

Several *in vitro* assays have been developed, or are currently under development, with the aim of finding an alternative method to the HIST for monitoring residual PTx activity in aP vaccines. The International Working Group for Alternatives to HIST is coordinating the acquisition and distribution of aP vaccine samples from manufacturers to research laboratories for generation of data using *in vitro* methods to evaluate vaccines spiked with a known amount of PTx. Data from the various alternative assays will be presented at the upcoming workshop and will form the basis for identifying *in vitro* methods for future assessment in the next international collaborative study.

The following methods will be evaluated and may be used to generate data to be presented at the upcoming workshop:

1. Binding assay: used to assess the amount of PTx/toxoid binding activity to the glycoprotein fetuin
2. Enzymatic assay: monitors the residual ADP-ribosylation of the PTx/toxoid
3. Cell-based assays: monitor the generation of cAMP or decrease in cellular ATP following exposure to PTx
4. Genetic assays: determine potential genomic markers of PTx activity

This workshop will provide a forum to discuss and review the *in vitro* protocols and available data from the International Working Group for Alternatives to HIST study and will suggest future collaborative projects using prepared materials. The workshop will also review additional new methods and approaches for aP vaccine safety testing that should improve test accuracy, precision, and efficiency while also reducing or replacing the use of animals in vaccine safety testing. Finally, the workshop will address the path toward global validation, acceptance, and implementation of scientifically valid alternative methods for aP vaccines.

#### **Preliminary Workshop Agenda and Registration**

Registration information, draft agenda, and additional meeting information are available on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov/meetings/HISTWksp-2012/HISTWksp.htm>) and upon request from NICEATM (see **FOR FURTHER INFORMATION CONTACT**).

#### **Call for Abstract Submissions**

NICEATM and ICCVAM invite the submission of abstracts for scientific

posters to be displayed during this workshop. Guidelines for the submission of abstracts are available at <http://iccvam.niehs.nih.gov/meetings/HISTWksp-2012/HISTWksp-AbstractSubmit-508.pdf>. Abstracts must be submitted by email to [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). The deadline for abstract submission is October 12, 2012. The corresponding author will be notified regarding the abstract's acceptance within 21 working days of the submission deadline. Guidelines for poster presentations will be sent to the corresponding author with notification of acceptance.

#### **Background Information on NICEATM and ICCVAM**

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

#### **References**

- Bache C, Hoonakker M, Hendriksen C, Buchheit K–H, Spreitzer I, Montag T. 2012. Workshop on Animal Free Detection of Pertussis Toxin in Vaccines—Alternatives to the Histamine Sensitization Test. *Biologicals* 40: 309–311.
- Corbel MJ, Xing DK–L. 2004. Toxicity and potency evaluation of pertussis vaccines. *Exp Rev Vaccines* 3: 89–101.
- Isbrucker R. 2011. Alternative safety testing strategies for acellular pertussis vaccines. *ALTEX Proceedings*, 1/12, Proceedings of WC8: 77–80.
- Stokes WS, Kulpa-Eddy J, McFarland RM.

2011. The International Workshop on Alternative Methods to Reduce, Refine and Replace the Use of Animals in Vaccine Potency and Safety Testing—Introduction and Summary. In: *International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions* (Kulpa-Eddy J, McFarland R, Stokes WS, eds). *Procedia Vaccinol* 5: 1–15.

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Centers for Disease Control and Prevention**

**[30Day–12–12EK]**

#### **Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

#### **Proposed Project**

Process and Intermediate Outcome Evaluation of “Teenage Pregnancy Prevention: Integrating Services, Programs, and Strategies through Community-Wide Initiatives”—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### **Background and Brief Description**

CDC is currently providing funding to nine state and community awardees, and five national organizations, to examine innovative, evidence-based teenage pregnancy prevention programs. Efforts are focused in communities with high rates of teen pregnancy in underserved African American and Latino youth. Components of these efforts include (1) implementing evidence-based or evidence-informed prevention programs; (2) linking teens to quality

health services; (3) educating stakeholders (parents, community leaders, and other constituents) about relevant evidence-based or evidence-informed strategies to reduce teen pregnancy; and (4) supporting the sustainability of the community-wide teen pregnancy prevention effort through capacity building and improved coordination of services.

CDC proposes to collect the information needed to conduct a process and intermediate outcome evaluation of these efforts. The information collection and evaluation plan will systematically document capacity building within funded communities and the extent to which communities implement multi-component, community-wide initiative activities. Respondents for the nine state and community awardees will include the project director/coordinator for each site, evaluators, and other program staff.

In addition, to gain a variety of perspectives, information will be requested from multiple community and clinical partners associated with each state or community awardee (e.g., program implementers and core advisory group members). Information collected from these respondents will include needs assessments. Finally, CDC will collect information about the training and technical assistance needs of state and community awardees, and national organizations, which have been funded to support community-wide teen pregnancy prevention (TPP) activities.

The training and technical assistance reporting forms will be submitted to CDC electronically through an interactive web-based system. The remaining information collection forms will initially be fielded in hardcopy, but respondents may submit the completed forms to CDC via electronic mail. To allow flexibility based on awardee

preferences, web-based reporting options may be implemented for all forms. Assessment and performance information will be reported to CDC annually. Training and technical assistance needs will be reported monthly so that CDC can provide immediate, targeted technical assistance as needed.

The assessment information, performance measures and training and technical assistance information to be collected are critical to understanding (1) the teen pregnancy prevention needs of each target community, (2) quality implementation practices associated with evidence-based programs and contraceptive access, and (3) the impact of implemented strategies.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,150.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
State and Community Awardees.	State and Community Awardee Project Director/Project Coordinator Needs Assessment.	9	1	45/60
	State and Community Awardee Performance Measure Reporting Tool.	50	1	4
	State and Community Awardee Staff Needs Assessment .....	50	1	45/60
	State and Community Awardee Training and Technical Assistance Reporting Tool.	50	12	1
National Organization Awardees.	National Organization Awardee Training and Technical Assistance Reporting Tool.	15	12	1
Community and Clinical Partners.	Community and Clinical Partner Clinical Partner Needs Assessment.	50	1	1
	Community and Clinical Partner Program Implementation Partner Needs Assessment.	100	1	45/60

Dated: August 23, 2012.

**Ron A. Otten,**

*Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science, Office of the Directors, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act

(Pub. L. 92-463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

#### Times and Dates (All Times are Mountain Time)

8:15 a.m.–5:45 p.m., September 18, 2012.

8:15 a.m.–5:45 p.m., September 19, 2012.

8:15 a.m.–12:00 p.m., September 20, 2012.

#### Public Comment Times and Dates (All Times are Mountain Time)

6:00 p.m.–7:00 p.m.\*, September 18, 2012.

6:00 p.m.–7:00 p.m.\*, September 19, 2012.

\*Please note that the public comment periods may end before the times

indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend public comment sessions at the start times listed.

**Place:** Denver Marriott Tech Center, 4900 South Syracuse Street, Denver, Colorado 80237; Telephone: 303-779-1100; Fax: 303-740-2523. Audio Conference Call via FTS Conferencing: The USA toll-free, dial-in number is 1-866-659-0537 with a pass code of 9933701.

**Status:** Open to the public, limited only by the space available. The meeting space accommodates approximately 150 people.

**Background:** The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to