

referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to

Sherette.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at (202) 395-5806.

Proposed Project: Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form Extension—OMB No. 0990-0263—Office for Human Research Protections.

Abstract: The Federal Policy for the Protection of Human Subjects, known as

the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)]. The Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form. That form is designed to promote uniformity among departments and agencies, and to help ensure common means of

ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research. Respondents are institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule). There are an estimated total of 25,000 human research studies supported each year, an average of 2 certifications per institution and an estimated one-half hour per certification, for a total burden of 12,000 hours. Data is collected as needed.

ESTIMATED ANNUALIZED BURDEN IN HOURS FOR IRB CERTIFICATION BURDEN

Form name	Number of respondents	Number of responses per respondent	Hours per response	Response burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	12,000	2	30/60	12,000

Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting. The meeting is open to the public. Preregistration is required for both public attendance and comment. Individuals who wish to attend the meeting and/or participate in the public comment session should register at <http://www.hhs.gov/nvpo/nvac>, email nvpo@hhs.gov or call (202) 690-5566 and provide name, organization, and email address.

DATES: The meeting will be held on February 7-8, 2012. The meeting times

and agenda will be posted on the NVAC Web site at <http://www.hhs.gov/nvpo/nvac> as soon they become available.

ADDRESSES: The meeting will be held at the U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: The National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715-H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 690-5566; Fax: (202) 690-4631; email: nvpo@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

The topics to be discussed at the NVAC meeting will include seasonal

influenza, implementation of the National Vaccine Plan, and vaccine safety. The meeting agenda will be posted on the NVAC Web site: <http://www.hhs.gov/nvpo/nvac> prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/phone listed above at least one week prior to the meeting. Members of the public will have the opportunity to provide comments at the NVAC meeting, limited to five minutes per speaker, during the public comment periods on the agenda. Individuals who would like to submit written statements should email or fax their comments to the National Vaccine Program Office at least five business days prior to the meeting.

Dated: January 17, 2012.

Mark Grabowsky,

Deputy Director, National Vaccine Program Office, Alternate Designated Federal Officer, National Vaccine Advisory Committee.

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