DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–22–001, Panel B, Occupational Safety and Health Education and Research Centers (ERC); Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–22–001, Panel B, Occupational Safety and Health Education and Research Centers (ERC); February 23–24, 2023, 12 p.m.–5 p.m., EST, in the original FRN. The meeting was published in the **Federal Register** on December 9, 2022, Volume 87, Number 236, page 75632. The meeting is being amended to change the Notice of Funding Opportunity (NOFO) number and should read as follows:

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–23–003, Panel B, Occupational Safety and Health Education and Research Centers (ERC).

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505; Telephone: (304) 285–5951; Email: *MGoldcamp@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–00901 Filed 1–18–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Protection of Human Subjects and Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 21, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0130. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Protection of Human Subjects; Informed Consent; and Institutional Review Boards—21 CFR Parts 50 and 56

OMB Control Number 0910–0130—Extension

This information collection supports Agency regulations pertaining to the protection of human subjects, informed consent, and responsibilities of institutional review boards (IRBs) as set forth in parts 50 and 56 (21 CFR parts 50 and 56). Parts 50 and 56 apply to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. The regulations in parts 50 and 56 are intended to protect the rights and safety of subjects involved in such investigations. The regulations also contain the standards for composition, operation, and responsibilities of IRBs that review clinical investigations regulated by FDA.

21 CFR Part 50—Protection of Human Subjects

Provisions in part 50 provide for the protection of human subjects involved in FDA-regulated clinical investigations. With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Basic elements of informed consent are set forth in § 50.25 (21 CFR 50.25) and include, among other things: (1) a statement of the purpose and duration of a subject's participation in the research; (2) a description of the procedures to be followed; (3) identification of any experimental procedures; (4) a description of risks, benefits, and appropriate alternative procedures or treatments; (5) a description of extent to which confidentiality of records identifying the subject will be maintained; (6) certain contact information; and (7) a statement that participation is voluntary and may be discontinued at any time. Additional elements set forth in § 50.25 are required in the informed consent as appropriate. Exceptions to these requirements are governed by 21 CFR 50.23, which requires both investigator and physician to certify in writing that necessary elements for exception from general requirements have been satisfied; and § 50.24 (21 CFR 50.24), which covers exception from informed consent requirements for emergency research. In accordance with § 50.27 (21 CFR 50.27) informed consent must be documented, except as provided in § 56.109(c) (21 CFR 56.109(c)), which provides for an IRB to waive documentation of informed consent in certain circumstances.

Informed consent must be documented using a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the

time of consent. For each clinical investigation reviewed by an IRB, we believe there will typically be one associated written consent form developed by an investigator. In some cases, investigators will seek IRB approval of changes in the research and/or consent form after initial IRB approval. For some multi-institutional clinical investigations, the IRB of each institution involved may separately conduct initial and continuing review of the research, including review of the written consent form to determine whether it is in accordance with § 50.25. However, in cases where a multi-institutional clinical investigation uses a single IRB review process, there may only be one IRB conducting such reviews. Additional safeguards are required for children, as prescribed in subpart D (21 CFR 50.50 through 50.56) of the regulations.

21 CFR Part 56—Institutional Review Boards

The general standards for the composition, operation, and responsibilities of an IRB are set forth in part 56. IRBs serve in an oversight capacity by reviewing, among other things, informed consent documents and protocols for FDA-regulated studies, to make findings required to approve research, and document IRB actions. Part 56 also regulates the administrative activities of IRBs reviewing FDA-regulated research including, among other things, identification of types of IRB records that must be prepared and maintained. Required recordkeeping includes documentation pertaining to written procedures, proposals reviewed, committee membership, meeting minutes, actions taken by the IRB, correspondence, as well as other functional and operational aspects of the IRB. Finally, the regulations describe administrative actions for noncompliance, including both disqualification of IRBs or IRB parent institutions, as well as reinstatement and alternative and additional actions.

Description of Respondents: Respondents to the information collection are IRBs that review and approve clinical investigations regulated by FDA and clinical investigators of such research who obtain informed consent of human subjects prior to research participation.

In the **Federal Register** of June 24, 2022 (87 FR 37867), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the annual burden for the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
56.113; suspension or termination of research	2,520	1	2,520	0.5 (30 minutes)	1,260
56.120(a); IRB response to lesser administration actions for noncompliance.	7	1	7	10	70
56.123; reinstatement of an IRB or an institution	1	1	1	5	5
Total					1,335

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on available data, there are approximately 2,520 IRBs overseeing FDA-regulated clinical research. We have organized the table summarizing estimated annual reporting burden to list only one requirement per row recognizing that some provisions may also include recordkeeping or third-party disclosure tasks. We believe we have accounted for all burden cumulatively across the information collection activity tables and invite comments on our estimates.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
50.24; exceptions from informed consent for emergency research.	8	3	24	1	24
50.27; documentation of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400
56.115; IRB records (documentation of IRB activities)	2,520	14.6	36,792	40	1,471,680
Total					1,522,104

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We characterize activities associated with §§ 50.24 and 50.27 as recordkeeping burden. We assume each of the 2,520 IRBs meets an average of 14.6 times annually and assume 40 hours of person-time per meeting are required to meet the IRB recordkeeping requirements of § 56.115. We also assume most recordkeeping is completed electronically.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
50.25; elements of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.109(d); written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	0.5 (30 minutes)	2,520
56.109(e); written notification to approve or disapprove research.	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(g); IRB written statement about public disclosures to sponsor of emergency research under § 50.24.	8	2	16	1	16
Total	.....	.....	.....	.....	103,336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We characterize activities associated with §§ 50.25 and 56.109(d) and (e) as disclosure burden. We estimate that eight IRBs per year will receive a request to review emergency research under § 50.24, thus requiring written notification under § 56.109(g) from the IRB to the sponsor. We estimate that it will take an IRB approximately 1 hour to prepare each written statement, for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Dated: January 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00974 Filed 1–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0084]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with the Adverse Event Program for Medical Devices (Medical Program Safety Network (MedSun)).

DATES: Either electronic or written comments on the collection of information must be submitted by March 20, 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 March 20, 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–2017–N–0084 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network).'' 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