Supporting Statement for an Information Collection Request (ICR)
Under the Paperwork Reduction Act (PRA)

EXECUTIVE SUMMARY

Identification of the Information Collection – Title and Numbers

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

ICR Numbers: EPA ICR No.: 2195.06, 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). The EPA regulations at 40 CFR part 26 protect subjects of "third-party" human research (i.e., research that is not conducted or supported by the EPA).[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 a cognizant local Human Subjects 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.

This renewal ICR estimates the third-party response burden from complying with the requirements in 40 CFR part 26.

[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

Summary Total Annual Bottom Line Burden

Collection Activity	Annual Burden Hours	Annual Costs
Annual Respondent Burden and Costs		
Research Involving Intentional Exposure of Human Subjects	8,156	$847,205
All Other Submitted Research with Human Subjects	120	$12,010
Respondent Total	**8,276**	**$859,215**
Annual Agency Burden		
Research Involving Intentional Exposure of Human Subjects	3,430	$206,324
All Other Submitted Research with Human Subjects	120	$11,038
Agency Total	**3,550**	**$217,361**

SUPPORTING STATEMENT

1. Explain the circumstances that make the collection of information necessary.

The 2006 Appropriations Act, Public Law No. 109-54, required the EPA to issue a final rule (Attachment A) addressing third-party intentional dosing human toxicity studies for pesticides, and the EPA conduct of intentional dosing human toxicity studies for pesticides (Attachment B). This ICR applies to all the information collection activities identified in the 2006 rule that the EPA promulgated in response to the Congressional mandate, and which amended 40 CFR part 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 generally require the EPA to determine that a pesticide would not present any "unreasonable adverse effects on the environment"[2] 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 generally 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

[2] 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) . . ."

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).

Sections 3(c)(5), 3(g), 4(g)(2), and 25 of FIFRA and sections 408(b)(2)(A)(ii) and 408(e)(1)(C) of FFDCA are included as Supporting Statement attachments C and D, respectively.

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, and to protect the interests, rights and safety of human research subjects, 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 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.

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 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 launched the Pesticide Submission Portal (PSP) 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. 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 document type. The public may request copies of studies that are non-confidential by submitting a Freedom of Information Act (FOIA) request.

4. Describe efforts to identify duplication

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 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 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.

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) 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.

OMB regulations require agencies to provide a statement indicating whether 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 an explanation of the decision (5 CFR 1320.5(a)(iii)(E)).

The EPA encourages respondents who submit study protocols and/or reports to the EPA to submit this information electronically. OPP launched the Pesticide Submission Portal (PSP) 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. The PSP is a critical step in achieving the vision of a fully electronic work environment. If registrants want to submit paper copies or CDs of study data to the EPA, they can still do so. The EPA believes that the promotion and facilitation of the electronic submission option will make its pesticide regulation operations more efficient. This option can increase the efficiency of operations such as the delivery, review, data interchange capability, and archiving of data supporting national pesticide registration. The Agency expects that registrants will spend less time and money preparing copies and sending their submissions using the electronic submission option and stand to benefit from the efficiencies that the EPA expects to experience during data reviews.

8. If applicable, provide a copy and identify the date and page number of publication(s) 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.

Pursuant to 5 CFR 1320.8(d), EPA published a notice in the Federal Register on September 1, 2021 (86 FR 49022; FRL-8735-01-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.

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

1. Agricultural Handler Exposure Assessment Task Force (AHETF) **- Responded**
2. American Chemistry Council/Antimicrobial Exposure Assessment Task Force-II (AEATF-II) **- Responded**
3. Carroll-Loye Labs

The two respondents indicated that the hourly labor rates used by EPA are less than the industry labor rates incurred by the respondents. The burden hours estimated by individual respondents are higher than EPA's average of burden hours in some instances and lower in others. (The respondents' figures are included in Table 1 in Attachment H.) This renewal ICR contains revised estimates that take into account the consultation responses. The two respondents both indicated that they are not planning to submit protocols during the next renewal cycle; one is planning to submit a single completed study report based on a previously-reviewed protocol. The renewal ICR revises the expected number of submissions during the next cycle based on this information.

For an explanation of the methodology, data, and assumptions used to calculate the revised estimated respondent burdens and costs, see Attachment I. Additionally, 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. The consultation participants explained that the instructions to respondents on what to submit and how to submit it would not be entirely clear to respondents who are

new to the process and one respondent suggested that information provided to respondents could be improved by asking for sufficient details.

Stakeholders suggested revisions to EPA's burden estimates in Table 1, Respondent Burden Estimates.

Stakeholders indicated that EPA's estimates for wage rates were significantly lower than the wage rates for consultants hired by each entity. However, neither stakeholder provided an alternative North American Industry Classification System (NAICS_ code for EPA to consider. Although respondents would prefer that EPA use industry labor rates, using the Bureau of Labor Statistics' BLS data allows EPA to be consistent between across sectors and occupations. If OPP were to separately research wages for each ICR, the methodology in determining the wages would not be consistent and the wage rates could not be compared between sectors and occupations. Some wages would be biased high, while others would be biased low. The BLS wages are categorized by NAICS codes, and therefore are industry specific. They are, however, national averages. Therefore, some of the high wages earned by specialists in high-cost localities are offset by others who are less specialized in lower cost localities.

Although respondents would prefer that the EPA use industry labor rates, using the BLS data allows the EPA to be consistent between across sectors and occupations. If OPP were to separately research wages for each ICR, the methodology in determining the wages would not be consistent and the wage rates could not be compared between sectors and occupations. Some wages would be biased high, while others would be biased low. The BLS wages are categorized by North American Industry Classification System (NAICS) codes, and therefore are industry specific. They are, however, national averages. Therefore, some of the high wages earned by specialists in high-cost localities are offset by others who are less specialized in lower cost localities.

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

This question is not applicable to this ICR

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

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.

No information of a sensitive or private nature is requested in conjunction with these information collection activities, and these information collection activities comply with the provisions of the Privacy Act of 1974 and OMB Circular A-108, as amended, "Responsibilities for the Maintenance of Records about Individuals by Federal Agencies.

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

The EPA is estimating only the incremental burden imposed upon respondents for compliance with the paperwork requirements established in the 2006 final rule. 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 under FIFRA section 3(c)(2)(B). The EPA assumes that IRBs are already in compliance with the current Common Rule requirements and therefore believes that there is no additional burden imposed upon IRBs for compliance with the paperwork requirements established in the 2006 final rule and discussed in this document.

Over the three-year period covered by this ICR renewal (September 2021 through August 2024), based on historical data analysis, respondents' planned submissions in the next ICR cycle, and knowledge of other upcoming submissions, the EPA estimates that respondents will submit to OPP an average of 4 pesticide protocols and 4 completed studies per year under FIFRA and/or FFDCA that will 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. Based on past experience, the EPA also expects to receive other types of pesticide research involving human subjects; an average of 10 of these types of studies may be submitted annually. 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 2006 final rule.

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 2006 final 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.

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 consultation with respondents.

As shown in Tables 1 and 2, the total annual estimated burden associated with all submitted pesticide research that involves intentional exposure of human subjects is 8,156 hours, and 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 8,276 hours.

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 Per Response	
	Management $195/hr	Technical $99/hr	Clerical $59/hr	Hours	Cost ($)
Rule familiarization and training	6	7	5	18	$2,155
Prepare and submit protocol for IRB review	18	83	13	114	$12,469
Prepare and submit protocol for review by the EPA and the HSRB	68	334	28	430	$47,886
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	$145,481
Store, file, and maintain records	7	20	8	35	$3,810
Total per response	154	1773	111	**2,039**	**$211,801**

Annual Burden: 2,039 hours per response * 4 responses per year = **8,156 hours**
Annual Costs: $211, 801 per response * 4 responses per year = **$847,205**

Please note that the 4 “responses” per year include 4 protocols plus 4 studies. This approach to defining responses is consistent with that used and approved for this ICR in previous years.

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 $195/hr	**Technical $99/hr**	**Clerical $59/hr**	**Hours**	**Cost ($)**
Rule familiarization and training	1	1	0	2	$294
Prepare and submit ethics information of completed human studies to the EPA	0	8	1	9	$848
Store, file, and maintain records	0	0	1	1	$59
Total per response	**1**	**9**	**2**	**12**	**$1,201**

Annual Burden: 12 hours per study * 10 studies submitted per year = **120 hours**
Annual Costs: $1,201 per study * 10 studies submitted per year = **$12,010**

The estimated annual cost for all respondents is $859,215 (Table 1 [$847,205] and 2 [$12,010]). Respondent labor rates are estimated to be $195, $99, and $59 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. The labor rates were derived from the Bureau of Labor Statistics' May 2020 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences).[3] These labor rates are fully loaded and include benefits and overhead costs (Attachment E).

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

There are no operational and/or maintenance costs.

14. Provide estimates of annualized cost to the Federal government.

The estimated Agency annual cost is $372,104. 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

[3] Bureau of Labor Statistics. "May 2020 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.

the submissions. The Agency labor rates are $139, $92, and $51 per hour for management, technical, and clerical staff, respectively. The labor rates were derived from the Bureau of Labor Statistics' May 2020National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 999100 (Federal Executive Branch).[4] 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. For the pre-rule human research which does not require HSRB review, the EPA assumes that 10 of the studies will be submitted by outside parties and the remaining 10 will be located by the EPA at the Agency's own initiative and therefore will not be subject to 40 CFR 26.1303.

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

Activities	**Average Burden Hours Per Response**			**Total Per Response**	
	Management $139/hr	**Technical $92/hr**	**Clerical $51/hr**	**Hours**	**Cost ($)**
Rule familiarization and training	1	2	0	3	$323
Primary Review of Scientific and Ethical Aspects of a Protocol	3	210	0	213	$19,734
Primary Review of Scientific and Ethical Aspects of a Completed Study Report	3	235	0	238	$22,034
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	$ 102
Total per response	7	841	2	**850**	**$51,581**

*****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 2020 rate of $59/hour), plus the cost of the EPA Office of the Science Advisor (OSA) technical

[4] Bureau of Labor Statistics. "May 2020 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 999100 – Federal Executive Branch." Accessed at http://www.bls.gov/oes/current/naics4_999100.htm.

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.
Annual Burden: 850 hours per response x 4 per year = 5,950 hours plus 30 for OSA review of HSRB report = 5,980 hours

Annual Costs: $51,581 x 4 responses/year = $206,324

Please note that the estimated 4 "responses" per year include 4 protocols plus 4 studies. This approach is consistent with that used and approved for this ICR in previous years.

Table 4. Weighted Average Agency Burden and Cost Estimates – Research Involving Intentional Exposure – All Other Submitted Research with Human Subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $139/hr	Technical $92/hr	Clerical $51/hr	Hours	Cost ($)
Rule familiarization and training	0	0	0	0	0
Primary Review of Ethical Aspects of a Completed Study Report	0	6	0	6	552
Store, file, and maintain records	0	0	0	0	0
Total per response	**0**	**6**	**0**	**6**	**552**

Annual Burden: 6 hours per study x 20 per year = **120 hours**

Annual Costs: 552 x 20 responses/year = **$11,038**

Please note that, for the pre-rule 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 will not be subject to 40 CFR 26.1303. This approach is consistent with that used for this ICR in previous submissions.

15. Explain the reasons for any program changes or adjustments reported in Items 13 (or 14) of OMB Form 83-I.

The total annual estimated respondent burden is expected to decrease by 1,966 hours from 10,242 hours for the currently approved ICR to 8,276 hours for this renewal ICR. There is a slight increase in estimated annual respondent burden associated with preparation of protocols and studies; the increase reflects the comments from stakeholders. The anticipated number of responses per year has decreased from five per year to four per year based on the consultation responses in Attachment H, submissions to the Agency in the recent past, and recognition that some of the studies underway will be submitted prior to the start of the ICR renewal period. EPA took into account time estimates obtained during the consultation process. During the comment period for this ICR, the Agency consulted with respondents who intend to submit human research in the future and have submitted studies in the past. The anticipated number

of responses per year has decreased based on the conclusion of the work of one task force conducting human studies and one outstanding study from the other task force that has been responsible for the majority of submissions to the Agency in the recent past. The annual burden per activity is estimated to be 2,031 hours per response for research involving intentional exposure of human subjects, and 12 hours per response for all other submitted research with human subjects.

The overall estimated annual Agency burden is expected to decrease slightly due to the number of responses which we expect to receive during the timeframe for this ICR renewal, the nature of the research to be submitted and reviewed over the next three years, and the involvement of staff who will be new to the process of reviewing human research.

16. For collections whose results will be published, outline the plans for tabulation and publication.

A periodic collection schedule is not appropriate for the information collection activity. The information collection activity is initiated by the respondents and therefore the EPA expects that respondents will engage in the activities described in this ICR only once, whenever developing and performing a given research study that involves human subjects as governed by the EPA's regulations.

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.

This question not applicable to this ICR.

18. Explain each exception to the certification statement identified in Item 19 of OMB Form 83-I.

EPA does not request an exception to the certification of this information collection.

SUPPLEMENTAL INFORMATION

Annual respondent burden for this collection of Human Subjects information requirements is estimated to average 1,446 hours per response involving intentional exposure of human subjects, and 12 hours per response for all other submitted research with human subjects. Burden is defined at 5 CFR 1320.3(b). This estimate includes the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Under PRA, 44 U.S.C. 3501 *et seq*., 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 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.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OPP-2021-0315, which is available at http://www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the Docket ID Number identified above.

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

Please note that due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

LIST OF ATTACHMENTS

The attachments listed below can be found in the docket for this ICR or by using the hyperlink that is provided in the list below. The docket for this ICR is accessible electronically through http://www.regulations.gov using Docket ID Number: EPA-HQ-OPP-2021-0315.

Attachment	Description
A	**Final Rule – 2006 Amendment of 40 CFR part 26; Protections for Test Subjects in Human Research**
B	**Appropriations Act, 2006, Pub. L. No. 109-54**

Attachment	Description
C	FIFRA Sections 3(c)(5), 3(g), 4(g)(2), and 25
D	FFDCA Sections 408(b)(2)(A)(ii) and 408(e)(1)(C)
E	Estimated Wage Rates for Pesticide Registrants Using BLS NAICS 541710
F	Standard Wages for the Federal Government Using BLS NAICS 999100
G	Display Related to OMB Control #2070-0169 -Listings of Related Regulations in 40 CFR 9.1
H	Consultation Summary
I	Explanation of Methodology and Data Used to Calculate Respondent Burdens and Costs