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 meeting will open to the public at 8:30 a.m. on Tuesday, October 25, followed by opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair. The Subpart A Subcommittee (SAS) will then present their report, including recommendations regarding single IRB review and the draft joint OHRP–FDA draft guidance, “Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.” This will be followed by the Subcommittee on Harmonization’s (SOH) report, including recommendations involving clustered randomized trials, benchmarking, and the “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,” Appendix M.

SAS was established by SACHRP in October 2006. The subcommittee 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.

SOH was established by SACHRP at its July 2009 meeting and 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. On Wednesday, October 26, 2016, SACHRP will discuss recommendations from the SOH on the FDA Draft Guidance “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,” issued July 27, 2016.

The meeting will adjourn at 4:30 p.m. October 26, 2016. Time for public comment sessions will be allotted both days.

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. Registration is required for participation in the on-site public comment session; individuals may register on the day of the meeting.

Individuals who would like to submit 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. Note that public comment must be relevant to agenda topics.


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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Modifications of Healthy People 2020 Objectives

AGENCY: Office of the Secretary, Office of the Assistant Secretary of Health, Office of Disease Prevention and Health Promotion, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services solicits written comments regarding a new objective proposed to be added to Healthy People 2020 since the fall 2015 public comment period. Public participation helps shape Healthy People 2020, its framework, objectives, organization, and targets. Healthy People provides opportunities for public input periodically throughout the decade to ensure that Healthy People 2020 reflects current public health priorities and public input. The updated set of Healthy People 2020 objectives will be incorporated on www.HealthyPeople.gov. This set will reflect further review and deliberation by the topic area workgroups, Federal Interagency Workgroup on Healthy People 2020, and other Healthy People 2020 stakeholders.

DATES: Written comments will be accepted until 5:00 p.m. ET on October 27, 2016. Written comments will be accepted via an online public comment database at http://www.healthypeople.gov/2020/about/history-development/Public-Comment; by mail at the Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, Attn: Public Comment, 1101 Wootton Parkway, Rockville, MD 20852; or email—HP2020@hhs.gov.


SUPPLEMENTARY INFORMATION: For three decades, Healthy People has provided a comprehensive set of national 10-year health promotion and disease prevention objectives aimed at improving the health of all Americans. Healthy People 2020 objectives provide a framework by presenting a comprehensive picture of the nation’s health at the beginning of the decade, establishing national goals and targets to be achieved by the year 2020, and monitoring progress over time. The U.S. Department of Health and Human Services is soliciting the submission of written comments regarding a new objective proposed to be added to Healthy People 2020 since the fall 2015 public comment period.

Healthy People 2020 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the federal government, with a common interest in improving the nation’s health. Public comments were a cornerstone of Healthy People 2020’s development. During the first phase of planning for Healthy People 2020, HHS asked for the public’s comments on the vision, mission, and implementation of Healthy People 2020. Those comments helped set the framework for Healthy People 2020. The public was also invited to submit comments on proposed Healthy People 2020 objectives, which helped shape the final set of Healthy People 2020 objectives.

The public is now invited to comment on a new objective proposed to be added to Healthy People 2020, which can be found at http://www.healthypeople.gov/2020/about/history-development/Public-Comment. This new objective was developed by the HIV topic area workgroup led by the Centers for Disease Control and Prevention and Health Resources and Services Administration. It has been reviewed by the Federal Interagency Workgroup on Healthy People 2020 and is presented now for the public’s review and comment. Comments are restricted to this specific HIV objective. Having reached the midpoint in the decade, Healthy People will not be soliciting proposals for additional new objectives. Written comments will be accepted at http://www.healthypeople.gov/2020/about/history-development/Public-Comment. The public will also be able...
to submit written comments via mail, fax, and email (see contact information above). Comments received in response to this notice will be reviewed and considered by the appropriate topic area workgroup, Federal Interagency Workgroup on Healthy People 2020, and other Healthy People 2020 stakeholders.


Don Wright,
Deputy Assistant Secretary for Health
(Disease Prevention and Health Promotion).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; O10 Review: Heroin Addiction.

Date: October 14, 2016.
Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005.

Contact Person: Jana Drgonova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, jdrgonova@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.