4164-01-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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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	No. of Respondents	No. 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	No. of Recordkeepers	No. 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	No. of Respondents	No. 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
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.

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