

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued
 [New burdens associated with the final rule]

Section	Type of respondent	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
164.520	Dissemination of Notice of Privacy Practices for Protected Health Information (health plans).	20,000,000	1	.00333335	66,667
164.520	Revision of Notice of Privacy Practices (providers).	697,000	1	.11111	77,444
Total	619,278

ONGOING ANNUAL BURDENS OF COMPLIANCE WITH THE RULES

Section	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
160.204	Process for Requesting Exception Determinations (states or persons).	1	1	16	16
164.504	Uses and Disclosures—Organizational Requirements	700,000	1	5/60	58,333
164.508	Uses and Disclosures for Which Individual authorization is required.	700,000	1	1	700,000
164.512	Uses and Disclosures for Research Purposes	113,524	1	5/60	9,460
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by paper mail).	100,000,000	1	0.25	416667
164.520	Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by electronic mail).	100,000,000	1	0.167	278333
164.520	Notice of Privacy Practices for Protected Health Information (health care providers—dissemination and acknowledgement).	613,000,000	1	3/60	30,650,000
164.522	Rights to Request Privacy Protection for Protected Health Information.	150,000	1	3/60	7,500
164.524	Access of Individuals to Protected Health Information (disclosures).	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (requests)	150,000	1	3/60	7,500
164.526	Amendment of Protected Health Information (denials)	50,000	1	3/60	2,500
164.528	Accounting for Disclosures of Protected Health Information.	70,000	1	3/60	5,833
Total	32,143,642

Total Hours: 32,762,920.

Darius Taylor,
 Deputy Information Collection Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

National Foundation on Fitness, Sports, and Nutrition Establishment Act; Delegation of Authority; Office of the Assistant Secretary for Health

Notice is hereby given that I have delegated to the Assistant Secretary for Health authority under Section 5 of the National Foundation on Fitness, Sports,

and Nutrition Establishment Act, Public Law 111-332 (Dec. 22, 2010). The delegation excludes the authorities to issue regulations and to submit reports to the Congress. This authority may be re-delegated.

I hereby affirm and ratify any actions taken by the Assistant Secretary for Health, or his subordinates, which involved the exercise of this authority delegated herein prior to the effective date of this delegation of authority.

This delegation is effective upon date of signature.

Dated: September 6, 2013.

Kathleen Sebelius,
 Secretary.

[FR Doc. 2013-22235 Filed 9-11-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, 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 a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the

SACHRP Web site at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

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.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Hubert H. Humphrey Building, Room 800, Washington, DC 20201.

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; 240-453-8141; fax: 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.

Dated: September 5, 2013.

Jerry Menikoff,

Director, Office for Human Research Protections,

Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

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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; 301-851-3300 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