EPA ICR No. 2195.03 **OMB Control No. 2070-0169**

ATTACHMENT D

Record of EPA Consultations With Respondents Regarding the ICR Renewal

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Consultation for OPP ICR Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (OMB Control # 2070-0169)

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

No. The AHETF data will either supplement the existing data in the Pesticide Handlers Exposure Database (PHED) or provide all of the data for scenarios that are not covered in PHED.

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well?

As stated above, the only available data are in PHED. The AHETF data will supplement rather than duplicate data in PHED.

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome?

This is not applicable to the AHETF.

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information?

The rule gives a general overall explanation on the process but does not cover exactly what needs to be submitted and how it needs to be submitted. Guidance on what and how to submit has been gained through trial and error. Once a procedure is established, this should be documented in some form of guidance from the EPA. It would also be helpful to have guidance on specific ethical requirements for conducting occupational exposure monitoring studies to improve the chances of getting favorable reviews the first time through.

b. Do you understand that you are required to maintain records?

Yes, keeping detailed records is standard practice for the AHETF as part of the GLP regulations. However, the volume of records that need to be kept has

increased significantly and there is still some question about exactly what records need to be documented from an ethical standpoint.

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand?

It is difficult and time-consuming for the AHETF to format the submission materials due to the large number of documents required for each study (e.g., protocols, informed consent forms, recruiting documents, input from experts, product labels and MSDS, and IRB materials) and the number of protocols that need to be included with each submission (i.e., all of the protocols covering a scenario are submitted together). It is virtually impossible to submit the documents required for each individual study without a great deal of duplication in the submission package. This duplication is the result of all protocols within a scenario being very similar with only minor differences from one study to the next. Therefore, many of the documents will be common to all studies within a scenario.

The need for a large number of pages is due primarily to the requirement for including all of the materials and correspondence exchanged between the AHETF and the IRB. This exchange of material accounts for over half of the submission and is largely a duplication of the protocols and informed consent forms. For example, the submission package covering two studies for the June HSRB review contained about 2300 pages. The submission package being prepared for the October HSRB review will also contain over 2000 pages covering six studies. Most of the 2000 pages will consist of materials and correspondence exchanged with the IRB.

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete?

The only form provided by EPA is a checklist of items from the rule that must be covered for every protocol. The form is taken directly from the Rule and is not especially difficult to complete, but does take a significant amount of time.

4. Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires that agencies make available electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper or electronically via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions?

The AHETF prefers electronic submissions.

b. Are you keeping your records electronically? If yes, in what format?

Yes, records are kept in several forms including MS Word, Excel, Adobe Acrobat, and e-mail files. Key documents are also stored on a task force server for easy access by AHETF members.

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information?

Most of the information is generated electronically, so converting this to hard copy for the submission would be an additional burden.

5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2007 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 32530 (Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing), published by the Bureau of Labor Statistics. The BLS rates for this industry are $103/hour for management, $71/hour for technical staff, and $41/hour for clerical staff. Do you think these labor rates are appropriate? Can you suggest another NAICS code that would be more appropriate?

The rates used by EPA are about half what it is costing the AHETF. The technical and management work of the AHETF is done by professional research scientists so a classification for researchers with MS or PhD degree requirements would be more appropriate. The more applicable rates are $225, $175, and $50 per hour for the management, technical, and clerical classifications.

b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the estimated number of times each year that class of activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections for the paperwork and recordkeeping burden of each activity over the period covered by the ICR renewal—i.e., between February 1, 2009 and January 31, 2012.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

Table 1
Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence			Total Per Response		
	Mgt. $103	Tech. $71	Clerical $41	Hours	EPA-Based Cost ($)	Actual AHETF Cost ($)
Rule familiarization and training[1]	10	10	10	30	2,150	4,500
Prepare and submit protocol for IRB review[2]	25	400	50	475	33,025	78,125
Prepare and submit protocol for EPA and HSRB review[3]	50	800	80	930	65,230	155,250
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[4]	50	1300	50	1400	99,500	241,250
Document ethical conduct of a completed study for which EPA and the HSRB have ***not*** reviewed the protocol[5]	NA	NA	NA	NA	NA	NA
Store, file, and maintain records[6]	0	10	0	10	710	1,750
TOTALS	135	2520	190	2845	200,615	480,875

Notes for Table 1:

[1] Consider this a one-time activity. Enter your estimate of what your total burden will be for rule familiarization and training during 2009-2012. Since the AHETF is already familiar with the rule, you may have little additional burden for this activity.

This will not be a one-time activity due to new people coming on board and normal turn-over of personnel. This will be an ongoing activity every year. Implementing future studies will require the AHETF to hire additional technical and clerical people to handle the increased work load with a requirement for training these personnel.

[2] Estimate your average paperwork burden of preparing for a single IRB review which would not have occurred but for the requirements of the human studies rule. Consider IRB reviews both before and after EPA/HSRB review.

There is a significant increase in the hours required for both IRB and EPA/HSRB review, but it is difficult to separate what part of this is attributable to the IRB and what part is attributable to EPA/HSRB. For example, there is an increase in the amount of documentation that now needs to be exchanged with the IRB, but much of this increase is a direct result HSRB decisions.

Notes for Table 1 (cont.):

[3] Estimate your average paperwork burden to prepare for submission to EPA a single field-study protocol proposing research involving intentional exposure of human subjects. Distribute the burden associated with developing a scenario design across all protocols in the scenario.

The AHETF believes it is more appropriate to provide the hours by scenario rather than by study for several reasons. The AHETF will be conducting up to five studies applicable to a single handler use scenario. The protocols will be very similar, differing primarily in the specific study location and crop. The HSRB requested that a scenario sampling plan plus the five protocols for that scenario be submitted each time as a single submission. Logistically, all of the material for the scenario could be written as a single protocol; it is broken into individual protocols only because of the HSRB request. This, in turn, results in significant duplication of effort and paper work that increases the costs. When the studies are completed, the results from all studies in a scenario will be analyzed and submitted in a monograph report for the entire scenario. With the similarities and duplications among the protocols, dividing the costs for a scenario by the number of studies within that scenario would be an underestimate of the cost for a single protocol.

[4] Estimate your average paperwork burden to document the ethical conduct of a single study for submission to EPA when the protocol has already been reviewed by EPA and the HSRB.

[5] Estimate your average paperwork burden to document the ethical conduct of a completed study for submission to EPA for which the protocol was not previously reviewed by EPA and the HSRB.

All present and future protocols will be reviewed by EPA (e.g. observational studies) and/or HSRB. The ethical conduct of observational studies will be the same as for other studies.

[6] Estimate your average paperwork burden for managing and archiving records of each submitted protocol or study report.

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

Table 2
Respondent Burden Estimates:
Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Feb 2009-Jan 2010	Feb 2010-Jan 2011	Feb 2011-Jan 2012
Prepare and submit protocol for IRB review[1]	4	4	4
Prepare and submit protocol for EPA and HSRB review[2]	4	4	4
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[3]	4	4	4
Document ethical conduct of a completed study for which EPA and the HSRB have ***not*** reviewed the protocol[4]	0	0	0
Store, file, and maintain records[5]	4	4	4

Notes for Table 2:
[1] Estimate the number of IRB submissions that would not have occurred but for the requirements of the human studies rule, including those both before and after EPA/HSRB review.
[2] Count as one occurrence a scenario design and all associated field study protocols reviewed by the HSRB at the same meeting.
[3] Count each field exposure study reported separately to EPA.

d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree?

The AHETF agrees.

e. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for?

The AHETF is not immediately aware of applicable activities.

AMERICAN CHEMISTRY COUNCIL

BIOCIDES PANEL
ANTIMICROBIAL EXPOSURE ASSESSMENT TASK FORCE II

AEATF RESPONSE TO EPA'S CONSULTATION FOR OPP ICR SUBMISSION OF PROTOCOLS AND STUDY REPORTS FOR ENVIRONMENTAL RESEARCH INVOLVING HUMAN SUBJECTS (OMB CONTROL # 2070-0169)

July 12, 2008

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

Response: *No. The AEATF data will either supplement the existing data collected as part of the Popendorf et al., 1992 study* (a study sponsored by the Chemical Manufacturers Association or CMA, now the American Chemistry Council or ACC), or data in the U.S. EPA's Pesticide Handlers Exposure Database (PHED). Alternatively, AEATF plans to provide data for additional antimicrobial use scenarios that are either not available in Popendorf et al., 1992 or PHED data sources, or these data will supplement these data sources. The AEATF has described the limitations of existing data and the need for confirmatory or additional data in a "governing document,"** which has been submitted to EPA's Office of Pesticide Programs (OPP) and the Human Studies Review Board (HSRB).*

**Popendorf, W., M. Selim, and B.C. Kross. 1992. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa, Institute of Agricultural Medicine and Occupational Health. Iowa City, Iowa.*

***Antimicrobial Exposure Assessment Task Force II (AEATF II), VOLUME 5, Governing Document for a Multi-Year Antimicrobial Chemical Exposure Monitoring Program. Interim Draft Document. February 13, 2008.*

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well?

Response: *As stated above, the only available data are in Popendorf et al., 1992, and PHED. Both of these data sets are in EPA's files. The AEATF data will provide additional scenario-specific data or supplement existing data, rather than duplicate those data in either Popendorf et al. 1992 or PHED.*

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome?

Response: *These data have been identified by EPA in various reregistration eligibility decision documents as being needed. Antimicrobial registrants also will need these data during registration reviews currently underway at EPA. Thus, these data need to be generated as rapidly as possible for regulatory decision making.*

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information?

Response: *The rule gives a general, overall explanation on the process, but does not cover exactly what needs to be submitted and how it needs to be submitted. Guidance on what and how to submit has been gained through a draft EPA PR Notice, helpful dialogue with EPA staff, and trial and error. Once a procedure is established, this should be documented in some form of guidance or final PR Notice from the EPA.*

Further, guidance needs to be provided on EPA's requirements for exposure monitoring data, since the only currently available guidance, the OPPTS Series 875 Guidelines, has been superseded by requirements that have been imposed as a result of the regulation that is the subject of this ICR request.

b. Do you understand that you are required to maintain records?

Response: *Yes. Generating and maintaining detailed records is standard practice for the AEATF as part of GLP regulations and compliance with regulations regarding studies involving human studies.*

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand?

Response: *It is difficult and extremely time-consuming for the AEATF to format the submission materials due to the large number of documents required for each study (e.g., protocol and associated study (scenario) design document, informed consent form, recruiting documents, appendices including product labels and MSDS, IRB-related materials and correspondence, and updates to the AEATF governing document).*

The need for a large number of pages is due primarily to the requirement for including all of the materials and correspondence exchanged between the AEATF

and the IRB, including all versions of a protocol(s) that were reviewed and revised. This exchange of material accounts for over half of the submission and is largely a duplication of the protocols and informed consent forms.

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete?

Response: *The only form provided by EPA is a checklist of items from a draft PR Notice that must be covered for every protocol submission. The AEATF uses this form and it is reasonably logical. The form represents a method for cross-referencing various required information sources defined in the rule and their respective locations in a protocol submission (which is a multi-volume set of documents). Thus, this form requires a substantial amount of time to complete.*

4. Electronic Reporting and Record Keeping

The Government Paperwork Elimination Act requires that agencies make available electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper, or electronically, via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions?

Response: *The AEATF prefers electronic submissions.*

b. Are you keeping your records electronically? If yes, in what format?

Response: *Yes. Records are kept in several forms including MS Word, Excel, Adobe Acrobat, and e-mail files. Key documents are also stored on a task force server for easy access by AEATF members.*

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information?

Response: *Most of the information is generated electronically, so converting this to hard copy for the submission would be an additional burden.*

5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2007 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 32530 (Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing), published by the Bureau of Labor Statistics. The BLS rates for this industry are $103/hour for management, $71/hour for technical staff, and $41/hour for clerical staff. Do you think these labor rates are appropriate? Can you suggest another NAICS code that would be more appropriate?

Response: *The rates for clerical staff are approximately appropriate but should be increased to $50 to reflect Washington, D.C., area rates. The rates for technical and management services for AEATF are approximately 2-fold higher that those listed above and should be increased to $175 and $225, respectively. The technical and management staff is made up of professional research and applied scientists with specialized expertise so a classification for persons with Masters or Doctoral degree requirements would be more appropriate.*

b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the estimated number of times each year that class of activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections for the paperwork and recordkeeping burden of each activity over the period covered by the ICR renewal—i.e., between February 1, 2009 and January 31, 2012.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

Table 1
Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence*			Total Per Response		
	Management $103 *($255 rev.)***	**Technical $71 *($175 rev.)*****	**Clerical $41 *($50 rev.) *****	**Total Hours**	**Cost ($)**	**Realistic Cost ($)*****
Rule familiarization and training (per protocol)[1]	*12*	*32*	*8*	*52*	*$3,836.00*	*$8,700.00*
Prepare and submit protocol for IRB review[2]	*24*	*120*	*40*	*184*	*$12,632.00*	*$28,400.00*
Prepare and submit protocol for EPA and HSRB review[3]	*40*	*320*	*40*	*400*	*$28,480.00*	*$67,000.00*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[4]	*24*	*80*	*24*	*128*	*$9,136.00*	*$20,600.00*
Document ethical conduct of a completed study for which EPA and the HSRB have ***not*** reviewed the protocol	*24*	*80*	*24*	*128*	*$9,136.00*	*$20,600.00*
Store, file, and maintain records[5]	*8*	*16*	*16*	*40*	*$2,616.00*	*$5,400.00*

**These rates are unrealistically low based upon fully loaded rates. Based on AEATF experience to data the rates should be 225/hr, 175/hr and 50/hr for management, technical and clerical, respectively. Thus, using the more realistic rates experienced by AEATF, the more realistic overall cost estimate is 2-fold higher (see estimates in "Realistic Cost ($)" column of Table 1).*
***Revised hourly rates used to develop cost estimated in column entitled Realistic Cost.*
****These cost estimates do not include hours contributed by registrant company management and technical staff; if these hours were included, the "Realistic Cost ($)."*

Notes for Table 1:

[1] *This is an estimate of the average burden per protocol activity. During a 4-year period some personnel "turnover" is expected each year. Further, based on AEATF experience, this task involves different persons for each protocol given that scenarios-specific studies require different expertise. The involvement of 3 management, 8 technical, and 2 clerical persons are assumed. The management and technical persons include both consultants and company/industry staff. In addition, while AEATF is already familiar with the rule in general, time is still required for this task because the submission process is still being "optimized" or changed, because different individuals may be involved from one submission to another.*

[2] *This is an estimate of the average paperwork burden of preparing for a single IRB review, which would not have occurred except for the requirements of the human studies rule. It considers IRB reviews both before and after EPA/HSRB review. This task includes consultants only. This task includes the study protocol and related informed consent materials, and responses to reviews of these materials. This task does not include review by the California EPA for those studies conducted in California.*

Please note that the AEATF plans to submit 18 protocols; thus, this per protocol cost estimate would be multiplied by 18 for the total cost.

[3] *This is an estimate of the average paperwork burden to prepare for submission to EPA a single field-study protocol proposing research involving intentional exposure of human subjects. It considers involvement of the study director, at least two technical experts, a manager and a clerical person. The task burden includes the effort associated with developing a scenario design document for a given scenario and related protocol(s).*

[4] *While the AEATF does not yet have direct experience with this task yet, the estimate provided represents a best estimate for the average paperwork burden to document the ethical conduct of a single study for submission to EPA when the protocol has already been reviewed by EPA and the HSRB.*

[5] *This is an estimate for the average paperwork burden for managing and archiving records of each submitted protocol or study report.*

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

Table 2
Respondent Burden Estimates:
Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Feb 2009-Jan 2010	**Feb 2010-Jan 2011**	**Feb 2011-Jan 2012**
Prepare and submit protocol for IRB review[1]	*5*	*5*	*6*
Prepare and submit protocol for EPA and HSRB review[2]	*5*	*5*	*6*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[3]	*4 (includes 2 protocols approved in 2008)*	*5*	*9*
Document ethical conduct of a completed study for which EPA and the HSRB have ***not*** reviewed the protocol	*0*	*0*	*0*
Store, file, and maintain records	*4*	*5*	*9*

Notes for Table 2:

[1] *This represents the estimated number of IRB submissions.*

[2] *In the case of AEATF, each scenario includes one study.*

[3] *This represents each completed field exposure study submitted to EPA.*

d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree?

Response: *The AEATF agrees.*

e. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for?

Response: *The AEATF believes that increased costs will be incurred to conduct exposure monitoring studies as a direct result of changes by EPA to the previously relied upon guidance in the OPPTS Series 875 Guidelines in implementing the human studies rule. These changes impact, among other activities, study design and sampling methods, and can be traced to the process involved in with the human studies rule. These changes result in significant increases in the burden associated with conducting exposure monitoring studies. The costs associated with the changes should be included in the estimate of incremental costs for each study performed in compliance with the human studies rule. The AEATF does not believe that these incremental costs have been considered in any other existing ICR, including the ICR authorizing Data Call-Ins.*

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For further information, please contact Has Shah at has_shah@americanchemistry.com or 703-741-5637.

Scott Carroll
Carroll-Loye Biological Research

Consultation for OPP ICR Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (OMB Control # 2070-0169)

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well?

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome?

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information?

b. Do you understand that you are required to maintain records?

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand?

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete?

4. Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires that agencies make available to the public electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper or electronically via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions?
Generally value for efficiency of preparation and transmission, possibly saving of paper.

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b. Are you keeping your records electronically? If yes, in what format?

Yes, in formats of software programs used for their creation: MS Word, MS Excel, SAS. Also Adobe pdf. Multiple electronic backups. Note that we also keep printed hardcopies in secure storage.

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information?

As our sponsors generally execute the formal submissions, I can only state referentially that we use electronic compilation to more efficiently provide electronic and printed reports to clients.

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5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2007 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 32530 (Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing), published by the Bureau of Labor Statistics. The BLS rates for this industry are $103/hour for management, $71/hour for technical staff, and $41/hour for clerical staff. Do you think these labor rates are appropriate? Can you suggest another NAICS code that would be more appropriate?

Much of the science we perform is relatively low tech and straightforward. Accordingly, I agree with the rate for technical staff. We don't have sufficient experience with clerical staff to comment on that category. Note that we use management rates that are much higher. The level of expertise and ability required to operate a contract laboratory in the current regulatory environment has exceeded the capacity of most established entities for a score of months. Working within the HSRB framework has required capacities well beyond those formerly required for the generation of entomological registration data. They have included the development of new scientific tests and new approaches to risk evaluation and minimization, the comprehension of the vocabulary, intentions, goals, and subcultural dynamics of the field bioethics, groping to understand the political pressures on EPA staff and the interactions of EPA staff and HSRB members, as well as the creation of protocols that meet wholly unprecedented demands on our field. Accordingly, our management rates are more comparable to those levied by consulting attorneys or physicians. Much of this work is beyond the capacity of technical staff and must be undertaken directly be management.

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b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the number of times each year that activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections

for unit costs over the period covered by the ICR renewal—i.e., between February 1, 2009 and January 31, 2012.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

We have no specific records that permit precise characterization of the paperwork increment resulting from the Human Studies Rule. A few months into the process, I began relating that the *overall* 'before' versus 'after' work increment for my business (including and beyond paperwork) was eight-fold. The values actually inserted into Table 1 are general guesses in which I mainly tried not to underestimate the amount of additional time required, as I typically do by a factor of a few hundred percent when planning individual projects.

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Table 1

Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence			Total Per Response	
	Management $103	Technical $71	Clerical $41	Hours	Cost ($)
Rule familiarization and training[1]	50	100	-	150	12K
Prepare and submit protocol for IRB review[2]	75	100	-	175	15K
Prepare and submit protocol for EPA and HSRB review[3]	50	50	-	100	9K
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[4]	20	80	-	100	8K
Store, file, and maintain records[5]	5	12	-	17	1K

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Notes for Table 1:

[1] Consider this a one-time activity. Enter your estimate of what your total burden will be for rule familiarization and training during 2009-2012. Since you are already familiar with the rule, you may have little additional burden for this activity.

[2] Estimate your average paperwork burden of preparing for a single IRB review which would not have occurred but for the requirements of the human studies rule. Consider IRB reviews both before and after EPA/HSRB review.

[3] Estimate your average paperwork burden of preparing a single submission to EPA of a protocol proposing research involving intentional exposure of human subjects. Treat each repellent testing protocol as a single protocol, however many test materials may be involved.

[4] Estimate your average paperwork burden to document the ethical conduct of a single study for submission to EPA when the protocol has already been reviewed by EPA and the HSRB. Treat all reports reflecting a single execution of one protocol as a single activity, however many test materials may be involved.

[5] Estimate your average paperwork burden for managing and archiving records of each submitted protocol or study report.

Note that the values inserted in Table 1 include costs associated with meeting the burdens of increased intensity of *science* review by the HSRB and EPA staff, as that judgment is a fundamental aspect of the Rule (to be balanced against the ethical liabilities, making the two elements inextricably interactive). Related to this, the absence of a request for more comprehensive characterization of the added costs for *reporting* study results to the agency is perplexing. In particular, for the fourth row of Table 1, this increment in science-scrutiny would approximately repeat (double) the value listed for the ethical elements.

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

Table 2
Respondent Burden Estimates:
Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Feb 2009-Jan 2010	Feb 2010-Jan 2011	Feb 2011-Jan 2012
Prepare and submit protocol for IRB review[1]	3	4	5
Prepare and submit protocol for EPA and HSRB review[2]	3	4	5
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[3]	3	4	5
Store, file, and maintain records[4]	3	4	5

Notes for Table 2:
[1] Count IRB submissions that would not have occurred but for the requirements of the human studies rule, including those both before and after EPA/HSRB review.
[2] Count each repellent testing protocol as a single occurrence, however many test materials it may involve.
[3] Count each executed repellent protocol only once, however many test materials or physical study volumes it may involve.
[4] This count will probably be the sum of the other numbers in the column

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d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree?

No– Moderate capital costs are entailed in the areas of both electronic and paper storage capacity and security. We have invested >$1000 in these contexts, but our first steps are stop-gaps. At some point soon we may need a new room dedicated to hardcopy storage. Double-sided printing of consent forms is extremely important to save storage space, and we spent $1000 on a printer that does that reliably and quickly.

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e. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for? **Yes– see note relating to Table 1, above.**

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Robin Todd
ICR, Inc

Consultation for OPP ICR Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (OMB Control # 2070-0169)

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

ICR INC RESPONSE:
If 'data' means repellency data on human generated in compliance with current EPA regulations, for given repellent products, then it is not available from any known public source

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well?

ICR INC RESPONSE
N/A

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome?

ICR INC RESPONSE
This would further delay what it is already a very slow process..

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information?

ICR INC RESPONSE
Some of the regulations are quite clear; others are not. However, the different (often conflicting) interpretations of these regulations by different EPA staff members and HSRB members are disturbing, and sometimes counter-productive and confusing. Some of the advice from the HSRB members and the EPA staff members has been clear and helpful.

b. Do you understand that you are required to maintain records?

ICR INC RESPONSE
Yes

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand?

ICR INC RESPONSE
Yes

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete?

ICR INC RESPONSE
There is one form. We have to use it. It is fairly clear, logical, and easy to complete

4. Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires that agencies make available to the public electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper or electronically via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions?

ICR INC RESPONSE
Good idea.

b. Are you keeping your records electronically? If yes, in what format?

ICR INC RESPONSE
Most records can be kept this way; some must remain as paper hardcopy. Wordperfect, Word and pdf.

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information?

ICR INC RESPONSE
Yes, except that EPA's spam filter kicks our submissions back, forcing us to use the old fashioned, paper intensive, expensive courier method (carbon footprint is huge!)

5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2007 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 32530 (Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing), published by the Bureau of Labor Statistics. The BLS rates for this industry are $103/hour for management, $71/hour for technical staff, and $41/hour for clerical staff. Do you think these labor rates are appropriate? Can you suggest another NAICS code that would be more appropriate?

ICR INC RESPONSE
These hourly rates are reasonable.

b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the number of times each year that activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections for unit costs over the period covered by the ICR renewal—i.e., between February 1, 2009 and January 31, 2012.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

Table 1
Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence			Total Per Response	
	Management $103	Technical $71	Clerical $41	Hours	Cost ($)
Rule familiarization and training[1]	1	1	1	3	?
Prepare and submit protocol for IRB review[2]	32	8	8		
Prepare and submit protocol for EPA and HSRB review[3]	15	4	4		
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[4]		4	2		
Store, file, and maintain records[5]	1	1	2		

Notes for Table 1:

[1] Consider this a one-time activity. Enter your estimate of what your total burden will be for rule familiarization and training during 2009-2012. Since ICR is already familiar with the rule, you may have little additional burden for this activity.

ICR INC RESPONSE

Very difficult to estimate; significant time required only if rule changes or if we hire new staff.

[2] Estimate your average paperwork burden of preparing for a single IRB review which would not have occurred but for the requirements of the human studies rule. Consider IRB reviews both before and after EPA/HSRB review.

[3] Estimate your average paperwork burden of preparing a single submission to EPA of a protocol proposing research involving intentional exposure of human subjects. Treat each repellent testing protocol as a single protocol, however many test materials may be involved.

ICR INC RESPONSE

The extra work that goes into the IRB submission preparation is because of the HSRB/ EPA requirements. The protocol and ICD have become larger and more detailed due to trying to comply with the regulations and interpretations of these regulations by different EPA and HSRB staff members. Required changes following all submissions usually necessitates an additional submission to the IRB. All of this paperwork must be tracked and included in each submission.

[4] Estimate your average paperwork burden to document the ethical conduct of a single study for submission to EPA when the protocol has already been reviewed by EPA and the HSRB. Treat all reports reflecting a single execution of one protocol as a single activity, however many test materials may be involved.

ICR INC RESPONSE

There is now the requirement to submit recruitment scripts, and expanded final reports. Estimate your average paperwork burden for managing and archiving records of each submitted protocol or study report.

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

ICR INC ASSUMPTIONS

The new Final Rule has so greatly increased the time and effort needed to conduct human repellency studies that most companies have stopped running tests, either by contractors or by the companies themselves, that it is likely that there will be far fewer studies than before the Rule came into effect (2006).

Table 2
Respondent Burden Estimates:
Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Feb 2009-Jan 2010	Feb 2010-Jan 2011	Feb 2011-Jan 2012
Prepare and submit protocol for IRB review[1]	2	2	2
Prepare and submit protocol for EPA and HSRB review[2]	2	2	2
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[3]	2	2	2
Store, file, and maintain records[4]	6	6	6

ICR INC note – each occurrence is a study i.e. predict that we will run 2 studies per year

Notes for Table 2:

[1] Count IRB submissions that would not have occurred but for the requirements of the human studies rule, including those both before and after EPA/HSRB review.

ICR Inc note: even prior to the New Rule, ICR was submitting all its human repellent study protocols to an IRB .

[2] Count each repellent testing protocol as a single occurrence, however many test materials it may involve.

[3] Count each executed repellent protocol only once, however many test materials or physical study volumes it may involve.

[4] This count will probably be the sum of the other numbers in the column

d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree?

ICR Inc Response; yes.

d. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for?

Time and expense of having to attend HSRB meetings, possibly EPA meetings, and consultation with outside contractors.

Joel Panara
Grayson Research LLC

Consultation for OPP ICR Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (OMB Control # 2070-0169)

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency? No.

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well? Not applicable.

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome? No.

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information? Yes.

b. Do you understand that you are required to maintain records? Yes.

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand? No.

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete? Guidance documents have been provided and were helpful.

4. Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires that agencies make available to the public electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper or electronically via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions? We prefer electronic submissions.

b. Are you keeping your records electronically? If yes, in what format? Yes. Documents are usually generated in Microsoft Office files and stored/submitted as pdf documents. We currently still archive paper copies.

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information? Yes, electronic submission reduces the burden of compliance.

5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2007 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 32530 (Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing), published by the Bureau of Labor Statistics. The BLS rates for this industry are $103/hour for management, $71/hour for technical staff, and $41/hour for clerical staff. Do you think these labor rates are appropriate? No, billing rates for management and technical staff are lower than our typical billing rates. Clerical staff rates are appropriate. Can you suggest another NAICS code that would be more appropriate? No.

b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the number of times each year that activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections for paperwork burdens over the period covered by the ICR renewal—i.e., between February 1, 2009 and January 31, 2012.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

Table 1
Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence			Total Per Response	
	Management $103	Technical $71	Clerical $41	Hours	Cost ($)
Rule familiarization and training[1]	2	8	0	10	774
Document ethical conduct of a completed study for which EPA and the HSRB have not reviewed the protocol[2]	5	16	8	29	1,979
Store, file, and maintain records[3]	1	4	4	9	551

The estimates provided are based on billing records for additional work performed on several studies to generate supplemental reports necessary to meet the rule.

Notes for Table 1:

[1] Consider this a one-time activity. Enter your estimate of what your total burden will be for rule familiarization and training during 2009-2012. Since you are already familiar with the rule, you may have little additional burden for this activity.

[2] Estimate your average paperwork burden to document the ethical conduct of a single study for submission to EPA for which the protocol was ***not*** previously reviewed by EPA and the HSRB.

[5] Estimate your average paperwork burden for managing and archiving records of each submitted study report.

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

Table 2
Respondent Burden Estimates:
Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Feb 2009-Jan 2010	Feb 2010-Jan 2011	Feb 2011-Jan 2012
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol	10	10	10
Store, file, and maintain records	10	10	10

Estimated number of occurrences is based on projected maximum capacity for the years noted.

d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree? Yes.

e. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for? *No. Please note Table 1 asks for burden estimates for studies whose protocols were NOT reviewed by EPA/HSRB prior to conduct (i.e. pre-rule studies). Table 2 asks for frequency associated with studies whose protocols WERE reviewed by EPA/HSRB. The incremental costs for studies initiated post-rule will be higher than those outlined in Table 1. The frequency associated with studies whose protocols were not reviewed by EPA/HSRB will be lower than outlined in Table 2.*