



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2021-0315; FRL-13347-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (EPA ICR Number 2195.07, OMB Control Number 2070-0169), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through April 30, 2026. Public comments were previously requested via the *Federal Register* on July 23, 2025 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA-HQ-OPP-2021-0315, to EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Office of Mission Critical Operations (Mail Code 7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202-566-1205; email address: siu.carolyn@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through April 30, 2026. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the *Federal Register* on July 23, 2025, during a 60-day comment period (90 FR 34657). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Based on this regulation EPA aims to assess the risks of exposure based on studies that may occasionally use humans. Specifically, the EPA regulations at 40 CFR 26 protect subjects of "third-party" human research (i.e., research that is not conducted or supported by the EPA) that may be submitted to EPA in support of pesticide product registration and/or labeling

or conducted to provide data for generic exposure databases. In addition to other protections, the regulations require affected entities to submit information to EPA and an institutional review board (IRB) prior to initiating, and to the EPA upon the completion of, certain studies that involve human research participants. The information collection activity consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws. If such research involves intentional exposure of human subjects, these individuals (respondents) are required to submit study protocols to the EPA and an IRB before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to the EPA. As such, the purpose of this document is to estimate the third-party response burden from complying with the requirements in 40 CFR 26.

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here.

Form number(s): None.

Respondents/affected entities: Entities potentially affected by this ICR include those that submit to EPA under FIFRA and/or FFDCa protocols and study reports for environmental research involving human subjects. North American Industrial Classification System (NAICS) codes identified in question 12 of the ICR.

Respondent's obligation to respond: Mandatory. 40 CFR 26.

Estimated number of respondents: 13 (total).

Frequency of response: On occasion.

Total estimated burden: 6,237 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated costs: \$742,361 (per year), which includes \$0 annualized capital or operation &

maintenance costs.

Changes in the Estimates: There is a decrease of 2,039 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This change, which is discussed in more detail in the ICR, reflects the decrease in anticipated number of respondent responses per year from 4 to 3 for the next three years. This change is an adjustment.

Courtney Kerwin,

Deputy Director, Data & Enterprise Programs Division.

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