

EPA ICR No. 2195.06

OMB Control No. 2070-0169

Attachment I

Explanation of Methodology and Data Used to Calculate Respondent Burdens and Costs

Burden Hours for Respondents

As required, EPA sent consultation questions about the burden and cost estimates to three respondents – the Agricultural Handler Exposure Task Force (AHETF), the Antimicrobial Exposure Assessment Task Force II (AEATF), and another third-party study sponsor who has conducted human research studies. The three organizations are experienced in submitting human research to the Office of Pesticide Programs (OPP). The workload of one organization did not allow for a response to EPA’s request. Consultation responses were received from AHETF and AEATF and are provided in Attachment H. To calculate new burden and cost estimates for this renewal ICR, EPA relied upon the estimates provided in the two consultation responses and knowledge of the range of protocols/studies to be submitted for review. EPA calculated an average of the different responses, recognizing that some study types are more complicated and costly to conduct than others.

The respondent burden and cost estimates that appear in Table 1 in the ICR, for research involving intentional exposure of human subjects, are the averages of the values in Table A (burden hour estimates for agricultural handler studies, from the AHETF’s consultation response) and Table B (burden hour estimates for antimicrobial exposure studies, from the AEATF’s consultation response). For activities where the AHETF did not include a burden estimate because they do not anticipate performing the activity during the next cycle, their response was not included in calculating the average. The consultation responses influenced the expected annual number of studies used in the calculations.

Hourly Rates for Respondents

The two respondents indicated that the hourly rates used by EPA for calculating the estimated costs are too low. In determining the rates, OPP uses a single source of data, the Bureau of Labor Statistics’ National Industry-Specific Occupational Employment and Wage Estimates and selects the appropriate occupational category. 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.

To estimate costs for regulated entities for this renewal ICR, EPA used wage rates from NAICS 541710 (Research and Development in the Physical, Engineering, and Life Sciences). The BLS fully-loaded hourly rates for this industry are \$195/hour for

management, \$99/hour for technical staff, and \$59/hour for clerical staff.

Agency Burden and Costs

The estimated burden and costs to the Agency are derived from input from EPA staff members who have prepared reviews for studies that were presented to the HSRB. Recognizing that some study types are more complicated and time consuming to review than others, EPA calculated a weighted average using the staff time estimates and the expected frequency of receiving different types of studies. The weighted averages are provided in ICR Tables 3 and 4. The wage rates EPA used to estimate Agency costs for this renewal ICR were from NAICS 999100 (Federal Executive Branch). The BLS fully-loaded hourly rates for Agency staff are \$139/hour for management, \$92/hour for technical staff, and \$51/hour for clerical staff.

Number of Transactions

The estimated number of transactions is based on the responses from the two respondents received during the recent consultation, information on other types of studies received during the previous consultation, EPA's historical experience, and knowledge of upcoming submissions.

RESPONDENT BURDEN HOUR ESTIMATES**Table A. Agricultural Handler Exposure Studies – Burden Hour Estimates from AHETF’s Consultation Response**

Activities	Average Burden Hours Per Occurrence			Total Per Response		
	Mgt \$195	Technical \$99	Clerical \$59	Total Hours	Cost (\$) Estimated by EPA	Actual Cost (\$) to
Rule familiarization and training (per protocol)	0	0	0	0	0	0
Prepare and submit protocol for IRB review	0	0	0	0	0	0
Prepare and submit protocol for EPA and HSRB review	0	0	0	0	0	0
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol	65	2,000	60	2,125	196,077	213,661
Store, file, and maintain records	5	5	5	15	1,412	1,762
TOTALS	70	2,005	65	2,140	197,489	215,424

Table B. Antimicrobial Exposure Studies – Burden Hour Estimates from AEATF’s Consultation Response

Activities	Average Burden Hours Per Occurrence			Total Per Response		
	Management \$195	Technical \$99	Clerical \$59	Total Hours	Cost (\$) Based on EPA Nos.	Based on Industry Cost (\$)
Rule familiarization and training (per protocol)	8	10	7	25	\$2,392	\$2,959
Prepare and submit protocol for IRB review	25	225	30	280	\$25,708	\$28,851
Prepare and submit protocol for EPA and HSRB review	100	500	40	640	\$61,970	\$71,223
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol	60	1,000	60	1,120	\$103,400	\$113,956
<i>Prepare and submit final report for EPA and HSRB review*</i>						

Store, file, and maintain records	10	40	10	60	\$5,583	\$6,487
TOTALS	203	1,775	147	2,125	\$199,052	\$223,476

Note: EPA combined the two figures in the shaded rows 4 and 5 above in order to fully reflect the respondent's input. This was necessary because the respondent added row 5* (above) entitled "prepare and submit final report for EPA and HSRB review." From EPA's perspective, row 4 is the essential activity in light of the required activities encompassed by this ICR and the language in the federal rule on protection of human subjects. Nonetheless, EPA combined the two figures in the shaded rows 4 and 5 above to fully reflect the respondent's input.

Table D. Documentation of Ethical Conduct of a Completed Study for which EPA and HSRB have NOT reviewed the Protocol (per requirements at §26.1303) – Using information compiled during previous ICR renewal process

Activities	Average Burden Hours Per Occurrence			Total Per Response	
	Management \$139	Technical \$92	Clerical \$51	Hours	Cost
Document ethical conduct of a completed study for which EPA and the HSRB have not reviewed the protocol	2	24	2	28	2,588

Table 1. Average Burden and Cost Estimates for Respondents – Research Involving Intentional Exposure of Human Subjects

Note: This table takes into account the different types of studies submitted for review.

Activities	Average Burden Hours Per Response			Total Per Response	
	Management \$195	Technical \$99	Clerical \$59	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 EPA and HSRB review	68	334	28	430	\$47,886
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol; prepare and submit	56	1,329	57	1,442	\$145,481

completed study for IRB, EPA, and HSRB Review					
Store, file, and maintain records	7	20	8	35	\$3,810
Total per response	155	1,773	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**

Table 2. Respondent Burden and Cost Estimates – All Other Submitted Research with Human Subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management \$195	Technical \$99	Clerical \$59	Hours	Cost (\$)
Rule familiarization and training	1	1	0	2	\$294
Prepare and Submit Ethics Information of Completed Human Studies to 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**

Agency Burden Hour Estimates -

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	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	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 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 4 per year = 3,400 hours plus 30 for OSA review of HSRB report = **3,430 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 definition of responses is consistent with that used and approved for this ICR in previous years.

Table 4. Weighted Average Burden and Cost Estimates for Agency – 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: 492 x 20 responses/year = **\$11,038**

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 previously for this ICR.

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

Collection Activity	Annual Burden Hours	Annual Costs
<i>Annual Respondent Burden and Costs</i>		
Research Involving Intentional Exposure of Human Subjects (Table 1)	8,156	\$847,205
All Other Submitted Research with Human Subjects (Table 2)	120	\$12,010
Respondent Total	8,276	\$859,215
<i>Annual Agency Burden</i>		
Research Involving Intentional Exposure of Human Subjects (Table 3)	3,430	\$206,324
All Other Submitted Research with Human Subjects (Table 4)	120	\$11,038
Agency Total	3,550	\$217,362

Number of Transactions: September 2012 – August 2015

Intentional Exposure Studies

1. **AHETF Monitoring Program**
 - See the consultation responses in Attachment H.
 - In Table 2 of consultation responses, AHETF estimates 2 completed studies per year for FY 17 and FY 18.
 - **Figures used in ICR: 2 “transactions” per year**

2. **AEATF Monitoring Program**
 - See the consultation responses in Attachment H.
 - In Table 2 of consultation responses, AEATF estimates 4 protocols in FY 2017, 3 studies in FY 2017, and 1 study in FY 2018, for a total of 8 over 3 years.
 - **Figures used in ICR: 2 “transactions” per year (2 protocols + 2 completed study reports)**

3. **Insect Repellent Efficacy Testing**
 - **Figures used in ICR: 2 “transactions” per year (2 protocols + 2 completed study reports)**

4. **Other Post-Rule Studies**
 - These could include exposure studies from sources other than the task forces, ADME studies, skin patch tests of irritation or sensitization, systemic toxicity tests, or others.
 - All would require submission of a protocol before execution and of a completed report after execution; both the protocol and the report would require EPA and HSRB review.
 - **Estimate: 1 protocol and 1 completed study per year.** (This is likely an over-estimate)

Studies which are Not Intentional Exposure

5. **Pre-Rule Completed Studies which do not measure or identify a toxic effect**
 - These studies do not go to the HSRB, but they do require an EPA ethics review. Historical level: 20 reviews per year.
 - Assume workload to remain constant over the time period of the ICR
 - **Estimate: 20 per year** (estimated that 10 studies/year are submitted from outside parties, and therefore subject to the requirements of 40 CFR 26.1303 requiring submitters to document the ethical conduct; estimated that 10 studies/year are located by the Agency at its own initiative, and therefore not subject to 40 CFR 26.1303)

TOTAL RESPONSES PER YEAR TO BE USED IN ICR ESTIMATES:

- **7 intentional exposure human studies** (rule familiarization + protocol stage where applicable + completed report stage + records storage)
- **20 studies/year** requiring EPA ethics review, but not HSRB review (pre-rule studies that do not measure or identify a toxic effect)