
DATES: The meeting will be held on Thursday, October 3, 2013 from 8:30 a.m. until 5:00 p.m. and Friday, October 4, 2013 from 8:30 a.m. until 4:30 p.m.


FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240–453–6909; email address: Julia.Gorey@hhs.gov.

SUPPLEMENTARY 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.

The meeting will open to the public at 8:30 a.m., Thursday, October 3. Following opening remarks from Dr. Jerry Menikoff, OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, the Subcommittee on Harmonization (SOH) will give their report.

SOH was established by SACHRP at its July 2009 meeting and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

Following opening remarks on the morning of October 4, the Subpart A Subcommittee (SAS) will give their report. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment; this subcommittee was established by SACHRP in October 2006.

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 September 30, 2013.


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

[FR Doc. 2013–22236 Filed 9–11–13; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Multi-Agency Informational Meeting Concerning Compliance with the Select Agent Regulations; Public Webcast

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public webcast.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces a public webcast for all interested parties, including individuals and entities possessing, using, or transferring biological agents and toxins. The purpose of the webcast is to provide guidance related to the select agent regulations established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The webcast is being organized by the U.S. Department of Agriculture (USDA)’s Animal and Plant Health Inspection Service (APHIS), HHS/CDC, and the Department of Justice’s Federal Bureau of Investigation (FBI), Criminal Justice Information Services. Changes to Section 11 (Security) of the select agent regulations including information security, physical security, and personnel suitability will be discussed. Topics will focus on additional requirements for entities possessing select agents and toxins designated as Tier 1 agents.

DATES: The webcast will be held on Friday, November 15, 2013 from 10 a.m. to 4 p.m. EST. All who wish to join the webcast must register by October 18, 2013. Registration instructions can be found on the Web site http://www.selectagents.gov.

ADDRESSES: The webcast will be broadcast from the APHIS facility, 4700 River Road, Unit 2, Riverdale, MD 20737.

FOR FURTHER INFORMATION CONTACT: APHIS: Dr. Keith Wiggins, APHIS Select Agent Program, 4700 River Road, Unit 2, Riverdale, MD 20737; 301–853–3300 option 1 (voice only); ASAP@aphis.usda.gov.

CDC: Diane Martin, Division of Select Agents and Toxins, Office of Public Health Preparedness and Response, CDC, 1600 Clifton Road, NE., MS A–46, Atlanta, GA 30333; (404) 718–2000; lrsat@cdc.gov.

SUPPLEMENTARY INFORMATION: Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, “Enhancing Controls on Dangerous Biological Agents and Toxins” (sections 201 through 221), provides for the regulation of certain biological agents and toxins by HHS (subtitle A, sections 201–204) and USDA (subtitle B, sections 211–213), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). HHS/CDC regulates the possession, use or transfer biological agents and toxins that have the potential to pose a severe threat to public health and safety. The HHS/CDC select agent regulations can be found at 42 CFR part 73.

USDA/APHIS has a parallel program that regulates the possession, use or transfer biological agents that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The USDA/APHIS select agent regulations can be found at 7 CFR part 331 and 9 CFR part 121.

The Criminal Justice Information Service (CJIS) in the Federal Bureau of Investigation (FBI) conducts security risk assessments of all individuals and nongovernmental entities that require access to select agents and toxins.

The webcast announced here is an opportunity for the regulated community (i.e., registered entity responsible officials, alternate responsible officials, and entity owners) and other interested individuals to obtain specific regulatory guidance and information on standards concerning security issues related to the select agent regulations. Representatives from HHS/CDC, USDA/APHIS, and the FBI will be present during the webcast to address questions from and concerns of the web participants.

Changes to Section 11 (Security) of the select agent regulations including...
information security, physical security, and personnel suitability will be discussed. Presenters will focus on the additional requirements for entities possessing select agents and toxins designated as Tier 1 agents or toxins. A question and answer session will follow each presentation.

Registration instructions can be found on the Web site http://www.selectagents.gov. Registration must be completed by October 18, 2013. Registration is required for participation to the webcast. This is a 100% webcast; therefore, in person participation cannot be accommodated.

Participants will be able to submit questions during the webcast at selectagentwkshp@cdc.gov. Closed-captioning services will be provided during the webcast.


Tanja Popovic,
Deputy Associate Director for Science, Centers for Disease Control and Prevention (CDC),

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Dates and Times: October 16, 2013 8:00 a.m.–5:00 p.m., October 17, 2013 8:00 a.m.–12:00 noon (EDT) on Tuesday, October 8, 2013;

Place: Centers for Disease Control and Prevention (CDC), Global Communications Center, Building 19, Room 247/248, 1600 Clifton Road NE., Atlanta, Georgia 30333.

Status: Open to the public limited only by the space available. The meeting room will accommodate up to 30 people. Public participants should pre-register for the meeting as described in Additional Information for Public Participants.

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHP), concerning strategies and goals for the programs and research within OPHP, monitoring the overall strategic direction and focus of the OPHP Divisions and Offices, and administration and oversight of peer review of OPHP scientific programs. For additional information about the Board, please visit: http://www.cdc.gov/phpr/science/counselors.htm

Matters To Be Discussed: Agenda items for this 2-day meeting include: (1) Briefings and BSC deliberation on the following topics: Program response to recommendations made in the Joint Report from the National Biodefense Science Board and the OPHP BSC; program response to recommendations made in the peer review of the Career Epidemiology Field Officer Program; Hurricane Sandy Research; emergency preparedness and response communication challenges; development of an emergency risk communication research framework; community approaches to healthcare preparedness; National Health Security Preparedness Index Update; systems thinking in disaster management; assessing CDC’s Emergency Management Program through accreditation; (2) BSC liaison representative updates to the Board highlighting organizational activities relevant to the OPHP mission.

Agenda items are subject to change as priorities dictate.

Additional Information for Public Participants: Members of the public that wish to attend this meeting should pre-register by submitting the following information by email, facsimile, or phone (see Contact Person for More Information) no later than 12:00 noon (EDT) on Tuesday, October 8, 2013;

• Full Name,
• Organizational Affiliation,
• Complete Mailing Address,
• Citizenship, and
• Phone Number or Email Address Contact Person for More Information:
Marquita Black, Office of Science and Public Health Practice, Executive Assistant, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop D–44, Atlanta, Georgia 30333, Telephone: (404) 639–7325; Facsimile: (404)639–7977; Email: OPHP.BSC._questions@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH or Institute)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates: 8:00 a.m.–5:00 p.m., October 16, 2013 (Closed), 8:00 a.m.–5:00 p.m., October 17, 2013 (Closed).

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314. Telephone: (703) 684–5900, Fax: (703) 684–0653.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute’s standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broadly-based research endeavors in keeping with the Institute’s program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals:

Matters To Be Discussed: The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and occupational health-related grant applications.

These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92–463. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, Ph.D., NIOSH Health Scientist, 2400 Executive Parkway, Mailstop E–20, Atlanta, Georgia 30345, Telephone: (404) 498–2511, Fax: (404) 498–2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and