

**Supporting Statement for  
An Information Collection Request (ICR)**

**1. IDENTIFICATION OF THE INFORMATION COLLECTION**

**1(a). Title and Number of the Information Collection**

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

OMB Control No.: **2070-0169**

EPA ICR No.: **2195.05**

Docket ID No.: **EPA-HQ-OPP-2015-0713**

**1(b). Short Characterization**

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). As revised in 2006 and 2013, EPA regulations at 40 CFR Part 26 protect subjects of “third-party” human research (i.e., research that is not conducted or supported by EPA).<sup>1</sup> 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 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 dosing of human subjects, these individuals (respondents) are required to submit study protocols to 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 EPA.

This renewal ICR estimates the third party response burden from complying with the requirements in 40 CFR Part 26, as amended in 2006 and 2013.

**2. NEED FOR AND USE OF THE COLLECTION**

**2(a). Need/Authority for the Collection**

The 2006 Appropriations Act, Public Law No. 109-54, required EPA to issue a final rule addressing third-party intentional dosing human toxicity studies for pesticides, and EPA conduct of intentional dosing human toxicity studies for pesticides (Attachment B). This ICR applies to all of the information collection activities identified in the 2006 rule that EPA promulgated in response to the Congressional mandate and which amended 40 CFR Part 26. The 2013 revisions

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1 To access the revised regulation go to: <http://www.gpo.gov/fdsys/pkg/FR-2013-02-14/html/2013-03456.htm>

do not change information provided in this ICR because the revisions did not result in changes to the information collection activities and related burden estimates. 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 EPA to determine that a pesticide would not present any "unreasonable adverse effects on the environment"<sup>2</sup> 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 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." 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 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(b). Practical Utility/Users of the Data**

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 EPA extended the requirements of the Agency's 1991 Common Rule, 40 CFR Part 26, prospectively to third-party research intended for submission to EPA under the pesticide laws and involving intentional exposure of non-pregnant, non-nursing adult human subjects. The information provided allows 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 EPA a report of research with human subjects must submit concurrently documentation of the ethical conduct of the research. This information collection activity allows EPA to ensure all human subjects in research conducted by EPA (first party), conducted by entities with support from EPA (second parties), or conducted by third parties with the intention to submit it to EPA, are treated ethically.

## **3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA**

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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) . . ."

### **3(a). Non 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 EPA.

### **3(b). Public Notice Prior to ICR submission to OMB**

Pursuant to 5 CFR 1320.8(d), EPA published a Federal Register (FR) Notice on December 24, 2015 (80 FR 80360) soliciting comment on this information collection activity and the Agency's intent to renew the OMB approval of this ICR. No comments were submitted to EPA solely in reaction to the FR Notice but comments were submitted in response to the associated consultation process, described next. The FR Notice and the renewal ICR are located in the docket for this action, which can be accessed at: <http://www.regulations.gov> using the docket ID number EPA-HQ-OPP-2015-0713.

### **3(c). Consultations**

During preparation of this ICR renewal, EPA staff contacted three representatives to seek feedback on the burden estimates in the ICR and the clarity of guidance provided. This is the same process used for past ICR submissions. Two of the three representatives, listed below, responded and provided feedback. Due to his workload, the third representative was unable to provide feedback in response to EPA's request for consultation.

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Respondents' answers to EPA's consultation questions are provided in Attachment H.

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 which takes into account the different types of studies to be reviewed, in addition to the estimated burden hours submitted by the respondents. (The methodology for revised labor rates are included in Attachment H; the

respondents' figures are in Table 1 of this attachment.) Section 6 of this renewal ICR contains revised estimates that take into account the consultation responses.

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 forms could be improved by asking for sufficient details.

### **3(d). Effects of Less Frequent Collection**

Not applicable. This is an event-driven information collection activity and is conducted only as information is submitted to 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.

### **3(e). General 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. 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 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 not be 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 IRBs and third-party researchers; 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)).

Respondents who submit study protocols and/or reports to EPA may elect to submit certain eligible 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 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 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 EPA, they can still do so. 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 EPA expects to experience during data reviews.

**3(f). Confidentiality**

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 EPA's CBI regulations at 40 CFR Part 2, Subpart B.

**3(g). Sensitive Questions**

This information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108. No information of a sensitive or private nature is requested in conjunction with this information collection activity. The protection of human research subjects' privacy is a basic, long-standing principle within the scientific community. Reports of human research submitted to federal agencies should not identify subjects by name, or include recognizable photographs, or otherwise identify them. On the rare occasion that the Agency receives identifying information, such information will be treated as confidential and not released to third parties unless required by law.

**4. THE RESPONDENTS AND THE INFORMATION REQUESTED**

**4(a). Respondents/NAICS Codes**

This collection of information applies to any entity that submits to EPA protocols and study reports for environmental research involving human subjects under FIFRA and/or FFDCA. Although EPA has only received such third-party research in conjunction with FIFRA from pesticide registrants, it is conceivable that other entities could submit such information to EPA under FIFRA and/or FFDCA in the future. The North American Industrial Classification System (NAICS) code for the principal respondents to this ICR is 541710 (Research and Development in the Physical, Engineering, Life Sciences).

**4(b). Information Requested**

**(i) Data items, including record keeping requirements**

The regulation sets forth those additional information activities that are necessary to ensure the protection of human subjects of research when such research is submitted to EPA for consideration under FIFRA and/or FFDCA.

**(ii) Respondent Activities**

The following information activities are required:

- *Rule Familiarization and Training* - read, and understand what data are to be submitted and understand the protocols must be developed to comply with the Common Rule.
- *Submit Protocol to an IRB and EPA* – Prepare and submit a proposal for test protocol to IRB for review. After approval by the IRB, submit the proposal and related documentation, including a record of the IRB approval, to EPA.
- *Prepare and Submit Ethics Information for EPA Review* - once a study is conducted, compile applicable records to document ethical conduct of the research.
- *Store, File and Maintain Information* – ensure that research information is placed in central records as required by FIFRA and consistent with section 3(e) of this ICR.

**5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT**

**5(a). Agency Activities**

EPA's information-related activities associated with this collection consist of the following:

- *Conduct Prior Review on Study Protocol* – review and comment on study protocol, document comments/review.
- *Review Ethical Aspect of a Protocol and Study Report* – make formal EPA determination on usefulness and ethical aspects of the study.
- *Record and Report Information* – Document any formal decisions made.
- *Store, File and Maintain Information* – compile information into appropriate databases and archive.

**5(b). Collection Methodology and Management**

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 more timely and accurately to queries from registrants and the public, including requests made under the FOIA.

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 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 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 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 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

#### **5(c). Small Entity Flexibility**

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 EPA's consideration on human research in its various program offices, 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, EPA has not provided any special flexibility for small entities.

#### **5(d). Collection Schedule**

A periodic collection schedule is not appropriate for the information collection activity. The information collection activity is initiated by the respondents and therefore 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 EPA's regulations.

### **6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION**

The activities imposed by the rule consist of reporting and record-keeping requirements. Respondents' activities are detailed in Section 4(b)(ii) of this ICR. The burden and cost estimates for this renewal ICR were calculated using recent data on submissions of human research and averages of time estimates provided by respondents during the consultation period, taking into account the range of protocols and studies to be submitted. Section 6(a) of this ICR explains the methodology used to calculate the respondent burden, and burden and cost estimates are listed in Tables 1, 2 and 5. EPA's burden estimates and methodology are detailed in Section 6(c). Consultation with respondents occurred during the public comment period on the draft and the results of that consultation were taken into account, as appropriate, in the final ICR burden calculations.

### **6(a). Estimating Respondent Burden**

EPA is estimating only the incremental burden imposed upon respondents for compliance with the paperwork requirements established in the 2006 final rule. 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 EPA in a Data Call-In under FIFRA section 3(c)(2)(B). EPA does assume that IRBs are already in compliance with the 1991 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 2016 through August 2019), based on historical data analysis and knowledge of upcoming submissions, EPA estimates that respondents will submit to OPP an average of 7 pesticide protocols and 7 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, 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 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 EPA's amendments. Therefore, 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 IRB, EPA, and HSRB review; communicating with IRB and EPA staff regarding required changes to a protocol; communicating with EPA about HSRB recommendations; and documenting protocol changes made at the recommendation of an IRB, EPA, or the HSRB. Activities which 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, 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 10,122 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 10,242 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 \$168/hr	Technical \$87/hr	Clerical \$50/hr	Hours	Cost (\$)
Rule familiarization and training	3	4	3	10	\$1,002
Prepare and submit protocol for IRB review	11	83	13	107	\$9,719
Prepare and submit protocol for EPA and HSRB review	35	168	16	219	\$21,296
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol; prepare and submit completed study for IRB, EPA, and HSRB review	43	987	51	1,081	\$95,643
Store, file, and maintain records	6	15	8	29	\$2,713
<b>Total per response</b>	98	1,257	91	<b>1,446</b>	<b>\$130,373</b>

Annual Burden: 1,446 hours per response \* 7 responses per year = **10,122 hours**

Annual Costs: \$130,373 per response \* 7 responses per year = **\$912,611**

Please note that the 7 “responses” per year include 7 protocols plus 7 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 \$168/hr	Technical \$87/hr	Clerical \$50/hr	Hours	Cost (\$)

Rule familiarization and training	1	1	0	2	255
Prepare and submit ethics information of completed human studies to EPA	0	8	1	9	746
Store, file, and maintain records	0	0	1	1	50
<b>Total per response</b>	1	9	2	<b>12</b>	<b>1051</b>

Annual Burden: 12 hours per study \* 10 studies submitted per year = **120 hours**

Annual Costs: \$1051 per study \* 10 studies submitted per year = **\$10,510**

### 6(b). Estimating Respondent Costs

The estimated annual cost for all respondents is \$923,121. Respondent labor rates are estimated to be \$168, \$87, and \$50 per hour, respectively, for managerial, technical and clerical labor. In determining the rates, OPP uses a single source of data, the Bureau of Labor Statistics' (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 2014 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences).<sup>3</sup> These labor rates are fully loaded and include benefits and overhead costs (see Attachment E).

Although respondents would prefer that EPA use industry labor rates, using the 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 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.

### 6(c). Estimating Agency Burden and Cost

The estimated Agency annual cost is \$338,854. EPA 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. Agency labor rates are \$124, \$82, and \$46 per hour for management, technical, and clerical staff, respectively. The labor rates were derived from the Bureau of Labor Statistics' May 2014 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 999100 (Federal

<sup>3</sup> Bureau of Labor Statistics. "May 2014 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](http://www.bls.gov/oes/current/naics5_541710.htm).

Executive Branch).<sup>4</sup> 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, EPA assumes that 10 of the studies will be submitted by outside parties and the remaining 10 will be located by 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 \$124/hr	Technical \$82/hr	Clerical \$46/hr	Hours	Cost (\$)
Rule familiarization and training	1	2	0	3	\$288
Primary Review of Scientific and Ethical Aspects of a Protocol	3	210	0	213	\$17,592
Primary Review of Scientific and Ethical Aspects of a Completed Study Report	3	235	0	238	\$19,642
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	\$ 92
<b>Total per response</b>	<b>7</b>	<b>841</b>	<b>2</b>	<b>850</b>	<b>\$47,002</b>

\* 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 2014 rate of \$59/hour), plus the cost of 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 3 protocols and/or completed studies per report, so each topic costs an average of \$4,694.

Annual Burden: 850 hours per response x 7 per year = 5,950 hours plus 30 for OSA review of HSRB report = **5,980 hours**

Annual Costs: 47,002 x 7 responses/year = **\$329,014**

4 Bureau of Labor Statistics. "May 2014 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 999100 – Federal Executive Branch." Accessed at [http://www.bls.gov/oes/current/naics4\\_999100.htm](http://www.bls.gov/oes/current/naics4_999100.htm).

Please note that the estimated 7 “responses” per year include 7 protocols plus 7 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 \$124/hr	Technical \$82/hr	Clerical \$46/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	492
Store, file, and maintain records	0	0	0	0	0
<b>Total per response</b>	0	6	0	<b>6</b>	<b>492</b>

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

Annual Costs: 492 x 20 responses/year = **\$9,840**

Please note that, as discussed in section 6(c), for the pre-rule human research which does not require HSRB review, 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.

#### 6(d). Bottom Line Burden Hours and Cost Tables

The total estimate represents the information collection activities expected to occur annually over the next three years. Table 5 provides the total estimated annual burden and costs for respondents, as well as the total estimated annual burden and costs for the Agency:

**Table 5.** Total Annual Bottom Line Burden and Costs/Master Table

<b>Collection Activity</b>	<b>Annual Burden Hours</b>	<b>Annual Costs</b>
<i>Annual Respondent Burden and Costs</i>		
Research Involving Intentional Exposure of Human Subjects (Table 1)	10,122	\$912,611
All Other Submitted Research with Human Subjects (Table 2)	120	\$10,510
<b>Respondent Total</b>	<b>10,242</b>	<b>\$923,121</b>
<i>Annual Agency Burden</i>		
Research Involving Intentional Exposure of Human Subjects (Table 3)	5,980	\$329,014
All Other Submitted Research with Human Subjects (Table 4)	120	\$9,840
<b>Agency Total</b>	<b>6,100</b>	<b>\$338,854</b>

#### 6(e). Reasons for Change in Burden

The total annual estimated respondent burden is expected to decrease by 4,711 hours from 14,953 hours for the currently approved ICR to 10,242 hours for this renewal ICR. There is a slight decrease in estimated annual respondent burden associated with preparation of protocols and studies; this is due, in part, to the fact that new agricultural handler exposure protocols, which involve extensive preparation, are not expected during this ICR renewal period. The anticipated number of responses per year is based on the consultation responses in Attachment I, 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. In response to new information obtained by EPA during the consultation process, the Agency updated its burden calculations and supporting statement. The overall estimated annual Agency burden is expected to increase 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 from both the science and ethics perspectives.

#### 6(f) . Burden Statement

The total estimated annual paperwork burden for respondents to comply with this information collection activity is 10,242 hours. The annual burden per activity is estimated to be 1,446 hours per response for research involving intentional exposure of human subjects, and 12

hours per response for all other submitted research with human subjects.

In the context of the PRA, “burden” is defined at 5 CFR 1320.3(b). The 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 number for this information collection appears at the beginning and end of this document.

The Agency has established a docket for this ICR under Docket ID No. EPA-HQ-OPP-2015-0713, which is available at <http://www.regulations.gov>, or in person viewing at the OPP Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. This docket facility is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the reading room is 202-566-1744, and the docket telephone number is 703-305-5805.

You may submit comments regarding 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. Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2015-0713 and OMB Control No. 2070-0169, to (1) both EPA and OMB as follows:

- To EPA online using <http://www.regulations.gov> (our preferred method,) or by mail to: EPA Docket Center, Environmental Protection Agency Docket Center (EPA/DC), Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and

- To OMB by email to: [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). Address comments to *OMB Desk Officer for EPA*.

These addresses are for your comments - do not submit the information requested in this ICR to these addresses.

## 7. **Attachments List: Supporting Statement (EPA-HQ-OPP-2015-0713)**

Attachments to the supporting statement are available in the public docket established for this ICR under docket ID No. EPA-HQ-OPP-2015-0713. These attachments are available for online viewing at <http://www.regulations.gov> or otherwise accessed as noted below.

- Attachment A:** Final Rule - 2006 Amendment of 40 Part 26; Protections for Test Subjects in Human Research
- Attachment B:** Appropriations Act, 2006, Pub. L. No. 109-54
- Attachment C:** FIFRA Sections 3(c)(5), 3(g), 4(g)(2), and 25
- Attachment D:** FFDCA Sections 408(b)(2)(A)(ii) and 408(e)(1)(C)
- Attachment E:** Estimated Wage Rates for Pesticide Registrants Using BLS NAICS 541710

**Attachment F:** Standard Wages for the Federal Government Using BLS NAICS 999100

**Attachment G:** Display Related to OMB Control #2070-0169 -Listings of Related Regulations in 40 CFR 9.1

**Attachment H:** Consultation Responses

**Attachment I:** Explanation of Methodology and Data Used to Calculate Respondent Burdens and Costs