U.S. Environmental Protection Agency

Information Collection Request (ICR)

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

Title:	Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects
EPA ICR No.:	2195.07
OMB Control No.:	2070-0169
Docket ID No.:	EPA-HQ-OPP-2021-0315

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 (Ref 1.) 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.[1] 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

[1]To access the revised regulation go to: *https://www.govinfo.gov/content/pkg/CFR-2020-title40-vol1/pdf/CFR-2020-title40-vol1-part26.pdf*

document is to estimate the third-party response burden from complying with the requirements in 40 CFR 26.

Summary Total Burden and Costs

Information Collection	Number of Respondents	Annual Number of Responses	Responses per Respondent	Annual Time Burden (Hours)	Annual Cost Burden (Dollars)
Research Involving Intentional Exposure of Human Subjects	3	3	1	6,117	$728,511
All other Submitted Research with Human Subjects	10	10	1	120	$13,850
Total Respondent	13	13	n/a	**6,237**	**$742,361**
Total Agency				**2,670**	**$188,089**

SUPPORTING STATEMENT A

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The 2006 Appropriations Act, Public Law No. 109-54 (Ref. 2), required the EPA to issue a final rule addressing third-party intentional dosing human toxicity studies for pesticides, and the EPA conduct of intentional dosing human toxicity studies for pesticides. This ICR applies to all the information collection activities identified in the 2006 rule[2] that the EPA promulgated in response to the Congressional mandate, which amended 40 CFR 26. The 2013 and 2019 revisions did not change information provided in this ICR because the revisions did not result in changes to the information collection activities and related burden estimates. The EPA's statutory authority to require and collect the information identified already existed under FIFRA and FFDCA.

Sections 3(c)(5), 3(g) and 4(g)(2)(D) of FIFRA (Ref. 3) generally require the EPA to determine that a pesticide would not present any "unreasonable adverse effects on the environment"[3] when deciding to grant a new or amended pesticide registration or to continue an existing registration. Section 4(g)(2)(E) of FIFRA and section 408(b)(2)(A)(ii) of FFDCA (Ref. 4) generally

[2] 2006 Final Rule available at *https://www.federalregister.gov/documents/2006/02/06/06-1045/protections-for-subjects-in-human-research*

[3] Defined in FIFRA section 2(bb) as ". . . (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) . . ."

require the EPA to determine that there is a reasonable certainty that no harm will result from aggregate exposure to the residue of a pesticide chemical, including all anticipated dietary exposures and all other exposures for which there is reliable information when making pesticide tolerance decisions. FIFRA Section 12(a)(2)(P) forbids any person "to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable from, and (ii) freely volunteer to participate in the test." The EPA established this collection of information as part of the 2006 final rule as authorized under section 25 of FIFRA and section 408(e)(1)(C) of FFDCA to:

(1) ensure that sound and appropriate scientific data are available to the EPA when making regulatory decisions about pesticides as described in the previous paragraph; and,

(2) protect the interests, rights, and safety of human research subjects, as required under FIFRA section 12(a)(2)(P)[4].

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current collection.

In order to ensure the availability of sound and appropriate scientific data in its decisions, to protect the interests, rights and safety of human research subjects, and to confirm that the Agency relies on ethically-sound studies in decision-making, in 2006 the EPA extended the requirements of the Agency's 1991 Common Rule, 40 CFR part 26, prospectively to third-party research intended for submission to the EPA under the pesticide laws and involving intentional exposure of non-pregnant, non-nursing adult human subjects. In 2013, the rule was expanded to cover all research involving intentional exposure to pesticides regardless of the regulatory statute under which the submission is made. The information provided allows the EPA and the Human Studies Review Board (HSRB) to review protocols and related information before covered research involving human subjects is initiated, but after it has been reviewed and approved by a local IRB. In addition, anyone who submits to the EPA a report of research with human subjects must submit concurrently documentation of the ethical conduct of the research. This information collection activity allows the EPA to ensure all human subjects in research conducted by the EPA (first party), conducted by entities with support from the EPA (second parties), or conducted by third parties with the intention to submit it to the EPA, are treated ethically.

The information collected under this ICR has been used by the EPA to satisfy the regulatory requirements to consult with the HSRB on proposed research with human subjects before it is

[4] https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities

conducted and prior to reliance on the results of human research in regulatory decisions. After consultations with the HSRB, the information has been used to register new skin-applied insect repellent products, to refine occupational and residential risk assessments, and to set regulatory endpoints. Additionally, information collected under this ICR provides documentation about the ethical conduct of research with human subjects, enabling the EPA to determine whether it can rely on the human research submitted.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The EPA's Office of Pesticide Programs (OPP) completed a major review of its information tracking systems to improve their efficiency and accuracy. This review resulted in improvements to the information system, which will improve the quality of the Agency's databases and allows the EPA to respond timelier and accurately to queries from registrants and the public, including requests made under the Freedom of Information Act (FOIA).

The EPA also investigated the possibility of providing optional electronic data transfer services to the industry as a means of minimizing the burden of registration activities. The Agency's pesticide program, along with the pesticide industry, recognizes the advantages in terms of accuracy, speed, cost and personnel from electronic data transfer technologies. In addition, OPP consulted with industry associations and other federal agencies and participated in an Agency-wide workgroup to develop electronic reporting standards intended to facilitate collection of information from industry.

OPP uses the Pesticide Submission Portal (PSP) (Attachment A) to leverage the Agency's Central Data Exchange (CDX) platform and allow pesticide registrants to submit a wide variety of regulatory actions to the EPA electronically, forgoing the need to submit either paper or CDs/DVDs. The type of eligible information and regulatory actions that can be submitted via the PSP is explained on the EPA's website[5]. The PSP is a critical step in achieving the vision of a fully electronic work environment. If registrants want to submit paper copies of study data or CDs to the EPA, they can still do so.

OPP does not publish any studies submitted. However, it maintains records of each study in the Office of Pesticide Programs Information Network (OPPIN) and provides public access to OPPIN bibliographies through the National Pesticides Information Retrieval System (NPIRS). NPIRS supports searches for technical documents submitted to the EPA by registrants. Information is categorized by chemical, subject, submission date, laboratory, guideline number, and

[5] *https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications*

document type. The public may request copies of studies that are non-confidential by submitting a FOIA request.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The information requirements identified in the regulations at 40 CFR part 26 do not duplicate other federal agency information collections. Other federal agencies have adopted the Common Rule, and the U.S. Food and Drug Administration (FDA) has established requirements similar to those in the Common Rule for third-party researchers who perform human testing intended for submission to FDA. None of those requirements, however, apply to third-party research that is intended for submission to the EPA.

5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.

Although the Agency cannot predict whether or how many small entities might engage in the subject matter research, the burden and related cost for researchers to comply with these information collection activities is estimated to be a comparatively small portion of the overall cost of performing such studies. After reviewing the history of the EPA's consideration of human research in its various program offices, the EPA estimates that only a limited number of third-party human studies conducted will be intended for submission to the Agency in support of regulatory action and therefore will be impacted by these activities each year. Because both the number of affected studies is relatively small and the estimated current costs of compliance with the Common Rule are low, the potential overall burden and costs from these activities to third parties are also estimated to be small, regardless of their size. As a result, the EPA has not provided any special flexibility for small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

This is an event-driven information collection activity and is conducted only as information is submitted to the EPA for consideration. The parties consulted stated that the data collected are not available from another source and the frequency of collection could not be reduced and still produce the same outcome. There is no set frequency for the collection of this information.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

a) **requiring respondents to report information to the agency more often than quarterly;**

b) requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

c) requiring respondents to submit more than an original and two copies of any document;

d) requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;

e) in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;

f) requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

g) that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

h) requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

The only guideline established under the Paperwork Reduction Act (PRA) that may be exceeded in this collection is the time period for retaining records. The EPA's requirement at 40 CFR 169.2(k) (Ref. 5) states that records containing research data relating to registered pesticides be retained for as long as the registration is valid, and the producer remains in business. Registrations are valid until they are either voluntarily canceled or withdrawn by the registrant or until the EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records are not required to be retained for more than three years will be exceeded in this collection activity. This is an existing requirement that was not changed by the 2006 final rule. In any case, the recordkeeping requirement merely codifies the usual and customary business practices of pesticide manufacturers who will retain the records; therefore, no burden is attributed to the activity.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken in response to the comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside EPA to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or report.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

Pursuant to 5 CFR 1320.8(d), EPA published a notice in the Federal Register on July 23, 2025 (90 FR 34657; FRL-12695-01-OCSPP), announcing the planned renewal of this information collection activity, soliciting public comment on specific aspects of the ICR and providing a 60-day public comment period. No substantive comments were received.

The EPA also consulted (6) stakeholders, specifically asking them for their assessment of the regulatory burden estimates expressed by the Agency in this ICR (Attachment C). The stakeholders consulted were:

- Carroll-Loye Biological Research
- Mancozeb Task Force
- Antimicrobial Exposure Assessment Task Force/American Chemistry Council
- Mimikai
- Citrefine International Limited
- Arctech Innovation

Of those consulted, EPA received comments from 0 companies.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts are provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

The EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure that provide strict instructions regarding access to and contact with documents confidential business information (CBI). These procedures comply with the EPA's CBI regulations at 40 CFR part 2, Subpart B.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

The information collection activities do not include questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information.

a) **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

b) **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**

c) **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'**

The EPA is estimating only the incremental burden imposed upon respondents for compliance with the paperwork requirements established in the 2006 final rule and retained in the revisions to the rule in 2013 and 2019. The EPA is neither estimating, de novo, the estimated paperwork burden for compliance with the 1991 Common Rule in this ICR nor the paperwork burden associated with the generation of certain study data that are

already covered by other ICRs, such as those requested by the EPA in a Data Call-In (OMB Control No. 2070-0174) under FIFRA section 3(c)(2)(B). The EPA assumes that IRBs are already in compliance with the current Common Rule requirements and therefore there is no additional burden imposed upon IRBs for compliance with the paperwork requirements established in the 2006 final rule or subsequent revisions and discussed in this document. While the EPA assumes that researchers conducting these studies would already be required to comply with the 1991 Common Rule requirements, they will be subject to some additional paperwork requirements under the EPA's amendments. Therefore, the EPA is estimating only the burden and costs associated with the paperwork activities that are described in the 2019 final rule.

Responses, Number and Burden, by Type

EPA identifies two types of studies that must be reviewed by the IRB: those that involve intentional exposure of human subjects to pesticides and others that involve observational research. EPA took into account that some study types are more complex than others and there are differences in the preparation of protocols versus completed studies; with that in mind, the EPA calculated an average of the time estimates for each activity using information provided during previous consultation with respondents.

Based on historical submissions, the EPA estimates that an average of 3 pesticide protocols and 3 completed studies per year under FIFRA and/or FFDCA will be submitted for review because they involve intentional exposure of human subjects. Some years may involve a higher number of submissions, while other years may involve lower numbers depending on the timing of when protocols or studies must be completed. Please note that the 3 "responses" per year include 3 protocols plus 3 studies. This approach to defining responses is consistent with that used and approved for this ICR in previous years.

Respondent activities that are within the scope of this ICR include: preparing and submitting protocols, supporting documents, and completed study reports for review by the IRB, the EPA, and the HSRB; communicating with staff from the IRB and the EPA regarding required changes to a protocol; communicating with the EPA about the HSRB recommendations; and documenting protocol changes made at the recommendation of an IRB, the EPA, or the HSRB. Activities that are unrelated to the paperwork and recordkeeping requirements of the rule, such as the costs of conducting the research, are not incremental paperwork or recordkeeping costs and therefore are not within the scope of this ICR.

Annual burden and costs are determined through average burden hours and total costs per response. As shown in Table1, the total annual estimated burden associated with all submitted pesticide research that involves intentional exposure of human subjects is 6,117 hours= (2,039 hours per response * 3 responses per year). The annual burden is the annual

estimated burden for all other pesticide research that involves human subjects is 120 hours. Therefore, the total annual respondent burden for this information collection activity is estimated to be 6,237 hours. The estimated annual cost for all respondents is $728,511 (=$242,837 per response * 3 responses per year). Respondent labor rates are estimated to be $224, $113, and $72 per hour, respectively, for managerial, technical and clerical labor. In determining the rates, OPP uses a single source of data, the BLS National Industry-Specific Occupational Employment and Wage Estimates and selects the appropriate occupational category.

Table 1. Weighted average burden and cost estimates for respondents for research involving intentional exposure of human subjects

Activities	Average Burden Hours Per Response			Total Costs Per Response	
	Management $224/hr	Technical $113/hr	Clerical $72/hr	Hours	Cost ($)
Rule familiarization and training	6	7	5	18	$2,495
Prepare and submit protocol for IRB review	18	83	13	114	$14,347
Prepare and submit protocol for review by the EPA and the HSRB	68	334	28	430	$54,990
Document ethical conduct of a completed study for which the EPA and the HSRB have reviewed the protocol; prepare and submit completed study for review by the IRB, the EPA, and the HSRB	56	1,329	57	1,442	$168,825
Store, file, and maintain records	7	20	8	35	$4,404
Total per response	154	1773	111	**2,039**	**$242,837**

Annual Burden: 2,039 hours per response * 3 responses per year = **6,117 hours**
Annual Costs: $242,837 per response * 3 responses per year = **$728,511**

Table 2 shows respondent burden and cost estimates for all other submitted research with human subjects. The Annual Burden: is shown as 12 hours per study * 10 studies submitted per year which is equivalent to 120 hours. Annual costs are derived as the product of $1,385 per study * 10 studies submitted per year, which is = $13,850. The labor rates were derived from the Bureau of Labor Statistics' May 2025 National Industry Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences).[6] These labor rates are fully loaded and include benefits and overhead costs (Attachment D).

[6] Bureau of Labor Statistics. "May 2025 National Industry-Specific Occupational Employment and Wage Estimates: 541710 – Research and Development in the Physical, Engineering, and Life Sciences." Accessed at http://www.bls.gov/oes/current/naics5_541710.htm.

Table 2. Respondent burden and cost estimates for all other submitted research with human subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $224/hr	Technical $113/hr	Clerical $72/hr	Hours	Cost ($)
Rule familiarization and training	1	1	0	2	$337
Prepare and submit ethics information of completed human studies to the EPA	0	8	1	9	$976
Store, file, and maintain records	0	0	1	1	$72
Total per response	**1**	**9**	**2**	**12**	**$1,385**

Annual Burden: 12 hours per study * 10 studies submitted per year = **120 hours**
Annual Costs: $1,385 per study * 10 studies submitted per year = **$13,850**

Respondents, number and frequency of submission

It is assumed that there is 1 respondent per 1 response based on past ICR burden estimates. However, EPA is open to comment from the public on this assumption.

13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

a) **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

b) **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment**

process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

c) Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

There are no operational and/or maintenance costs.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

The estimated Agency annual cost is $188,089, as shown in Table 3. Costs are estimated through identifying annual burden hours multiplied by annual costs. The EPA's activities include communicating with respondents, reviewing the ethical aspects of submitted study protocols and completed study reports, making presentations to the HSRB, documenting decisions, and information management activities to record, file, and track the submissions. The Agency labor rates are $160, $107, and $59 per hour for management, technical, and clerical staff, respectively. The labor rates were derived from the Bureau of Labor Statistics' May 2025 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 999100 (Federal Executive Branch).[7] These labor rates are fully loaded and include benefits and overhead costs (see Attachment F). The details of the calculations are identified in Tables 3 and 4 in this section. The Human Studies Rule requires data submitters to provide information about the ethical conduct of human studies regardless of whether they involve intentional exposure and require EPA to consult with the HSRB (40 CFR 26.1303). The Agency reviews the ethical conduct of such research regardless of the need to consult with the HSRB. For the human research that does not require HSRB review, the EPA assumes that 10 the studies will be submitted by outside parties, and therefore subject to the requirements at 40 CFR 26.1303 to submit information on the ethical conduct at the time of the data submission to the Agency. EPA assumes that an additional 10 human studies that do not require HSRB review will be located by the EPA at the Agency's own initiative and therefore will not be subject to 40 CFR 26.1303. Please note that for the human research that does not require HSRB review, the EPA assumes that 10 of the 20 studies will be located at the Agency's own initiative and therefore

[7] Bureau of Labor Statistics. "May 2025 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 999100 – Federal Executive Branch." Accessed at http://www.bls.gov/oes/current/naics4_999100.htm.

will not be subject to 40 CFR 26.1303. This approach is consistent with that used for this ICR in previous submissions.

Table 3. Weighted average Agency burden and cost estimates for research involving intentional exposure

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $160/hr	Technical $107/hr	Clerical $59/hr	Hours	Cost ($)
Rule familiarization and training	1	2	0	3	$374
Primary Review of Scientific and Ethical Aspects of a Protocol	3	210	0	213	$22,933
Primary Review of Scientific and Ethical Aspects of a Completed Study Report	3	235	0	238	$25,606
Secondary Review of Scientific and Ethical Aspects of a Protocol	197				$4,694*
Secondary Review of Scientific and Ethical Aspects of a Completed Report	197				$4,694*
Store, file, and maintain records	0	0	2	2	$118
Total per response	7	841	2	**850**	**$58,420**

*HSRB members are special government employees; their time should be reflected as part of Agency burden. Cost of HSRB members working on the HSRB report (collectively spending 197 hours per HSRB report in FY 2011, compensated at the rate of $59/hour which is , equivalent to the wage of a special government employee) plus the cost of the EPA Office of the Science Advisor (OSA) technical staff working on the HSRB report (30 hours per report, at the technical staff rate of $82/hour). Each HSRB report covers an average of 2 protocols and/or completed studies per report, so each topic costs an average of $4,694. The HSRB wage was verified in May 2025 with email communication from US EPA Human Resources, where the HSRB wage is equivalent to a GS-15 Step 1. Annual Burden: 850 hours per response x 3 per year = 2,550 hours plus 30 for OSA review of HSRB report = 2,580 hours
Annual Costs: $58,420 x 43 responses/year = $175,259. Please note that the estimated 3 "responses" per year include 3 protocols plus 3 studies. This approach is consistent with that used and approved for this ICR in previous years.

Table 4 shows the annual burden hours and costs for human subjects that do not require HSRB review. Burden hours are determined by rule familiarity and training, primary review of ethical aspects of the final report, and various storage requirements. Annual burden hours were estimated as 6 hours per study multiplied by 20 per year equaling 120 hours. Annual costs are shown as $12,830, which is $642 per response times 20 per year.

Table 4. Weighted Average Agency Burden and Cost Estimates – Research Involving Human Subjects That Does Not Require HSRB Review – All Other Submitted Research with Human Subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $160/hr	Technical $107/hr	Clerical $59/hr	Hours	Cost ($)
Rule familiarization and training	0	0	0	0	0
Primary Review of Ethical Aspects of a Completed Study Report	0	6	0	6	642
Store, file, and maintain records	0	0	0	0	0
Total per response	**0**	**6**	**0**	**6**	**642**

Annual Burden: 6 hours per study x 20 per year = **120 hours**
Annual Costs: 642 x 20 responses/year = **$12,830**

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

There is a decrease of 2,039 in hours in the total estimated respondent burden compared with that identified 8,276 hours in the ICR currently approved by OMB.[8] This decrease is a result of the decrease in anticipated number of respondent responses per year from 4 to 3 for the next three years. These changes are an adjustment.

16. For collections whose results will be published, outline the plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

The Agency does not intend to publish results of this information collection.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

The Agency plans to display the expiration date for OMB approval of the information collection on all instruments.

[8] 2, 039 hours was the individual total response then times it by 3 for the total number of responses submitted each year (2,039 X 3) = total respondent burden is 6,117 annually. Subtract this from the currently approved total burden from the last ICR (8,276 - 6,117) = 2,159 difference in hours.

18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

This information collection complies with all provisions of the Certification for Paperwork Reduction Act Submissions.

SUPPLEMENTAL INFORMATION

PRA Burden Statement

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2070-0169). Responses to this collection of information are mandatory for certain persons, as specified at 40 CFR 26. 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 public reporting and recordkeeping burden for this collection of information is estimated to be 2,039 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Data and Enterprise Programs Division, Deputy Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address."

You can also provide comments to the Office of Information and Regulatory Affairs, Office of Management and Budget via *https://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.

All comments received by EPA will be included in the 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. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

LIST OF ATTACHMENTS AND REFERENCES

The attachments listed below can also be found in the docket for this ICR. The docket for this ICR is accessible electronically through *https://www.regulations.gov* using Docket ID Number: EPA-HQ-OPP-2021-0315.

Attachment	Description
A	Pesticide Submission Portal
B	Consultation Summary

Attachment	Description
C	Methodology and Data Used to Calculate Respondent Burdens and Costs and estimated Wage Rates

References

40 CFR 26 available at *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-A/part-26?toc=1*

40 CFR 169.2 available at *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-169/section-169.2*

Appropriations Act, 2006, Pub. L. No. 109-54 available at *https://www.congress.gov/109/plaws/publ54/PLAW-109publ54.pdf*

FFDCA Sections 408(b)(2)(A)(ii) and 408(e)(1)(c) available at *https://www.regulations.gov/document/EPA-HQ-OPP-2021-0315-0003*

FIFRA Section 3(c)(5), 3(g), 4(g)(2) and 25 available at ***https://www.govinfo.gov/content/pkg/COMPS-10326/pdf/COMPS-10326.pdf***