E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2021-0315; FRL-12695-01-OCSPP]

Agency Information Collection Activities; Proposed Renewal Collection and Request for Comment; Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (EPA ICR No. 2195.07 and OMB Control No. 2070-0169). This ICR represents a renewal of an existing ICR that is currently approved through April 30, 2026. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number Docket ID No. EPA-HQ-OPP-2021-0315, online at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Office of Program Support

(Mail Code 7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1205; email address: *Siu.Carolyn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects

EPA ICR No.: 2195.07

OMB Control No.: 2070-0169

ICR Status: This ICR is currently approved through April 30, 2026. Under the PRA, 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. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the ***Federal Register*** when approved, are displayed either by publication in the ***Federal Register*** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The U.S. Environmental Protection Agency (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, per 40 CFR 26.

Estimated number of potential respondents: 13.

Frequency of response: On occasion.

Total estimated average number of responses for each respondent: 1.

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

Total estimated costs: $742,361 (per year), includes $0 annualized capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 2,159 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease is a result of the anticipated number of responses per year from four to three for the next three years. These changes are an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another ***Federal Register*** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq*.

Dated: July 18, 2025.

Nancy B. Beck

Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2025-13819 Filed: 7/22/2025 8:45 am; Publication Date: 7/23/2025]