ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is reopening the comment period for the notice entitled ''In-Home Disposal Systems for Opioid Analgesics; Request for Information'' published in the **Federal Register** of April 4, 2023. FDA is reopening the comment period to allow interested persons additional time to develop and submit comments.

DATES: FDA is reopening the comment period on the notice published April 4, 2023 (88 FR 19959). Either electronic or written comments must be submitted by November 6, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 6, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–0917 for ''In-Home Disposal Systems for Opioid Analgesics; Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 4, 2023 (88 FR 19959), FDA published a notice requesting information and comments that will assist the Agency in assessing whether in-home disposal products can be expected to meet the public health goal of mitigating the risk of nonmedical use or overdose if the Agency were to require drug manufacturers to make in-home disposal products available to patients under a risk evaluation and mitigation strategy. The Agency requested information and comments on the issues that were discussed at the public workshop convened by the National Academies of Sciences, Engineering, and Medicine's Forum on Drug Discovery, Development, and Translation entitled ''Defining and Evaluating In-Home Disposal Systems for Opioid Analgesics'' on June 26 and 27, 2023. Interested persons were originally given until August 28, 2023, to submit comments on in-home disposal systems for opioid analgesics.

FDA is reopening the public docket to allow interested persons additional time to submit comments. We note that there is a listening session on October 5, 2023, with federally recognized American Indian and Alaska Native tribes on the safe disposal of opioid analgesics. The Agency believes that reopening the comment period for an additional 45 days will allow adequate time for interested persons to submit comments without significantly delaying Agency decision-making on these important issues. FDA is reopening the comment period for 45 days, until November 6, 2023.

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20516 Filed 9–21–23; 8:45 am]

BILLING CODE 4164–01–P

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 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, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Wednesday, October 18, 2023, from 9:00 a.m. until 5:00 p.m., and Thursday, October 19, 2023, from 9:00 a.m. until 4:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website as this information becomes available.

ADDRESSES: This meeting will be held in person and webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted at least one week prior to the meeting at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

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 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 SACHRP meeting will open to the public at 9:00 a.m., on Wednesday, October 18, 2023, followed by opening remarks from Julie Kaneshiro, Acting Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with an expert panel discussion on the ethical and regulatory considerations for the inclusion of LGBTQI+ populations in HHS research. This will be followed by discussion of IRB effectiveness, topic #4 of the recently published GAO report #GAO–23–104721, Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness. The meeting then will turn to a discussion of the best interests standard for permitting continued participation of subjects in a suspended or terminated research study. Following this the committee will discuss IRB review of research that may be considered uninformative.

On Thursday, October 19th, the committee will welcome ADM Rachel Levine for commentary and remarks; this will be followed by continued discussion of the previous day's topics. The meeting will adjourn by 4:00 p.m. October 19, 2023.

Time will be allotted for public comment on both days of the meeting. The public may submit written public comment in advance to *SACHRP@hhs.gov* no later than midnight October 13, 2023, ET. Written comments will be shared with SACHRP members and may read aloud during the meeting. Public comment must be relevant to topics being addressed by the SACHRP.

Dated: September 13, 2023.

Julia G. Gorey,

Executive Director, SACHRP. Office for Human Research Protections.

[FR Doc. 2023–20577 Filed 9–21–23; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, 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: National Institute of Mental Health Special Emphasis Panel; Individually Measured Phenotypes to Advance Computational Translation in Mental Health (IMPACT–MH) (U01 & U24).

Date: October 19–20, 2023.

Time: 9:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; ALACRITY: Advanced Laboratories for Accelerating the Reach and Impact of Treatments for Youth and Adults with Mental Illness Centers.

Date: October 19, 2023.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Regina Dolan-Sewell, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20852, (240) 796–6785, *regina.dolan-sewell@nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative: Brain Behavior Quantification and Synchronization—Data Coordination and Artificial Intelligence Center.

Date: October 20, 2023.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Evon Abisaid, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20852, 301–827–0399, *ereifejes@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)