Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
December 13, 2010 Public Teleconference Meeting
Docket Number: EPA–HQ–ORD–2010–0919
HSRB Web Site: http://www.epa.gov/osa/hsrb

Committee Members: (See EPA HSRB Members list – Attachment A)

Date and Time:	Monday, December 13, 2010, 3:00 p.m. – 4:30 p.m. (See *Federal Register* Notice – Attachment B)	
Location:	Via teleconference	
Purpose:	The EPA Human Studies Review Board provides advice, information, and recommendations on issues related to the scientific and ethical aspects of human subjects research.	
Attendees:	Chair:	Sean Philpott, Ph.D., M.S. Bioethics
	Vice Chair:	Janice Chambers, Ph.D., D.A.B.T.
	Board Members:	George C.J. Fernandez, Ph.D. Vanessa Northington Gamble, M.D., Ph.D. Sidney Green, Jr., Ph.D., Fellow ATS Dallas E. Johnson, Ph.D. Michael D. Lebowitz, Ph.D., FCCP José E. Manautou, Ph.D. Rebecca T. Parkin, Ph.D., M.P.H. William J. Popendorf, Ph.D. Virginia Ashby Sharpe, Ph.D.
Meeting Summary:	Meeting discussions generally followed the issues and general timing as presented in the meeting Agenda (Attachment C), unless noted otherwise in these minutes.	

INTRODUCTORY REMARKS

Mr. Jim Downing (Designated Federal Officer [DFO], Human Studies Review Board (HSRB), Office of the Science Advisor [OSA], U.S. Environmental Protection Agency [EPA or Agency]) opened the teleconference meeting and welcomed Board members on behalf of the EPA Science Advisor Dr. Paul Anastas and the Program in Human Research Ethics. He noted that the Agency appreciates the Board members' time and work in preparing for the meeting and deliberations. He also welcomed EPA colleagues and members of the public. The purpose of this teleconference meeting was to review the decisions made by the Board at the October 27-28, 2010 HSRB meeting and to finalize the Board report from that meeting.

MEETING ADMINISTRATIVE PROCEDURES

As DFO, Mr. Downing serves as the liaison between the HSRB and EPA and ensures that Federal Advisory Committee Act (FACA) requirements are met. As DFO, he also works with the appropriate officials to ensure that all applicable ethics regulations are satisfied. Each Board member has been briefed on the provisions of the federal conflict of interest laws and has filed a standard government financial disclosure form that has been reviewed to ensure that all ethics disclosure requirements have been met. Mr. Downing reminded participants that meeting times listed on the agenda would be approximate, and that Board members should introduce themselves before speaking. At the appropriate time, members of the public may provide public comments; these must be limited to 5 minutes.

Copies of the meeting materials are available on regulations.gov under the docket number EPA-HQ-ORD-2010-0919. According to FACA requirements, meeting minutes, including descriptions of the discussions and conclusions reached by the Board will be prepared. These minutes will be certified by the Chair within 90 days of the meeting and posted at www.regulations.gov and on the HSRB Web site.

MEETING PROCESS

Dr. Sean Philpott explained that the Board would discuss the final draft Board report, focusing on the charge questions presented to the Board at the October 2010 meeting and summarizing the Board's response. The report is intended to be a summary of the HSRB's consensus recommendations and not a detailed technical document. The Agency and study sponsors have access to detailed meeting minutes for additional information.

For each charge question, Board members would have an opportunity to raise concerns they may have about Board conclusions and rationales. Dr. Philpott requested that the HSRB focus on substantive changes to the report that directly affect the Board's recommendations. Board members should submit typographical and grammatical corrections to Dr. Philpott and Mr. Downing via e-mail and they will be incorporated into the final report.

PUBLIC COMMENTS

Dr. Philpott invited public comment on the draft October 2010 HSRB meeting report. No public comments were presented. Dr. Philpott stated that one public comment was received via e-mail in response to the *Federal Register* announcement of the Board's teleconference meeting, but this comment focuses on the question of whether or not compounds such as the pesticides that the HSRB reviews should be tested on animals or humans. Because the comment does not relate directly to any of the issues discussed at the October 2010 meeting, he did not read it into the record.

BOARD DISCUSSION AND DECISION ON FINAL REPORT

Carroll-Loye Biological Research, Inc. Protocol No Mas-003: Field Efficacy Test of 16% Para-menthane-3,8-diol (PMD) and 2% Lemongrass Oil-based Repellent "No Mas" Against Mosquitoes

Dr. Philpott reviewed the Board's conclusions regarding Carroll-Loye Biological Research, Inc. protocol No Mas-003, which describes a study to test the repellent efficacy of a lotion formulation containing 16% PMD and 2% lemongrass oil ("No Mas") against three species of mosquitoes in the field. The Board was asked whether the proposed No Mas-003 field repellency study, if revised as suggested in EPA's review and if the research is performed as described, will likely generate scientifically reliable data useful for assessing the efficacy of the tested material in repelling mosquitoes (page 8, line 273). The Board concluded by concurring with the Agency's assessment that the proposed field repellency study protocol is likely to generate such scientifically reliable data. Dr. Philpott inquired if the Board members had comments on the Board's response to the charge question. The Board members did not have comments on the recommendation or rationale.

The ethics charge question for this protocol asked whether the research is likely to meet the applicable requirements of 40 Code of Federal Regulations (CFR) Part 26, subparts K and L, if the proposed field repellency study protocol No Mas-003 is revised as suggested in EPA's review and if the research is performed as described (page 9, line 309). The Board concluded that the protocol, if modified in accordance with EPA and HSRB recommendations, is likely to meet the applicable requirements. No Board members had comments on the recommendation or detailed rationale in the report.

Several Board members had recommended, during the report-writing process, that the HSRB develop a template for writing the scientific recommendations and rationale similar to the template for responses to ethics questions. This topic will be included on the administrative agenda for the January 2011 Board meeting.

Proposed Agricultural Handler Exposure Task Force (AHETF) Scenario and Protocol AHE-400: Backpack and Handgun Application of Liquid Sprays in Utility Rights-of-Way

Dr. Philpott explained that AHETF's proposal presents an agricultural handler exposure scenario involving backpack and handgun application of liquid pesticides along utility rights-of-way. Study participants would be asked to apply and potentially load one of four surrogate pesticides, with a total of 21 participants (three volunteers each from seven geographically distinct regions) enrolled using a purposive sampling method. During the October 2010 HSRB meeting, the Board was asked to address whether the proposed AHETF Right-of-Way application scenario and field study proposal AHE-400, if revised as suggested in EPA's review, and if the research is performed as described, is likely to generate scientifically reliable data useful for assessing the exposure of workers who apply pesticides in utility rights-of-way using backpack or handgun sprayers (page 13, line 475). The Board concurred with EPA's assessment that the proposed scenario and protocol AHE-400 is likely to generate scientifically reliable data.

Dr. Michael Lebowitz noted that the Board's recommendation did not describe adequately the Board's concerns in its discussions at the October 2010 HSRB meeting. At that time, the HSRB concluded that the protocol would provide useful data, but the issue of variability was raised a number of times in comments, both at the meeting and during preparation of the draft meeting report. There are only 21 sample points and the variability is high. If the study was replicated, results also could vary significantly, and concluding that the data would be "reliable" would be inappropriate. Dr. Philpott noted that Dr. Lebowitz had submitted comments during preparation of the report, and he had made a change in the detailed recommendations and rationale to remove the phrase "scientifically reliable" so that line 493 (page 13) reads "this protocol will likely generate data that may be useful for assessing the exposure" of pesticide handlers. Dr. Philpott suggest that a similar change be made at lines 486 and 487 (page 13) if the Board approved.

Dr. Janice Chambers cautioned that by removing the phrase "scientifically reliable," the Board would not be addressing the charge question. Dr. Philpott asked Board members and the Agency staff on the call for input on whether describing the data only as potentially useful adequately addresses EPA's charge. Mr. John Carley (Office of Pesticide Programs [OPP], EPA) believed that EPA would prefer the HSRB to address the charge question using the term "scientifically reliable data." He noted that although the concerns that the scenario could result in highly variable data were not without basis, the Board has not had the same concern about the term "reliable" with similar scenarios it has reviewed previously. The sample size, with seven clusters of three, is not statistically less reliable than a five-by-five sample, and the variability of individual behavior is not greater than in other scenarios. Dr. Chambers commented that the proposed locations are more variable than an orchard or row crop field, but she did not have a problem with the use of the term "reliable" because this does not mean that every situation would be the same. Dr. Lebowitz stated that the question concerned EPA's definition of "reliable" in the charge question; if trustworthy is meant rather than reproducible, the response would be different. He did not recall EPA instructing that the Board use the same words in its responses as in the charge question.

Dr. Philpott stated that there seemed to be Board consensus that the study would yield data that is trustworthy and useful for analysis, but the fundamental concern is that the variability inherent in the different proposed study environments calls into question the reproducibility of those data, should this design be replicated. Dr. William Popendorf suggested that the problem of variability should have been put into the model that determined the 3X factor, and he was unsure whether the same expected variability within the data was present in many other scenarios. If the 3X value is valid, then the mean value of those data should be as reliable as in any other scenario. Dr. Johnson responded that the data would be useful, but until the study is conducted the HSRB will not know whether the data are likely to be reproducible.

Dr. José Manautou stated that a clear definition of "scientifically reliable data" was needed. Dr. Chambers responded that the Board previously had not considered reproducibility when discussing reliability. Dr. Philpott noted that this case highlights a need for the Board to define its interpretation of some of the terms in the charge questions; the Board did not speak to a specific definition of "scientifically reliable" during the October 2010 HSRB meeting and therefore it should not be addressed within the meeting report. The Board's concerns have been

noted by the Agency and will be captured in the meeting minutes. He proposed that the Board come to consensus on how to phrase its response to the charge question so that the meeting report may be finalized. During the next HSRB meeting in January 2011, he will ask the lead discussants to be explicit about their definitions or interpretations of the phrase "scientifically reliable data."

Dr. Lebowitz suggested that the statements in question be reworded to read "is likely to generate scientific data, reliable in the sense that it is trustworthy." Dr. Philpott suggested that the Board not use a value-laden term like "trustworthy." Dr. Popendorf suggested that the statements should be kept as written. Dr. Philpott noted general consensus that in this case, an acceptable definition of scientific reliability would be data that are accurate within the context of the study, but that may not be reproducible should the scenarios be repeated. He would like to capture this idea in the report so that the Agency and the sponsors have an accurate assessment of the Board's interpretation. Dr. Lebowitz suggested leaving the recommendation as written, but adding Dr. Philpott's statement in the detailed recommendations. Dr. Philpott noted that the report states, on line 507 (page 14): "However, the Board noted a few weaknesses in the proposed study design. In particular, the variability in individual dermal and inhalation exposure levels may be extremely high because of the diversity of terrains and locations selected for the study and the opportunity for large (but potentially categorical) personal differences in application practices." Dr. Lebowitz suggested adding the following text after this sentence, "As such, results may not be reproducible should the study be repeated." Dr. Johnson added that the term "reliable" might be appropriate and that will be assessed when the Board reviews the data after the study is conducted. Once the data are received, it will be clear how accurately exposure can be assessed.

Dr. Philpott suggested that the HSRB recommendation (line 486, page 13) be changed from "is likely to generate scientifically reliable data" to "may generate scientifically reliable data." Drs. Rebecca Parkin, Chambers, and Manautou agreed. Dr. Philpott stated that with this change and the addition of the sentence Dr. Lebowitz suggested (above), the Board achieved consensus that the study may generate scientifically reliable data, but recognized that a high level of variability that may result from the diversity of terrain, location, and personal differences in application practices may call into question the data's reproducibility.

The ethics charge question asked whether the proposed scenario and protocol, if revised as suggested in EPA's review and if the research is performed as described, is likely to meet the applicable requirements of 40 CFR Part 26, subparts K and L (page 14, line 524). The Board concluded that the protocol, if modified in accordance with EPA and HSRB recommendations, is likely to meet the applicable requirements. Dr. Philpott noted that the primary concern raised by the Board was the task force conclusion that the risk of toxicity from pesticide-handling was not considered and the risk of surrogate toxicity would not be listed in the consent forms or the protocol. The HSRB strongly recommended that, given the scripted nature of the study, the risk of exposure to pesticides should be categorized as a risk due to study participation, albeit one that is appropriately minimized. The Board further made minor suggestions on how the study protocol should be modified, such as addressing some of the discrepancies noted in the exclusion criteria, and suggesting that study participants undergo handwashing prior to eating or smoking

to reduce the risk of accidental ingestion of the surrogate compound. Board members had no further comments or questions on the recommendation.

Completed Scenario Monograph and Study Report from the Antimicrobial Exposure Assessment Task Force II (AEATF–II): Dermal and Inhalation Exposure of Professional Janitorial Workers Applying Liquid Antimicrobial Products to Indoor Floors Using Bucket and Mop (AEA-03)

Dr. Philpott commented that during the report writing process, Dr. Popendorf noticed some data entry errors in the presentation of results from the mop study; these have been adequately resolved. The corrections did not affect the conclusions nor are they likely to affect the Board's recommendation, but there will be changes to EPA's presentation on the docket.

The Board was asked to address two scientific charge questions: (1) was the research reported in the AEATF–II completed study report AEA-03 and associated supplemental reports faithful to the design and objectives of the protocol and governing documents of the AEATF-II (page 17, line 674); and (2) has the Agency adequately characterized, from a scientific perspective, the limitations that should be considered when using these data in estimating exposure of those who apply antimicrobial floor-cleaning products with mop and bucket (page 18, line 678).

Dr. Popendorf will submit a separate report to the Agency with recommendations regarding some of the data limitations for the development of exposure models that he noted at the meeting, but that the HSRB did not have time to discuss in detail. These are mentioned in the report as being included in an appendix, but they will be sent to the Agency separately. The report has been modified accordingly. Line 779 (page 20) has been changed to read "Although not discussed in detail by the Board at the October 2010 meeting, several of these factors are discussed in a separate report submitted independently by HSRB member Dr. William Popendorf to the Agency." Dr. Chambers suggested that Dr. Popendorf not be mentioned by name, and Dr. Philpott agreed to remove his name from the sentence. All Board members will receive a copy of these recommendations.

In response to the charge questions, the Board concurred with the Agency's assessment that the research was conducted in a manner that was reasonably faithful to the design and objectives of the protocol and governing documents of the AEATF-II. The Board also concluded that the Agency had adequately, but not completely, characterized the limitations on those data that should be considered when using the data in estimating exposure of those who apply antimicrobial floor-cleaning products with mop and bucket. Those concerns about factors that may have been overlooked or underestimated are summarized in the Board's detailed recommendations and rationale (page 18, line 694).

Dr. Parkin pointed out that line 737 (page 19), which reads: "However, although the presumption of proportionality was demonstrated for dermal exposure and the amount of AI handled, the rationale supporting the presumption of proportionality for inhalation exposure needs to be recalculated but based on current data may not be as clear and consistent as for the dermal exposure," is unclear. Dr. Popendorf responded that the need to recalculate arose because

the correlation was based on concentration versus dose, so it did not include time. The current data do not correlate with the amount of active ingredient handled (AaiH); based on that, the recalculated data may not correlate either. He suggested adding "to include duration of exposure" after the word "recalculated" on line 740 (page 19) and ending the sentence at that point. Dr. Popendorf suggested that the phrase "but based on current data may not be as clear and consistent as for the dermal exposure" be deleted because it is speculation.

Dr. Manautou called the Board's attention to the sentence on line 713 (page 18) that reads: "While this lack of information places potentially important limitations on how the inhalation data should be interpreted, in the professional opinion of at least one Board member the impact of differences among the test sites are likely to be within a factor of about two and thus not substantively change the overall mean exposure levels." He asked whether it was necessary to stress that this comment was the opinion of one member. Dr. Philpott responded that this was an opinion that was not discussed at the meeting and was not part of the HSRB's consensus recommendation. Dr. Chambers questioned whether the Board had phrased anything like that in the past, and Dr. Philpott replied that it had used this phrasing when there had been disagreements in response to ethics questions when reviewing pre-rule studies. Mr. Downing commented that the phrase "in the professional opinion" had not been used previously by the Board. Dr. Philpott noted that "in the professional opinion of at least one Board member" could be changed to state "some Board members felt that…" Several Board members agreed to this change. However, Dr. Lebowitz questioned inclusion of the sentence. Dr. Lebowitz stated that most indoor environment studies show a factor of at least five in difference in air exchange due to ventilation. Dr. Popendorf asked whether this was in buildings like those being discussed in this study. Dr. Lebowitz responded that it was, and that the data were in the EPA Building Assessment Survey and Evaluation (BASE) database derived from a discussion of the Integrated Human Exposure Committee of the EPA Science Advisory Board. It is also included in a 1981 National Academy of Sciences (NAS) report on indoor pollutants. Dr. Chambers noted that this should be cross-referenced to add substance to the sentence. Dr. Lebowitz recommended removing the sentence because the Board has not had sufficient discussion on the topic. Dr. Philpott noted that if there were no objections, he would remove the sentence, but suggested that a reference to the NAS report be included. Dr. Popendorf suggested that a 1981 reference would not be applicable to the buildings under discussion. Dr. Lebowitz suggested the Integrated Human Exposure Committee of EPA's Science Advisory Board and the EPA BASE database be referenced instead, but he did not have the specific reference. Dr. Philpott asked Mr. Carley if the Agency would like additional guidance or references for consideration of the impact of heating, ventilating, and air conditioning (HVAC) systems on inhalation exposures. Mr. Carley responded the statement that the topic should be addressed with greater care is sufficient. Dr. Philpott will delete the sentence, but asked that Mr. Downing look for the reference that Dr. Lebowitz mentioned and send it to the HSRB members. Mr. Downing agreed to do so.

On line 753 (page 19), Dr. Lebowitz suggested removing the phrase "One Board member observed, however, that" and stating instead that "The Agency's reliance on hand wash data should be examined more closely to ensure that it has not overcorrected face and neck residue estimates." Dr. Popendorf questioned the sentence on line 755 that states "Another Board member questioned whether the model actually supports the conclusion of proportionality for some of the dermal configurations." Dr. Sidney Green, Jr. stated that this sentence may relate to a

question he raised at the meeting regarding a statement made by an EPA presenter to the effect that the data that would be generated may not be broadly applicable, but were being used in risk assessment. His concern was that if not broadly applicable, the data should not be used for risk assessment. Dr. Parkin commented that her notes indicated that the Board member who raised the issue was not in attendance. Dr. Philpott noted that the first sentence under discussion (line 753) could be changed to "The Agency should carefully examine the hand wash data, however, to ensure that it does not over-correct for face and neck residue estimates." Mr. Carley mentioned that in reviewing the draft, Mr. Timothy Leighton (OPP, EPA) and he had discussed the sentence, and Mr. Leighton agrees that the hand wash data may have over-corrected for face and neck residues. With respect to the sentence on line 755, Mr. Leighton noted that the Agency's conclusion was that the data do not support proportionality for some of the clothing configurations. He added that the Board and the Agency are in basic agreement about these points. Dr. Philpott then suggested that the sentence on line 753 be changed to state that the Agency has already recognized that the hand wash data may over-correct for face and neck residue estimates. Dr. Parkin recommended that the sentence on line 755 be simplified to state that "additionally, the model may not always support the conclusion of proportionality for all clothing configurations." The Board members agreed to these two changes.

The ethics charge question asked whether available information supports a determination that the study was conducted in substantial compliance with 40 CFR Part 26, subparts K and L (page 20, line 785). The Board concurred with the Agency's assessment that the study was conducted in substantial compliance with the applicable requirements. The Board's detailed response notes that there were three minor protocol deviations, but that they were unlikely to have affected the integrity of the research or the safety of the study participants. For future reference, the HSRB recommended that the sponsors clarify the criteria used to establish participants' health status prior to study enrollment. Dr. Vanessa Northington Gamble noted that number 1(b) was listed twice, on lines 817 and 832 (page 21). Dr. Philpott had found this error and corrected it. Board members did not have further comments on the recommendation or rationale.

Revised Scenario Design and Associated Protocol from the Agricultural Handler Exposure Task Force (AHETF) Describing Proposed Research to Monitor Exposure of Workers Who Mix and Load Pesticides Formulated as Wettable Powders in Water-Soluble Packaging (AHE-120)

Dr. Philpott noted that this was a revised proposal that had originally been reviewed favorably by the Board at the June 2009 HSRB meeting, but one of the surrogate pesticides was no longer available in water-soluble packaging, and the AHETF proposed to substitute three additional surrogate compounds. The AHETF proposed to change some of the study sites because of the use patterns of those compounds.

The scientific charge question asked whether the revised task force protocol and field study proposal, if revised as suggested in EPA's review and performed as described, was likely to generate scientifically reliable data useful for assessing the exposure of handlers who mix and load pesticides in water-soluble packaging (page 23, line 943). The Board concluded that it concurred with the Agency's assessment that the protocol will generate such scientifically

reliable data. The Board cautioned, however, that these data may not be useful for creating distributions of worker exposure that are scientifically accurate or precise. No Board members had comments on the recommendation or rationale.

The ethics charge question asked if the revised AHETF scenario and field study proposal AHE-120 is revised as suggested in EPA's review, and if it is performed as described, whether the research is likely to meet the applicable requirements of 40 CFR Part 26, subparts K and L (page 25, line 1006). The Board concluded that the protocol is likely to meet the applicable requirements. The HSRB noted that exposure to the surrogate chemicals should be considered a risk of study participation because of the scripted nature of the study, and should be listed as such in the protocol and the informed consent documents. The Board noted that the risk, however, is appropriately minimized. In addition, the Board raised concerns about the Institutional Review Board (IRB) review of the protocol using an expedited procedure and recommended that future protocol revisions that involve such major changes should be reviewed under full IRB procedures. Dr. Philpott noted that Dr. Virginia Ashby Sharpe is leading a small working group to address task force questions and concerns about how to release individual study exposure data to study participants; the findings of this group will hopefully be presented to the HSRB at the January 2011 HSRB meeting or the subsequent March 2011 teleconference. There were no Board comments on the recommendation or rationale.

SUMMARY AND NEXT STEPS

Mr. Downing noted that the next face-to-face HSRB meeting would be held on January 26, 2011. The meeting will be held in Arlington, Virginia, at EPA's Potomac Yard conference center.

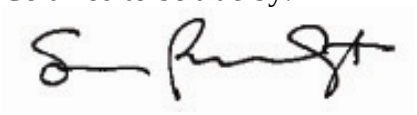
Dr. Philpott asked whether there were any Board member concerns or questions about the final October 2010 HSRB meeting report. All members present at the teleconference meeting agreed to accept the report if amended as discussed.

Dr. Philpott thanked Board members for their participation. The teleconference meeting was adjourned by the Chair at 4:30 p.m.

Respectfully submitted:

Jim Downing
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:



Sean Philpott, Ph.D., M.S. Bioethics
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public teleconference meeting reflect diverse ideas and suggestions offered by Board members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the Board members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final report prepared and transmitted to the EPA Science Advisor following the public meeting.

Attachments

Attachment A	HSRB Members
Attachment B	Federal Register Notice Announcing Meeting
Attachment C	Meeting Agenda

Attachment A

EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

*Sean Philpott, Ph.D., M.S. Bioethics — Term: 3/27/2006-10/31/2011
Director, Research Ethics
The Bioethics Program
Union Graduate College-Mt. Sinai School of Medicine
Schenectady, NY

Vice Chair

*Janice Chambers, Ph.D., D.A.B.T. — Term: 3/27/2006-10/31/2011
William L. Giles Distinguished Professor
Director, Center for Environmental Health Sciences
College of Veterinary Medicine
Mississippi State University
Mississippi State, MS

Members

*George C.J. Fernandez, Ph.D. — Term: 5/1/2010-8/31/2013
Director, Center for Research Design and Analysis
University of Nevada – Reno
Reno, NV

*Vanessa Northington Gamble, M.D., Ph.D. — Term: 10/19/2009-10/31/2012
University Professor of Medical Humanities
Gelman Library
The George Washington University
Washington, DC

*Sidney Green, Jr., Ph.D., Fellow ATS — Term: 10/19/2009-10/31/2012
Department of Pharmacology
Howard University College of Medicine
Howard University
Washington, DC

*Dallas E. Johnson, Ph.D. — Term: 8/31/2007-8/31/2013
Professor Emeritus
Department of Statistics
Kansas State University
Manhattan, KS

*Michael D. Lebowitz, Ph.D., FCCP — Term: 3/27/2006-8/31/2012
Retired Professor of Public Health
(Epidemiology) & Medicine & Research Professor of Medicine
University of Arizona
Tucson, AZ

*José E. Manautou, Ph.D. — Term: 5/1/2010-8/31/2013
Associate Professor of Toxicology
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^Jerry A. Menikoff, M.D. — Term: 3/27/2006-8/31/2012
Director, Office for Human Research Protections
Department of Health and Human Services
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*Rebecca T. Parkin, Ph.D., M.P.H — Term: 10/1/2007-8/31/2013
Professorial Lecturer (EOH)
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Washington, DC

*William J. Popendorf, Ph.D. — Term: 10/19/2009-10/31/2012
Professor Emeritus
Department of Biology
Utah State University
Logan, UT

Virginia Ashby Sharpe, Ph.D. — Term: 5/1/2010-8/31/2013
National Center for Ethics in Health Care
Veterans Health Administration
Department of Veterans Affairs
Washington, DC

*^Linda J. Young, Ph.D. — Term: 3/28/2008-8/31/2012
Department of Statistics
Institute of Food and Agricultural Sciences
University of Florida
Gainesville, FL

*Special Government Employee (SGE)
^Not in attendance at the December 13, 2010 teleconference

Attachment B

FEDERAL REGISTER NOTICE ANNOUNCING MEETING

[Federal Register: November 29, 2010 (Volume 75, Number 228)]
[Notices]
[Page 73078-73080]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr29no10-82]

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2010-0919; FRL-9232-5]

Human Studies Review Board (HSRB); Notification of a Public Teleconference To Review Draft Report From the October 27-28, 2010 HSRB Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Human Studies Review Board (HSRB) announces a public teleconference meeting to discuss its draft report from the October 27-28, 2010 HSRB meeting.

DATES: The teleconference will be held on Monday, December 13, 2010 from 3-5 p.m. (Eastern Time).

Location: The meeting will take place via telephone only.

Meeting Access: For information on access or services for individuals with disabilities, please contact Lu-Ann Kleibacker at least ten business days prior to the meeting using the information under FOR **FURTHER INFORMATION CONTACT**, so that appropriate arrangements can be made.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in section I, under subsection D, of this notice.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to receive further information should contact Jim Downing at telephone number: (202) 564-2468; fax: (202) 564-2070; e-mail address: downing.jim@epa.gov, or Lu-Ann Kleibacker at telephone number: (202) 564-7189; fax: (202) 564-2070; e-mail address: kleibacker.lu-ann@epa.gov; mailing address: U.S. Environmental Protection Agency, Office of the Science Advisor, Mail Code 8105R, 1200 Pennsylvania Ave., NW., Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA Web site at http://www.epa.gov/osa/hsrb/.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA-HQ-ORD-2010-0919, by one of the following methods: http://www.regulations.gov: Follow the on-line instructions for submitting comments.

E-mail: ORD.Docket@epa.gov.

Mail: ORD Docket, U.S. Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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Hand Delivery: EPA Docket Center (EPA/DC), Public Reading Room, Infoterra Room (Room Number 3334), EPA West Building, 1301 Constitution Ave., NW., Washington, DC 20460, Attention Docket ID No. EPA-ORD-2010-0919. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2010-0919. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comments includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. If you send an e-mail comment directly to EPA, without going through http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet.

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to persons who conduct or assess human studies on substances regulated by EPA or to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this notice. If you have any questions regarding the applicability of this notice to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I access electronic copies of this document and other related information?

In addition to using regulations.gov, you may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

Docket: All documents in the docket are listed in the index under the docket number. Even though it will be listed by title in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Copyright material will be publicly available only in hard copy. Publicly available docket materials are electronically available either through http://www.regulations.gov or in hard copy at the ORD Docket, EPA/DC, Public Reading Room, Infoterra Room (Room Number 3334), 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

C. What should I consider as I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you use that support your views.
4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and **Federal Register** citation.

D. How may I participate in this meeting?

You may participate in this meeting by following the instructions in this section. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-ORD-2010-0919 in the subject line on the first page of your request.

1. *Oral comments*. Requests to present oral comments will be accepted up to December 6, 2010. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments at the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via e-mail) to Lu-Ann Kleibacker listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, December 6, 2010 in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, public comments may be possible.
2. *Written comments*. Although you may submit written comments at any time, for the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit your comments at least five business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, December 6, 2010. You should submit your comments using the instructions in section I, under subsection C, of this notice. In addition, the Agency also requests that persons submitting comments directly to the docket also provide a copy of their comments to Lu-Ann Kleibacker or Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit

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on the length of written comments for consideration by the HSRB.

E. Background

The EPA Human Studies Review Board will be reviewing its draft report from the October 27-28, 2010 HSRB meeting. The Board may also discuss planning for future HSRB meetings. Background on the

October 27-28, 2010 HSRB meeting can be found at **Federal Register** 75 193, 61748 (October 6, 2010) and at the HSRB Web site http://www.epa.gov/osa/hsrb/. The October 27-28, 2010 meeting draft report is now available. You may obtain electronic copies of this document and certain other related documents that might be available electronically from the http://www.regulations.gov Web site and the HSRB Internet home page at http://www.epa.gov/osa/hsrb/. For questions on document availability or if you do not have access to the Internet, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: November 19, 2010.
Paul T. Anastas,
EPA Science Advisor.
[FR Doc. 2010-29814 Filed 11-26-10; 8:45 am]
BILLING CODE 6560-50-P

Attachment C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (EPA)
HUMAN STUDIES REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE MEETING
Monday, December 13, 2010
3:00 p.m. - 5:00 p.m. (Eastern Time)*

HSRB MEETING FOR REVIEW AND APPROVAL OF THE DRAFT OCTOBER 27-28, 2010 HSRB MEETING REPORT

HSRB Web Site: http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566-1752
Docket Number: EPA–HQ–ORD–2010–0919

Meeting location via telephone only

3:00 PM	**Convene Meeting and Identification of Board Members** – Jim Downing (Designated Federal Officer [DFO], HSRB, Office of the Science Advisor [OSA], EPA)
3:10 PM*	**Meeting Administrative Procedures** – Jim Downing (HSRB DFO)
3:15 PM	**Meeting Process –** Sean Philpott, Ph.D. (HSRB Chair)
3:20 PM	**Public Comments**
3:30 PM	**Board Discussion and Decision on Final Report –** Sean Philpott, Ph.D. (HSRB Chair)

The Board's response to EPA charge questions presented at the October 27-28, 2010 meeting.

Carroll-Loye Biological Research, Inc. Protocol *No Mas 003,* a Field Efficacy Test of PMD and Lemongrass Oil-based Repellent "No Mas" Against Mosquitoes

Charge to the Board:

If the proposed field repellency study protocol No Mas 003 is revised as suggested in EPA's review and if the research is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the efficacy of the tested material in repelling mosquitoes?

Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

A new scenario design and associated protocol from the Agricultural Handler Exposure Task Force (AHETF) to measure dermal and inhalation exposure to applicators who use backpack sprayers or hand gun sprayers to apply pesticides in utility rights-of-way

Charge to the Board:

If the proposed AHETF Right-of-Way application scenario and field study protocol AHE400 is revised as suggested in EPA's review and if it is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of workers who apply pesticides in utility rights-of-way with backpack or hand gun sprayers?
- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Completed scenario monograph and study report from the Antimicrobial Exposure Assessment Task Force II (AEATF–II): Dermal and Inhalation Exposure of Professional Janitorial Workers Applying Liquid Antimicrobial Products to Indoor Floors Using Bucket and Mop

Charge to the Board:

In the completed scenario monograph and study report AEA03 from the AEATF–II:

- Was the research reported in the AEATF–II completed study report AEA03 and associated supplemental reports faithful to the design and objectives of the protocol and governing documents of AEATF-II?
- Has the Agency adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating exposure of those who apply antimicrobial floor-cleaning products with mop and bucket?
- Does available information support a determination that the study was conducted in substantial compliance with 40 CFR 26, subparts K and L?

Revised scenario design and associated protocol from the Agricultural Handler Exposure Task Force (AHETF) describing proposed research to monitor exposure of workers who mix and load pesticides formulated as wettable powders in water-soluble packaging

Charge to the Board:

If the revised AHETF scenario and field study proposal AHE120 is revised as suggested in EPA's review, and if it is performed as described:

- Is the research likely to generate scientifically reliable data, useful for assessing the exposure of handlers who mix and load pesticides in water-soluble packaging?
- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

4:55 PM **Summary and Next Steps –** Sean Philpott, Ph.D. (HSRB Chair) and Jim Downing (HSRB DFO)

5:00 PM **Adjournment**

* Please be advised that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Jim Downing via telephone: (202) 564-2468 or email: downing.jim@epa.gov.