

information to investigators will take 1 hour per disclosure. FDA estimates that disclosing information to any committee or group formally designated to oversee research involving human subjects will average 10 minutes per disclosure.

The revised draft guidance also references examples of disclosing information to study subjects such as informed consent. On average, two disclosures per respondent will be provided to study subjects. FDA estimates this will take 30 minutes per disclosure.

The total burden for the collection of information under this revised draft guidance is estimated to be approximately 2,158 hours.

The revised draft guidance also refers to previously approved collections of information. The revised draft guidance includes a recommendation that persons who intend to study tobacco products meet with FDA to discuss research plans. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RegulationsGuidance/UCM305282.pdf>).

The collections of information in the guidance referenced have been approved under OMB control number 0910-0731. The collections of information in section 801(e) of the FD&C Act and 21 CFR 1.101(b) have been approved under OMB control number 0910-0482; the collections of information for the Safety Reporting Portal have been approved under OMB control number 0910-0645; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910-0673.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the revised draft guidance at either <https://www.regulations.gov> or <https://www.fda.gov/TobaccoProducts/Labeling/RegulationsGuidance/default.htm>.

Dated: February 15, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary's National Advisory Council on Migrant Health (NACMH) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at <https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html>.

DATES: May 22, 2019, 9:00 a.m. to 5:00 p.m. Eastern Time (ET), and May 23, 2019, 9:00 a.m. to 5:00 p.m. ET.

ADDRESSES: The meeting will be held in-person. The address for the meeting is The College at Brockport, State University of New York (SUNY), Cooper Hall, 350 New Campus Drive, Brockport, New York 14420.

FOR FURTHER INFORMATION CONTACT: Esther Paul, Designated Federal Official, (DFO), Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, 16N38B, Rockville, Maryland 20857; (301) 594-4300; or epaul@hrsa.gov.

SUPPLEMENTARY INFORMATION: NACMH provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 217 of Title 42 U.S.C. 218 of the Public Health Service (PHS) Act.

During the May 22-23, 2019, meeting, NACMH will hear presentations from a federal official and experts, and discuss issues facing migrant and seasonal agricultural workers, including the status of agricultural worker health at the local and national levels. Topics addressed at this meeting include health care for aging farmworkers, oral health, and sexual harassment in the agricultural industry. In addition, during the first day of the meeting, on May 22, 2019, the council will hear public comments from migratory and seasonal agricultural workers regarding matters affecting their health. Agenda items are subject to change as priorities dictate. Refer to the NACMH website for any updated information concerning the meeting at <https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html>.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACMH should be sent to Esther Paul, DFO, using the contact information above at least three business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Esther Paul at the address and phone number listed above at least 10 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443-6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault