DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, 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-committee/meetings/index.html.

DATES: The meeting will be held on Tuesday, July 25, 2017, from 8:30 a.m. until 5:00 p.m., and Wednesday, July 26, 2017, from 8:30 a.m. until 2:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: SACHRP@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, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and 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.

The Subcommittee on Harmonization (SOH) was established by SACHRP in July 2009 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.

The SACHRP meeting will open to the public at 8:30 a.m., on Tuesday, July 25, 2017, followed by opening remarks from Dr. Jerry Menikoff, Director, Office for Human Research Protections and Dr. Stephen Rosenfeld, SACHRP Chair. The SOH will present their recommendations regarding the new Common Rule’s compliance dates and transition provisions, as well as for the interpretation and implementation of the broad consent provision, followed by the SAS discussing their report on the interpretation of the new exemption involving benign behavioral interventions. The Tuesday, July 25, meeting will adjourn at approximately 5:00 p.m.

The Wednesday, July 26, meeting will begin at 8:30 a.m. with discussion of recommendations from the SAS regarding the new Common Rule’s expedited review requirements.

The meeting will adjourn at approximately 2:30 p.m., July 26, 2017. Time for public comment sessions will be allotted both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to issues currently being addressed by the SACHRP. Individuals submitting written statements as public comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days 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 one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: June 27, 2017.

Julia G. Gorey, Executive Director, Secretary’s Advisory Committee on Human Research Protections.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Stakeholder Listening Session on Strategies for Improving Parity for Mental Health and Substance Use Disorder Coverage

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public stakeholder listening session on Strategies for Improving Parity for Mental Health and Substance Use Disorder Coverage. The public meeting, mandated in the 21st Century Cures Act, seeks public comment on improved Federal and State coordination related to section 2726 of the Public Health Service Act, section 712 of the Employee Retirement Income Security Act of 1974, section 9812 of the Internal Revenue Code of 1986, and any comparable provisions of State law. The public meeting will seek participation from the required stakeholders in statute, State health commissioners, State agencies, State attorneys general, the National Association of Insurance Commissioners, health insurance issuers, providers of mental health and substance use disorder services, consumers, advocates, and other interested parties and organizations.

Dated: June 27, 2017.

Julia G. Gorey, Executive Director, Secretary’s Advisory Committee on Human Research Protections.

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DATE: June 27, 2017.

Julia G. Gorey, Executive Director, Secretary’s Advisory Committee on Human Research Protections.

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