


4. Includes those cited in Endnote 3 plus:

[FR Doc. E9–15910 Filed 7–2–09; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary’s Advisory Committee on Human Research Protections

AGENCY: Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary’s Advisory Committee on Human Research Protections (SACHRP) will hold its twentieth meeting. The meeting will be open to the public.

DATE: The meeting will be held on Tuesday, July 21, 2009 from 8:30 a.m. until 5 p.m. and Wednesday, July 22, 2009 from 8:30 a.m. until 5 p.m.


FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240–453–8141; fax: 240–453–6909; e-mail address: sachrp@osophs.dhhs.gov.

SUPPLEMENTAL INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

On July 21, 2009, the Committee will discuss a summary of comments from the recent OHRP-issued advance notice of proposed rulemaking on institutional review board (IRB) accountability, as well as hear a summary of Clinical and Translational Science Awards pediatric research issues. SACHRP will also spend time focusing on long-range future planning regarding new subcommittees and areas of focus. The day will conclude with a panel discussion addressing the question of how to evaluate IRB effectiveness.

On July 22, 2009, the Committee will hear a report from the Subpart A Subcommittee focusing on issues surrounding consent for future use of specimens or data. This subcommittee was established by SACHRP at its October 4–5, 2006 meeting and is charged with developing recommendations for consideration by SACHRP about the application of Subpart A of 45 CFR part 46 in the current research environment. SACHRP will then hear a presentation of the recent National Academy of Sciences report entitled “Conflict of Interest in Medical Research, Education and Practice,” followed by a panel discussion.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business Friday, July 17, 2009. Information about SACHRP and the draft meeting agenda will be posted on the SACHRP Web site at: http://www.hhs.gov/ohrp/sachrp/index.html.

Dated: June 29, 2009.

Jerry Menikoff,
Director, Office for Human Research Protections Executive Secretary, Secretary’s Advisory Committee on Human Research Protections.

[FR Doc. E9–15783 Filed 7–2–09; 8:45 am]

BILLING CODE 4150–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice of meetings via conference call.

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 two teleconference meetings. The meetings are open to the public. Pre-registration is required for both public attendance and comment. Individuals who wish to attend the meetings and/or participate in the public comment session should either e-mail nvpo@hhs.gov or call 202–690–5566 to register.

DATES: The meetings will be held on July 27, 2009, from 3 p.m. to 5 p.m. EDT and on August 24, 2009, from 3 p.m. to 5 p.m. EDT.

ADDRESSES: The meetings will occur by teleconference. To attend, please call 1–888–627–1385, passcode “NVAC.”

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Krull, Public Health Advisor,
National Vaccine Program Office, 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) 260–1165; e-mail: nvpow@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. section 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.

These are special meetings of the NVAC. Discussions will surround issues related to the Novel Influenza A (H1N1) outbreak. The Committee will discuss the activities and actions of the various HHS agencies and Federal advisory committees that address vaccine issues as it relates to the mission of NVAC.

Representatives of State and local health associations will also provide their perspective.

For these special meetings, members of the public are invited to attend by teleconference via a toll-free call-in phone number. The call-in number will be operator assisted to provide members of the public the opportunity to provide comments to the Committee. Public participation and ability to comment will be limited to space and time available. Public comment will be limited to no more than three minutes per speaker. Pre-registration is required for both public attendance and comment. Individuals who plan to attend and need special assistance, such as accommodation for hearing impairment or other reasonable accommodations, should notify the designated contact person at least one week prior to the meeting.

Any members of the public who wish to have printed material distributed to NVAC should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business one week before each meeting (conference call). A draft agenda and any additional materials will be posted on the NVAC Web site (http://www.hhs.gov/nvpo/nvac/) prior to the meeting.

Dated: June 29, 2009.

Bruce Gellin,
Deputy Assistant Secretary for Health, Director, National Vaccine Program Office.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Proposed Project: Cross-community Evaluation of the Native Aspirations Project—NEW

The Substance Abuse and Mental Health Services Administration’s (SAMHSA), Center for Mental Health Services (CMHS) will conduct the Cross-Community Evaluation of the Native Aspirations Project. The cross-community evaluation has two tiers. Community-specific activities (Tier 1) are tied to key components of a community plan developed in each participating community that guides program planning and local evaluation through data-driven frameworks and inquiry. Tier I activities will include process and impact evaluation activities to determine the stage of readiness of communities to implement programs, how accurately community plans reflect the needs and characteristics of each community, how well local resources for American Indian/Alaska Native (AI/AN) youth are mobilized, the experience and impact of the Gathering of Native Americans (GONA), and the impact of the Native Aspirations program on the community. Core cross-community data collection activities (Tier II) are cross-community and include process and impact indicators such as community-level knowledge and awareness of suicide, violence, bullying, and substance abuse; prosocial and help-seeking behaviors among Native youth; and the provision of services specific to Native youth through existing service systems. Tier II activities are directly tied to the primary objectives of the Native Aspirations Project and are designed to augment data collection through the collection of community- and systems-level change measurement. Activities include the Service Provider Focus Groups and the Community Knowledge, Awareness and Behavior Survey (C–KABS).

Data will be collected from Native adults and youth involved in the Community Mobilization Plan (CMP) meeting and the Gathering of Native Americans (GONA), key program stakeholders, Native youth service providers (e.g., teachers, mental health providers, case workers, juvenile justice providers), and other community members (Native youth and adults). Data collection will take place in 25 AI/AN communities across three cohorts.

Data collection for the Native Aspirations Cross-community Evaluation will occur over a 3-year period of grant funding for each cohort. Clearance is requested for a 3-year period of data collection that spans FY 2009 through FY 2012 during which Cohorts 3 and 4 will receive 3 years of data collection and Cohort 5 will receive 2 years of data collection with the final year to be submitted in an OMB renewal package. The following describes the specific data collection activities and the 9 data collection instruments to be used, followed by a summary table of respondents and respondent burden.

Community Specific Data Collection Activities—Tier I

- GONA—Baseline Interviews (1 Version).
Each participating community will have the opportunity to hold a GONA focused on youth violence, bullying, substance abuse, and suicide concerns. Community GONAs follow four themes that correspond to indigenous values and are core resiliency factors for Native people. These values—belonging, mastery,