information

Estimated Funds Available for Competition: $500,000

Anticipated Number of Awards: 2

Range of Awards: $200,000 - 250,000 per budget period

Anticipated Start Date: 07/01/2015

Period of Performance: Not to exceed 1 year

Budget Period Length: 12 months

Type of Award: Cooperative Agreement. Agency substantial involvement is outlined in Section I.

Type of Application Accepted: Electronic via Grants.gov **ONLY unless an exemption is granted**

III. ELIGIBILITY INFORMATION

1. Eligible Applicants

- Nonprofit with 501C3 IRS status (other than institution of higher education)
- Nonprofit without 501C3 IRS status (other than institution of higher education)
- For-profit organizations (other than small business)
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- American Indian/Alaska native tribally designated organizations
- Alaska Native health corporations
- Urban Indian health organizations
- Tribal epidemiology centers
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

- Public (including city, county, regional, and State government) organizations and private nonprofit entities.

2. *Cost Sharing or Matching* : None

3. *Responsiveness and Screening Criteria*

Application Screening Criteria

All applications appropriately submitted will be screened to assure a level playing field for all applicants. If duplicate applications from the same organization for the same project are successfully submitted, only the last application received by the deadline will be reviewed. Applications that fail to meet the screening criteria described below will **not** be reviewed and will receive **no** further consideration.

1. Applications must be submitted electronically via www.grants.gov (unless an exemption was granted 2 business days prior to the deadline) by April 15, 2015

2. The Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ " x 11" inch page size, with 1" margins on all sides (top, bottom, left and right) and font size not less than 12 points.

3. The Project Narrative must not exceed **10 pages**. NOTE: The following items do not count toward the page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary and Budget narrative.

4. The total application including Appendices must not exceed **15 pages**. NOTE: items noted above do not count toward total page limit.

5. Proposed budget does not exceed maximum indicated in Range of Awards.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Information to Request Application Package

Application packages may be obtained electronically by accessing Grants.gov at http://www.grants.gov/. If you have problems accessing the application or difficulty downloading, contact:

Grant Operations Center, Office of Grants Management Operations Center, telephone 1-888-203-6161, or email ASH@LCGnet.com.

2. Content and Form of Application Submission

Application Format

Applications must be prepared using forms and information provided in the online grant application package.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Screening Criteria.

Project Narrative pages must be double-spaced.

The applicant should use an easily readable typeface, such as Times New Roman or Arial, 12-point font. Tables may be single spaced and use alternate fonts but must be easily readable. The page limit does not include budget, budget narrative/ justification, required forms, assurances, and certifications as described in Application Screening Criteria. All pages, charts, figures, and tables, whether in the narrative or appendices, should be numbered. Applications that exceed the specified page limits when printed on 8.5" X 11" paper by HHS/OASH/OGM will not be considered. We recommend applicants print out their applications before submitting electronically to ensure that they are within the page limit and are easily readable.

Appendices

Appendices should include any specific documents outlined in the Application Content section of this FOA. If not specified, appendices may include curriculum vitae, organizational structure, examples of organizational capabilities, or other supplemental information which supports the application. Brochures and bound materials should not be submitted. Appendices are for supportive information only and should be clearly labeled. All information that is critical to the proposed project should be included in the body of the application. Appendices created specifically for the application should use the same formatting required for the Project Narrative, including double-line spacing. However, appendix documents that were not created directly in response to this funding announcement, especially those imported from other sources and documents, may use other formatting but must be easily readable (e.g., organizational structure).

Project Abstract

Applicants must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application, and will form the basis for the application summary in grants management and program summary documents. Abstracts may be published by HHS/OASH and should not include sensitive or proprietary information.

Budget Narrative

The Budget Narrative text should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

Electronic Submission

The HHS Office of the Assistant Secretary for Health (HHS/OASH) requires all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, *will not* be accepted for review.

You may access the Grants.gov website portal at http://www.grants.gov. All HHS/OASH funding opportunities and grant application packages are made available on Grants.gov.

Applications will not be considered valid until all application components are received via Grants.gov by the HHS/OASH Office of Grants Management according to the deadlines

specified in the DATES section on page 1 of this announcement. Application submissions that do not adhere to the due date and time requirements will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process. This will aid in addressing any problems with submissions prior to the application deadline. Any files uploaded or attached to the Grants.gov application must be of the following file formats – Microsoft Word, Excel or PowerPoint, Adobe PDF, or image formats (JPG, GIF, TIFF, or BMP only). Even though Grants.gov allows applicants to attach any file format as part of their application, HHS/OASH restricts this practice and only accepts the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format identified above will not be accepted for processing and will be excluded from the application during the review process. The application must be submitted in a file format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. All documents that do not conform to the above will be excluded from the application during the review process.

A. **Important Grants.gov Information**

You may access the electronic application for this program on http://www.grants.gov. You must search the downloadable application page by the Funding Opportunity Number or CFDA number.

To ensure successful submission of applications, applicants should carefully follow the step-by-step instructions provided at http://www.grants.gov/web/grants/applicants/apply-for-

grants.html . These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information.

Applicants should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov.

- You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is *free and easy* to obtain.
- Instructions are available on the Grants.Gov web site as part of the organization registration process at http://www.grants.gov/web/grants/applicants/organization-registration.html.
- All applicants must register in the System for Account Management (SAM)). You should allow a *minimum* of five days to complete the SAM registration. Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You can register with the SAM online and it will take about 30 minutes (https://www.sam.gov.)

- You must renew your SAM registration each year. Organizations registered to apply for Federal grants through http://www.grants.gov will need to *renew* their registration in SAM.

- It may take 24 hours or more for SAM updates to take effect in Grants.gov, so potential applicants should ***check for active registration well before the application deadline.***
- Applicants must maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by an HHS agency.

An award cannot be made until the applicant has complied with these requirements. In accordance with 2 CFR 25.205, at the time an award is ready to be made, if the intended recipient has not complied with these requirements, HHS/OASH:

- May determine that the applicant is not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.

Should you successfully compete and receive an award, all first-tier sub-award recipients must have a DUNS number at the time the recipient makes a sub-award.

B. Application Content

Successful applications will contain the following information:

Project Narrative

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether or not your project meets the minimum requirements for a grant under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following components:

The components of the Project Narrative as part of the 10 page limit include:

Executive Summary

Problem Statement

Goal(s) and Objective(s)

Research Project

Special Target Populations

Expected Outcomes: how will the proposed study impact vaccine safety

Project Management

Data Management and Data Sharing Plan

Human Subjects and Privacy Issues

Dissemination

Organizational Capability

Executive Summary. This section should include a brief description of the proposed project, including: goal(s), objectives, outcomes, and products to be developed.

Problem Statement. This section should describe, in both quantitative and qualitative terms, the nature and scope of the specific and particular problem or issue, and the proposed intervention it is designed to address. It should detail how the project will potentially affect the targeted population, specific subgroups within those populations, and other interested stakeholders as identified. It is recommended that applicants focus their problem statement on the specific aspects of the history, extant literature, current status, and policy considerations bearing on the program area, and the roles of the

national, state, and local agencies responsible for their operation, rather than providing a broad or sweeping historical overview that is not directly related to the proposed interventions and activities.

Goals and Objectives. This section should consist of a description of the project's goal(s) and major objectives.

Research Project Proposal: This section should provide a clear and concise description of the research study you are proposing to use to address the need identified in the program announcement and the problem described in the "Problem Statement" above. Proposals should detail the research study, how the proposed study addresses the identified issues, and how they will assist in achieving the overall project goals and objectives. Also note any major barriers you anticipate encountering and how your project will be able to overcome those barriers.

Special Target Populations : This section should describe if the proposed project will target special populations.

Expected Outcomes: How will the proposed study impact vaccine safety

This section of the project narrative must clearly identify the measurable outcome(s) that will result from the project. HHS/OASH will not fund any project that does not include measurable outcomes. In addition to discussion in the narrative, applicants must describe how they envision the project will benefit the field of vaccine safety.

A "measurable outcome" is an observable end-result that describes how a particular intervention benefits consumers. It demonstrates the "impact" of the intervention. For example, a change in a client's financial, health, and/or functional status; mental well-being; knowledge; skill; attitude; awareness; or behavior. It can also describe a change in the degree to which consumers exercise choice over the types of services they receive, or whether they are satisfied with the way a service is delivered. Additional examples include: a change in the responsiveness or cost-effectiveness of a service delivery system; a new model of support or care that can be replicated; new knowledge; a measurable increase in community awareness; or a measurable increase in persons receiving services. A measurable outcome is not a measurable "output", such as: the number of clients served; the number of training sessions held; or the number of service units provided.

You should keep the focus of this section on describing ***what*** outcome(s) will be produced by the project. You should use the Evaluation section noted below to describe ***how*** the outcome(s) will be measured and reported. Your application will be scored on the clarity and nature of your proposed outcomes, not on the number of outcomes cited. In many cases, it is very appropriate for a project to have only ***ONE*** outcome that it is trying to achieve through the intervention reflected in the project's design.

Project Management. This section should include a clear delineation of the roles and responsibilities of project staff and subrecipients and how they will contribute to achieving the project's objectives and outcomes. It should specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the

project's on-going progress, preparation of reports; and communications with other partners and HHS/OASH. It should also describe the approach that will be used to monitor and track progress on the project's tasks and objectives. HHS/OASH expects that, throughout the grant period, the Project Director will have involvement in, and substantial knowledge about, all aspects of the project.

Data Management and Data Sharing Plan. Investigators who are working for or who are themselves covered entities under the Health Insurance Portability and Accountability Act (HIPAA) must consider issues related to the **Privacy Rule**, a Federal regulation under HIPAA that governs the protection of individually identifiable health information. The Department of Health and Human Services (DHHS) provides guidance on research and the Privacy Rule elsewhere (http://www.hhs.gov/ocr/). It should be noted that the Privacy Rule is relatively new, and additional information and guidance will be shared on the DHHS website as soon as it is available. Applicants must address shared data resources proposed for use in the project narrative.

Human Subjects and Privacy Issues. The rights and privacy of human subjects who participate in HHS federally funded research projects must be protected at all times. It is the responsibility of the investigators, their Institutional Review Board (IRB), and their institution to protect the rights of subjects and the confidentiality of the data. Prior to sharing, data should be redacted to strip all identifiers, and effective strategies should be adopted to minimize risks of unauthorized disclosure of personal identifiers. Stripping a dataset of items that could identify individual participants is referred to by several different terms, such as "data redaction," "de-identification of data," and anonymzing

data. In addition to removing direct identifiers, e.g., name, address, telephone numbers, and Social Security Numbers, researchers should consider removing indirect identifiers and other information that could lead to "deductive disclosure" of participants' identities. Deductive disclosure of individual subjects becomes more likely when there are unusual characteristics of the joint occurrence of several unusual variables. Samples drawn from small geographic areas, rare populations, and linked datasets can present particular challenges to the protection of subjects' identities.

Dissemination. This section should describe the method that will be used to disseminate the project's results and findings in a timely manner and in easily understandable formats to the target audience, the general public, and other parties who might be interested in using the results of the project. All appropriate findings and products will be posted on a HHS/OASH sponsored website as determined by the HHS/OASH project officer. Therefore, applicants should propose other innovative approaches to informing parties who might be interested in using the results of the project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project. HHS/OASH expects that nationwide dissemination of products and knowledge will occur.

Organizational Capability Statement. Each application must include an organizational capability statement and vitae for key project personnel. The organizational capability statement should describe how the applicant agency (or the particular division of a larger agency which will have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses. This

description should cover capabilities of the applicant agency not included in the program narrative, such as any current or previous relevant experience and/or the record of the project team in preparing cogent and useful reports, publications, and other products. If appropriate, include an organization chart showing the relationship of the project to the current organization.

Also include information about any contractual and/or supportive staff/organization(s) that will have a secondary role(s) in implementing the project and achieving project goals.

Budget Narrative

You are required to submit a combined one-year Budget Narrative A level-funded budget is equal to the exact dollar figure of the year one budget. ***Please Note:*** Because the proposal must demonstrate a clear and strong relationship between the stated objectives, project activities, and the budget, the budget justification should describe the ***cost estimated per proposed project, activity, or product.*** This budget justification should define the amount of work that is planned and expected to be performed and what it will cost. The Budget Narrative does not count toward your total application page limit.

Appendices

All items described in this section will count toward the total page limit of your application.

Work Plan. The Project Work Plan should reflect, and be consistent with, the Project Narrative and Budget.The Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, the work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task.

Letters of Commitment from Subrecipient Organizations and Agencies

Letters of Commitment are required for all organizations and entities that have been specifically named as a subrecipient to carry out any aspect of the project. The signed letters of commitment ***must detail*** the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the letter of commitment.

Letters of commitment are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. Applicants should NOT provide letters of "support," and letters of support such as this will not be considered during the review.

3. Submission Dates and Times

The deadline for the submission of applications under this Program Announcement is **5:00 p.m. Eastern Time on the date indicated in the DATES section on page 1 of this announcement.** Applications must be submitted by that date and time.

Applications that fail to meet the application due date will not be reviewed and will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with http://www.grants.gov . Grants.gov can take up to 48 hours to notify you of a successful submission.

Unsuccessful submissions will require authenticated verification from http://www.grants.gov indicating system problems existed at the time of your submission. For example, you will be required to provide an http://www.grants.gov submission error notification and/or tracking number in order to substantiate missing the cut off date.

4. Intergovernmental Review

This program is not subject to the Intergovernmental Review requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," as implemented by 45 CFR Part 100.

5. Funding Restrictions

The allowability, allocability, reasonableness and necessity of direct and indirect costs may be charged to HHS/OASH grants in accordance with Department regulations and policy effective at the time of the award. Current requirements are outlined in the following documents: 2 CFR § 220 (OMB Circular A- 21, for Institutions of Higher Education); 2 CFR § 225 (OMB Circular A–87, for State, Local, and Indian Tribal Governments); 2 CFR § 230 (OMB Circular A–122, for Nonprofit Organizations); and 45 CFR part 74, Appendix E (Hospitals). Copies of

the Office of Management and Budget (OMB) Circulars are available on the Internet at http://www.whitehouse.gov/omb/circulars/.

In order to claim indirect costs as part of a budget request, an applicant must have an indirect cost rate which has been negotiated with the Federal Government or a documented plan, in accordance with the applicable policy and regulation. The Health and Human Services Division of Cost Allocation (DCA) Regional Office that is applicable to your State can provide information on how to receive such a rate. A list of DCA Regional Offices is included in the grant application package for this announcement.

Salary Limitation:

The Consolidated Appropriations Act, 2014 (P.L. 113-76) and the subsequent Continuation Resolution for FY 2015 (P.L. 113-164) and FY2015 Omnibus; Consolidated and Further Continuing Appropriations Act (P.L. 113-235), limits the salary amount that may be awarded and charged to HHS/OASH grants and cooperative agreements. Award funds should not be budgeted to pay the salary of an individual at a rate in excess of Executive Level II. Currently, the Executive Level II salary of the Federal Executive Pay scale is $181,500. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under an HHS/OASH grant or cooperative agreement.

As an example of the application of this limitation: If an individual's base salary is $350,000 per year plus fringe benefits of 25% ($87,500) and that individual is devoting 50% of their time to this award, their base salary should be adjusted to $181,500, their direct salary would be $90,750 (50% FTE), fringe benefits of 25% would be $22,687.50, and a total of

$113,437.50 may be included in the project budget and charged to the award in salary/fringe benefits for that individual. See the breakdown below:

Individual's *actual* base full time salary: $350,000 50% of time will be devoted to project	
Direct salary	$175,000
Fringe (25% of salary)	$43,750
Total	$218,750
Amount that may be claimed on the application budget due to the legislative salary limitation: Individual's base full time salary *adjusted* to Executive Level II: $181,500 50% of time will be devoted to the project	
Direct salary	**$90,750**
Fringe (25% of salary)	**$22,687.50**
Total amount	**$113,437.50**

Appropriate salary limits will apply as required by law.

V. APPLICATION REVIEW INFORMATION

1. Criteria: Eligible applications will be assessed according to the following criteria:

   i. Background: The extent to which the applicant demonstrates experience and is established in the field of study. This section will also evaluate the history of the applicant of collaborating and working across fields of expertise to achieve common goals (25 points).

   ii. Program/Project Plan: The extent to which the applicant describes and discusses in detail the project description; including the project aims, objectives, and proposed outcomes. (40 points).

   iii. Management Plan: The extent to which the applicant provides a clear description of management experience and a clear management plan, the capacity to govern, make management decisions, outlining roles and responsibilities in establishing executive decisions and committees between multiple partners and multiple organizations, including personnel and resources. (15 points).

   iv. Target Population: The extent to which the applicant provides a clear a description of the special population to be included in the study. Provide a brief description of the participants and the geographic areas to be included (20 points).

2. Review and Selection Process

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that pass the screening and meet the responsiveness criteria if applicable. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section V.1, the reviewers will comment on and score the applications, focusing their comments and scoring decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance. Final award decisions will be made by the Director of the National Vaccine Program Office.

3. Anticipated Announcement and Award Dates

HHS/OASH seeks to award funds as much in advance of the estimated project start date shown in Section II "Award Information," as practicable, with a goal of 10-15 days.

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The HHS Office of the Assistant Secretary for Health does not release information about individual applications during the review process. If you would like to track your application, please see instructions at http://www.grants.gov/web/grants/applicants/track-my-application.html. The official document notifying an applicant that a project application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH Office of Grants Management. Successful applicants will receive this document via system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount of money awarded, the purposes of the grant, the anticipated length of the project period, terms and conditions of the grant award, and the amount of funding to be contributed by the grantee to project costs, if applicable. Grantees should pay specific attention to the terms and conditions of the award as indicated on the NOA, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the grant.

Unsuccessful applicants will be notified by the program office by email and/or letter and will receive summary comments pertaining to the application resulting from the review process. On occasion, some applicants may receive a letter indicating that an application was approved but unfunded. These applications are kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

2. Administrative and National Policy Requirements

In accepting the grant award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of 45 CFR parts 74 and 92, currently in effect or

implemented during the period of the grant or other Department regulations and policies effective at the time of the award.

In addition, recipients must comply with all terms and conditions outlined in their grant awards, the Department of Health and Human Services (HHS) Grants Policy Statement, requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts.

Grant funds may only be used to support activities outlined in the approved project plan. The successful applicant will be responsible for the overall management of activities within the scope of the approved project plan.

Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS/OASH mission to protect and advance the physical and mental health of the American people.

Acknowledgement of Funding

Federal grant support must be acknowledged in any publication developed using funds awarded under this program. All publications developed or purchased with funds awarded under this program must be consistent with the requirements of the program. Pursuant to 45 CFR § 74.36(a), HHS may reproduce, publish, or otherwise use materials developed under this grant for Federal purposes, and may authorize others to do so.

Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.hhs.gov/opa/grants/trafficking_in_persons_award_condition.html. If you are unable to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at http://dhhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html.

Pilot Whistleblower Protection

A standard term and condition of award will be in the final notice of award; all applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award, and requires that grantees inform their employees in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce.

Same-sex Spouses, Marriages, and Households

A standard term and condition of award will be included in the final Notice of Award (NOA) that states: "In any grant-related activity in which family, marital, or household considerations are, by statute or regulation, relevant for purposes of determining beneficiary eligibility or participation, grantees must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," HHS means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "same-sex marriages," HHS means marriages between two individuals validly entered into in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "marriage," HHS does not mean registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage."

Programmatic Reporting

Quarterly reporting is required. The purpose of the progress reports is to provide accurate and timely program information to program managers and to respond to Congressional, Departmental and public requests for information about the program. If a submission date falls

on a Saturday or Sunday, then the report will be due the following Monday. Progress reports must be submitted by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

A final progress report covering the entire project period is due 90 days after the end of the project period. Final reports must be submitted by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

Financial Reporting

Grantees are required to submit quarterly and annual Federal Financial Reports (FFR) (SF-425). Reporting schedules will be issued as a condition of grant award. A final FFR covering the entire project period is due 90 days after the end of the project period. FFRs must be submitted via upload to our grants management system (GrantSolutions.gov), in the FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note these FFR reports are separate submissions via the Division of Payment Services. At this time, data is not transferable between the two systems and you will report twice on certain data elements. Grantees receiving $500,000 or greater of Federal funds must also undergo an independent audit in accordance with OMB Circular A-133 or regulations and policy effective at the time of the award.

Non-competing Continuation Applications and Awards

Each year of the approved project period, grantees are required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well advance of the application due date.

FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (http://www.FSRS.gov) for all sub-awards and sub-contracts issued for $25,000 or more as well as addressing executive compensation for both grantee and sub-award organizations.

VII. AGENCY CONTACTS

Administrative and Budgetary Requirements and Program Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH Office of Grants Management grants specialist listed below.

Roscoe Brunson

1101 Wootton Parkway, Suite 550

Rockville, MD

Phone: 240-453-8822

Email: roscoe.brunson@hhs.gov

For information on program requirements, contact the program office

Dr. Karin Bok

Karin.Bok@hhs.gov

National Vaccine Program Office

Office of the Assistant Secretary for Health

US Department of Health and Human Services

Phone: 202-690-1191

Fax: 202-260-1165

VIII. OTHER INFORMATION

Application Elements

Application for Federal Assistance (SF-424)

Budget Information for Non-construction Programs (SF-424A)

Budget Narrative

Assurances for Non-construction Programs (SF-424B)

Disclosure of Lobbying Activities (SF-LLL)

Project Abstract Summary

Project Narrative

Appendices: Work Plan, Vitae for Key Project Personnel, and

Jan 7, 2015

Date: TBD

Dr. Bruce Gellin