

determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field titled "Category (Required)," on the "Your Information" page on www.regulations.gov. For this docket, however, FDA will not be following this general practice. Instead, FDA will post on <http://www.regulations.gov> comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on <http://www.regulations.gov> if you include that information in the body of your comments. For electronic comments submitted to <http://www.regulations.gov>, FDA will post the body of your comment on <http://www.regulations.gov> along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on <http://www.regulations.gov>, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of this guidance document at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm> or <http://www.regulations.gov>.

Dated: September 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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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, 5 U.S.C. App 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/mtgngs/index.html>.

DATES: The meeting will be held on Wednesday, October 21, 2015, from 8:30 a.m. until 5:00 p.m. and Thursday, October 22, 2015, from 8:30 a.m. until 4:30 p.m.

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

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; 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 meeting will open to the public at 8:30 a.m., on Wednesday, October 21, followed by opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair. The Committee will hear the Subpart A Subcommittee (SAS) and Subcommittee on Harmonization (SOH) reports on the recent Notice of Proposed Rulemaking (NPRM) titled Federal Policy for the Protection of Human Subjects (80 FR 53933, Sep. 8, 2015). Both days will be devoted to the discussion of the NPRM.

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.

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.

The meeting will adjourn at 4:30 p.m. October 22, 2015. 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. Pre-registration is required for participation in the on-site public comment session; individuals may pre-register the day of the meeting. Individuals who would like to submit written statements should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Dated: September 18, 2015.

Jerry Menikoff,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Hospital Data Abstraction Form, Formerly Entitled Evaluation of Emergency Department Crisis Center Follow-Up—(OMB No. 0930-0337)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct an evaluation to assess the impact of crisis center follow-up with patients admitted to emergency departments following a suicide attempt.