UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

SUBJECT: Information Collection Request (ICR) for the Human Studies Rule
Calculation of Burden and Cost

TO: File

FROM: Kelly Sherman
Human Research Ethics Reviewer
Office of Pesticide Programs

DATE: March 27, 2012

Burden Hours for Respondents

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 Carroll-Loye Biological Research (CLBR). These three organizations are experienced in submitting human subjects research to OPP, and are expected to make additional submissions over the next several years. The consultation responses received from these respondents indicated that EPA's previous estimates of the burden and cost were too low. To calculate new burden and cost estimates for this renewal ICR, EPA relied upon the estimates provided in the three consultation responses. EPA calculated a weighted 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 weighted averages of the values in Table A (burden hour estimates for agricultural handler studies, from the AHETF's consultation response), Table B (burden hour estimates for antimicrobial exposure studies, from the AEATF's consultation response), and Table C (burden hour estimates for insect repellant studies, from CLBR's consultation response). The weighted average was calculated by multiplying the burden hour estimates that appear in Tables A, B, and C by the expected number of each type of study, and then dividing the sum of those products by the total number of studies of all types expected per year. The expected number of studies per year was also determined from the consultation responses.

The respondent burden and cost estimates that appear in Table 2 in the ICR, for all other submitted research with human subjects, are based on the consultation response from Joel Panara at Grayson in 2008. Mr. Panara is familiar with submitting completed study reports to EPA for pre-rule research for which HSRB protocol review is not required, and his consultation response was based on his billing records for work performed on several studies to generate the reports necessary to meet the requirements of the rule. None of these types of studies was submitted to EPA over the past three years, so Mr. Panara's estimates from the previous ICR renewal process are still the most accurate prediction of costs.

Hourly Rates for Respondents

Two of the three 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.

The wage rates EPA used to estimate costs for regulated entities for this renewal ICR were from NAICS 541710 (Research and Development in the Physical, Engineering, and Life Sciences). The BLS fully-loaded hourly rates for this industry are $153/hour for management, $79/hour for technical staff, and $45/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 that others, EPA calculated a weighted average using the staff time estimates and the expected frequency of receiving different types of studies. The values calculated based on the staff input appear in Tables E and F. 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 $120/hour for management, $71/hour for technical staff, and $45/hour for clerical staff.

Number of Transactions

The estimated number of transactions is based heavily on the consultation responses from the three respondents, as well as 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	
	Management $153	Technical $79	Clerical $45	Hours	Cost ($)
Rule familiarization and training	5	5	5	15	1,385
Prepare and submit protocol for IRB review	25	300	50	375	29,775
Prepare and submit protocol for EPA and HSRB review	40	900	60	1,000	79,920
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	60	2500	50	2,610	208,930
Store, file, and maintain records	5	5	5	15	1,385
TOTALS	135	3,710	170	3,515	321,395

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

Activities	Average Burden Hours Per Occurrence			Total Per Response	
	Management $153	Technical $79	Clerical $45	Hours	Cost ($)
Rule familiarization and training	5	5	5	15	1,385
Prepare and submit protocol for IRB review	20	200	30	225	20,210
Prepare and submit protocol for EPA and HSRB review	200	600	40	840	79,800
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	40	1,000	40	1,080	86,920
Store, file, and maintain records	10	40	10	60	5,140
TOTALS	275	1,845	125	2,245	193,455

Table C. Insect Repellant Studies – Burden Hour Estimates from the Consultation Response from Carroll-Loye Biological Research

Activities	Average Burden Hours Per Occurrence			Total Per Response	
	Management $153	Technical $79	Clerical $45	Hours	Cost ($)
Rule familiarization and training	1	2	2	5	401
Prepare and submit protocol for IRB review	7	25	10	42	3,496
Prepare and submit protocol for EPA and HSRB review	5	3	7	15	1,317
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	5	10	5	20	1,771
Store, file, and maintain records	2	0	10	12	756
TOTALS	20	40	34	94	7,741

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 $153	Technical $75	Clerical $45	Hours	Cost ($)
Document ethical conduct of a completed study for which EPA and the HSRB have not reviewed the protocol	2	24	2	28	2,563

For ICR Table 1

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

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $153	Technical $79	Clerical $45	Hours	Cost ($)
Rule familiarization and training	4	4	4	12	1,108
Prepare and submit protocol for IRB review	17	175	30	222	17,776
Prepare and submit protocol for EPA and HSRB review	82	501	36	619	53,745
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	35	1,170	32	1,237	99,225
Store, file, and maintain records	6	15	8	29	2,463
Total per response	144	1,865	110	2,119	174,317

Annual Burden: 2,119 hours per response * 7 responses per year = 14,833 hours
Annual Costs: $174,317 per response * 7 responses per year = **$1,220,219**

For ICR Table 2

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

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $153	Technical $79	Clerical $45	Hours	Cost ($)
Rule familiarization and training	1	1	0	2	232
Prepare and Submit Ethics Information of Completed Human Studies to EPA	0	8	1	9	677
Store, file, and maintain records	0	0	1	1	45
Total per response	1	9	2	12	954

Annual Burden: 12 hours per study * 10 studies submitted per year = 120 hours
Annual Costs: $954 per study * 10 studies submitted per year = **$9,540**

Agency Burden Hour Estimates: Technical Staff[1]

Table E. Protocol + Completed Study Review

Study Type	Estimated Number of Protocols + Completed Reports per year	Estimated Number of Hours Per Protocol Review	Estimated Number of Hours Per Completed Study Review	Total Number of Hours
AHETF	2	160	340	1000
AEATF	2	160	300	920
Repellant Efficacy	2	120	120	480
Other Types of Post-Rule Intentional Exposure Studies	1	120	80	200
Weighted Average Number of Hours per Response				**371 hours per response**
Estimated Annual Number of Responses				**7**

Table F. Ethics Reviews for Pre-Rule Completed Studies Not Requiring HSRB Review

Study Type	Average Annual Number of Reviews[2]	Avg. Number of Hours Per Review	Annual Burden Hour Estimate
Pre-Rule completed studies that do NOT measure or identify a toxic effect	**20**	**4**	**80 hours**

Burden Hour Estimates: Management and Clerical

Management:

- Assume 3 hours for Protocol Reviews and Completed Study Reviews
- Assume zero hours for Ethics Reviews for studies not requiring HSRB Review

Clerical

- Assume 2 hours for Protocol Reviews and Completed Study Reviews
- Assume 0 hour for Ethics Reviews for studies not requiring HSRB Review

[1] Ag handler study estimates based on information from M. Crowley, J. Evans, and B. Sarkar and K. Sherman (EPA/OPP). Antimicrobial exposure study estimates based on information from T. Leighton and K. Sherman (EPA/OPP). Insect repellant study estimates based on information from C. Fuentes, K. Sweeney, and K. Sherman (EPA/OPP). Other study type estimates based on information from K. Sherman.

[2] Assumed that 10 of 20 studies are submitted from outside parties and the remaining 10 are located by EPA at the Agency's own initiative (and therefore not subject to 40 CFR 26.1303).

For ICR Table 3

Table 3. Weighted Average Burden and Cost Estimates for Agency – Research Involving Intentional Exposure

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $120	Technical $71	Clerical $45	Hours	Cost ($)
Rule familiarization and training	1	2	0	3	262
Primary Review of Scientific and Ethical Aspects of a Protocol	3	143	0	143	10,775
Primary Review of Scientific and Ethical Aspects of a Completed Study Report	3	229	0	232	16,619
Secondary Review of Scientific and Ethical Aspects of a Protocol	197				4,270*
Secondary Review of Scientific and Ethical Aspects of a Completed Report	197				4,270*
Store, file, and maintain records	0	0	2	2	90
Total per response	7	317	2	774	36,286

***** Cost of HSRB members working on the HSRB report (collectively spending 197 hours per HSRB report in FY 2011, compensated at the rate of $53/hour), plus the cost of EPA Office of the Science Advisor technical staff working on the HSRB report (30 hours per report, at the technical staff rate of $79/hour). Each HSRB report covers an average of 3 protocols and/or completed studies per report topics, so each topic costs an average of $4,270.

Annual Burden: 774 hours per response x 7 per year = **5,418 hours**
Annual Costs: 36,286 x 7 responses/year = **$254,002**

For ICR Table 4

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 $120	Technical $71	Clerical $45	Hours	Cost ($)
Rule familiarization and training	0	0	0	0	0
Primary Review of Ethical Aspects of a Completed Study Report	0	4	0	4	284
Store, file, and maintain records	0	0	0	0	0
Total per response	0	4	0	4	284

Annual Burden: 4 hours per study x 20 per year = 80 hours
Annual Costs: 284 x 20 responses/year = $5,680

For ICR Table 5

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

Collection Activity	Annual Burden Hours	Annual Costs
Annual Respondent Burden and Costs		
Research Involving Intentional Exposure of Human Subjects (Table 1)	14,833	$1,220,219
All Other Submitted Research with Human Subjects (Table 2)	120	$9,540
Respondent Total	14,953	$1,229,759
Annual Agency Burden		
Research Involving Intentional Exposure of Human Subjects (Table 3)	5,418	$254,002
All Other Submitted Research with Human Subjects (Table 4)	80	$5,680
Agency Total	5,498	$259,682

Number of Transactions: September 2012 – August 2015

1. AHETF Monitoring Program

- As of March 2012, protocol generation is nearly complete. The AHETF anticipates perhaps only 1 or 2 more protocols total.
- There are 5 studies in the field now (protocols approved, research ongoing)
- **Figures used in ICR: 2 "transactions" per year (2 protocols + 2 completed study reports)**

2. AEATF Monitoring Program

- **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 both EPA and HSRB review.
- **Estimate: 1 protocol and 1 completed study per year.** (This is likely an over-estimate)

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:

- **7 intentional exposure human studies** (rule familiarization + protocol stage + 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)