Final Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
December 12, 2017, Public Meeting
HSRB Website: www.epa.gov/osa/human-studies-review-board

Committee Members:	(See EPA HSRB Members List—Attachment A)	
Date and Time:	Tuesday, December 12, 2017, 2:00-3:30 p.m. EST	
Location:	Via Teleconference and Webinar	
Purpose:	The EPA HSRB provides advice, information and recommendations on issues related to the scientific and ethical aspects of human subject research.	
Attendees:	Chair:	Liza Dawson, Ph.D.
	Vice Chair:	Edward Gbur, Jr., Ph.D.
	Board Members:	Jennifer Cavallari, Sc.D., CIH Alesia Ferguson, Ph.D. Kyle L. Galbraith, Ph.D. Walter T. Klimecki, D.V.M., Ph.D. Jun Zhu, Ph.D.
	EPA:	Michelle Arling (EPA) Timothy Dole (EPA) Timothy Leighton (EPA)
	Study Sponsor:	Has Shaw (American Chemistry Council) Bryce Landenberger (Dow Chemical Co.) Brian Lange (Lange Research and Consulting, Inc.)
Absent:	Board Members:	Randy Maddalena, Ph.D.
Meeting Summary:	Meeting discussions generally followed the issues and general timing as presented in the Meeting Agenda unless noted otherwise.	

Tuesday, December 12, 2017

Convene Public Meeting

Mr. Tom O'Farrell (Designated Federal Officer [DFO], HSRB [or Board], Office of the Science Advisor [OSA], EPA [or the Agency]) convened the meeting at 2:13 p.m. and welcomed Board

members, EPA colleagues and members of the public. He expressed appreciation to the Board members for their service and thanked EPA's Office of Pesticide Programs (OPP) for preparing for this meeting. As DFO, Mr. O'Farrell, under the Federal Advisory Committee Act (FACA), serves as liaison between the HSRB and EPA and is responsible for ensuring that all FACA requirements are met regarding the operations of the HSRB. Also in his role as DFO, he must work with appropriate Agency officials to ensure that all applicable ethics regulations are satisfied. HSRB members were briefed on federal conflict-of-interest laws and have completed a standard government financial disclosure report, which has been reviewed to ensure that all ethics requirements are met.

Mr. O'Farrell informed the Board that the purpose of the meeting was to finalize the Board's report from the October 25, 2017 meeting. He mentioned that supporting documents for the meeting were attached to the meeting invite and available on the HSRB web site at www.epa.gov/osa/human-studies-review-board. He noted that the Agenda times were approximate, and the group would strive to allow adequate time for the Board's thorough deliberations and decisions, and any public comments.

Because this was a virtual meeting over the phone, Mr. O'Farrell encouraged the Board to work together to: 1) mute phone lines; 2) unmute phone lines before speaking; and 3) state their name before providing remarks. Mr. O'Farrell noted that meeting was being recorded.

In accordance with FACA requirements, the Agenda provides for a public comment time, offering the public the opportunity to provide comments to the Board. Mr. O'Farrell announced that he had no public comments, as of the start of the meeting. He stated that members of the public wishing to make a public comment must limit their remarks to five minutes. He explained that the HSRB Chair would call for public comments at the scheduled point in the Agenda.

In accordance with FACA requirements, meeting minutes, including a description of the matters discussed and conclusions reached by the Board, are prepared and must be certified by the meeting Chair within 90 days of this meeting. The approved minutes will be available on the HSRB website at www.epa.gov/osa/human-studies-review-board. The HSRB also will prepare a final report in response to questions posed by the Agency, which will include the Board's review and analysis of materials presented. The final report will be available on the HSRB website at www.epa.gov/osa/human-studies-review-board.

After taking attendance, Mr. O'Farrell then turned the meeting over to the HSRB Chair, Dr. Liza Dawson.

Virtual Meeting Operations

Dr. Dawson reviewed the operating procedures for the virtual meeting. She instructed Board members to use the Adobe Connect meetings feature that allows them to raise their hands in the webinar to be recognized by the Chair when offering comments. When voting, the Board members used the polling function in the webinar to agree or disagree with the proposal.

Introduction of Board Members

Dr. Dawson welcomed the Board members and asked them to introduce themselves, providing their names, affiliations and areas of expertise. Following those introductions, Mr. O'Farrell then asked other attendees to identify themselves.

Opening Remarks

Dr. Dawson opened the meeting by stating the purpose of the December 12, 2017 teleconference/webinar was to discuss the October meeting draft report and recommendations from the Board (the HSRB draft report). Dr. Dawson stated that everyone already had a chance to review the draft report; however, no comments via e-mail were received from Board members. Comments were received from Michelle Arling and EPA's Office of Pesticide Programs (OPP), which were helpful. Dr. Dawson assumed no other comments were sent and stated that any comments from Board members would be taken during the teleconference/webinar.

Main Issues

The main issue that requires the Board to reach consensus was respirator use; the one issue that was not resolved during the last meeting. During the last meeting, scientific reviewers (Dr. Cavallari and Dr. Ferguson) drafted a proposed recommendation on what decision-making criteria should be used to determine:

1. If respirators should be required for the study;
2. If required, what kind of respirator; and
3. If respirator fit testing should be required.

The type of exposure will dictate the level of respiratory protection for human subjects during the study. The proposed recommendation by Dr. Cavallari and Dr. Ferguson addressed:

1. An assessment of the type of exposure caused by the paint product;
2. The types of chemicals (e.g., volatiles) and particulates;
3. If there is exposure, what kind of respirator would be needed based on OSHA standards (meeting respiratory protection requirements for an employer).

The proposed recommendation further stated that if a respirator is required to meet OSHA standards, then fit testing should also be required. In addition, the proposed recommendation stated that study subjects could either use a respirator provided by their employer or use one provided by the study; this would allow the study to be more inclusive. After the recommendation was proposed, information came in from OPP regarding exposures from sprayers and chemicals in the paint product. This information was intended to inform the assessment about the respirators.

Addressing OPP Information in the Report

Dr. Dawson's first question to the Board was if the members would prefer to assess respiratory protection for study subjects based on the information provided by EPA/OPP regarding the respirators and developing a specific recommendation; or to keep the Board's recommendations as they were in the draft report and recommend that EPA/OPP to provide information to guide the decision about respirator use (Dr. Dawson's preferred alternative). Dr. Dawson noted that if the Board chose to let the existing recommendation stand, it should not be interpreted as a judgment against EPA/OPP's information but rather seen as framing the issues that need to be addressed. Dr. Dawson also noted that, given the Board members' availability and unfamiliarity with the subject matter (with the exception of Dr. Cavallari and Dr. Ferguson), it may not be appropriate at this time to weigh in on the information provided by EPA/OPP.

Dr. Dawson asked Dr. Cavallari and/or Dr. Ferguson if they had anything to add or if they would like to make any corrections to the opening statements/introduction.

Dr. Ferguson stated that her review of the EPA/OPP documents indicated that the information was helpful; however, she requested EPA's input on page 2 of their write-up, *Respiratory Requirements Evaluation.* This section describes how Safety Data Sheets (SDSs) and previous studies were used to perform calculations to determine what exposures may exist from volatiles and particulates. Calculations supported that exposure to particulates posed a greater concern than exposure to volatiles; for 30 gallons of paint, there is potential for exposure levels where respirators may be needed. Dr. Ferguson asked EPA/OPP attendees to comment.

Mr. Dole (EPA) agreed that under some scenarios in the protocol reviewed by the HSRB (protocol for study AEA10), respirators would be needed for indoor paint spraying.

Dr. Ferguson stated that when this conclusion is compared to the Board's recommendations, respirators will be needed for particulates and training will be required to meet OSHA standards regarding respirator use.

Dr. Cavallari stated that although the information provided by EPA/OPP was important, before the Board draws any final conclusions based on recommendations, the Board should request that EPA deliver a presentation describing how their data was analyzed. As such, at this time, Dr. Cavallari preferred to keep the Board's recommendations as they were in the draft report

Dr. Ferguson agreed with Dr. Cavallari's statement that more information would be needed for the Board understand how the EPA/OPP data was derived and why a respirator for particulates was needed.

Process and Procedures for Board's Final Recommendations

With respect to process and procedures, Dr. Dawson asserted that if the Board makes a recommendation, then it is up to EPA on how to respond; the Board does not weigh in on EPA's response to every point made by the Board. For example, if the Board finalizes its proposed recommendations, the Board is not required to review the response to the recommendation.

Michelle Arling (EPA) believed that this assertion was correct, with a caveat that one could use this information to refine the recommendation. EPA also looks to the Board to advise them on technical issues within their area of expertise.

Dr. Dawson recognized that the Board's recommendation may need to be refined but suggested that it may be better not to do the refinement of the Board's recommendation "on the fly." The existing recommendation can also be responded to; additional information does not render the existing recommendation moot. Dr. Dawson asked the Board about which approach should be taken: 1) refine its recommendations based on EPA's information; or 2) allow the existing recommendations to stand as they were in the draft report.

Dr. Cavallari prefers to keep the Board's recommendations as they were in the draft report because although the information provided was helpful, addition decisions need to be made based on a more thorough discussion.

Dr. Gbur agreed to keep the existing recommendations as they were in the draft report, stating that it was better to defer to the subject matter experts at EPA.

Medical Clearance Issue

Dr. Cavallari clarified that the Board recommended that the type and level of exposure be identified. She noted that in addition to fit testing, the draft report also recommended medical clearance.

Dr. Dawson asked whether OSHA standards require medical clearance for all types of respirators or just some.

Dr. Ferguson stated that some respirators required medical clearance, but if difficulty in breathing is observed in other respirators, then medical clearance would be required. Dr. Ferguson also agreed with keeping the recommendations as they were in the draft report because they match up with EPA's objective to determine what the exposures may be and if a respirator is needed.

Dr. Dawson agreed that the Board's existing recommendation was consistent with what EPA was already doing; however, Dr. Dawson asked for clarification if the Board would be requesting a medical clearance for respirators that do not require it.

Although Dr. Ferguson offered to look up the information and clarify later, Dr. Dawson preferred to finalize the language of the Board's report. Dr. Dawson asked if anyone on the phone from OPP had medical clearance information handy.

Mr. Dole (EPA) stated that, as a result of the analysis he performed in meeting a respirator protection factor of 2.5, the type of respirator required is of the type that provides the least breathing resistance. Under OSHA standards for voluntary respirator use, filtering face piece respirators do not need medical clearance. Only half-face cartridge respirators require medical

clearance. However, because respirator use will be required in the study, then medical clearance should also be required.

Given that information, Dr. Dawson asked whether the Board's existing recommendation would be consistent with the medical clearance requirement for the less burdensome type of respirator.

Mr. Dole (EPA) agreed with that statement.

Dr. Cavallari stated that this assertion was consistent with her understanding that mandatory respirator use, no matter what type, requires medical clearance.

Other Issues and Opportunity for Public Comment

Based on discussions during the teleconference/webinar, Dr. Dawson asserted that it was the Board's desire to keep the existing recommendations as they were in the draft report. Dr. Dawson solicited feedback from the Board on this assertion. No Board members responded.

Dr. Dawson asked the Board if there was any other issue in the draft report that warranted discussion. No Board members responded.

Dr. Dawson asked Mr. O'Farrell if there were any public participants on the phone who wanted an opportunity to comment. At that time, Dr. Dawson solicited comments from public participants on the teleconference/webinar, and there were no public comments.

Medical Records Issue

Mr. Bryce Landenberger (Dow Chemical Co.) expressed concerns about the study not being equipped to handle medical records; that is, they were in an odd position because typically the subjects' employers maintain private medical records, not researchers or study sponsors. Moreover, there may be a substantial amount of work associated with determining if the subject is fit to wear a respirator based on their medical history. As such, this may create a situation where the study may not be able to move forward.

Dr. Cavallari noted some issues associated with the EPA Report, including time-weighted average (TWA) on exposure to determine level of respiratory protection. In the EPA Report, there was a 6-hour maximum amount of time that workers are exposed; actual exposures in the study may be lower than those projected and listed in the table from EPA's Report. As such, there may be room in the study to get below exposure levels where respirators would not be required. Dr. Cavallari emphasized that this decision would have to be made by the study sponsors.

Dr. Dawson summarized that the issues in question were: 1) if the use of respirators would be voluntary or required; and 2) if medical clearance would be required.

Dr. Cavallari suggested that there may be ways to get exposure levels below the regulatory threshold levels that require respirators and still have a valid study.

Dr. Dawson understood this suggestion but believed the medical record issue brought up by Mr. Landenberger should be addressed; that medical records management may be more burdensome to the study than the use of respirators in the study. As such, Dr. Dawson would like to know more about what a medical evaluation would consist of; that is, if the evaluation would require the storage of detailed medical records. Dr. Dawson solicited the group for information on this issue.

Dr. Ferguson responded that her medical evaluation simply consisted of going to the physician and having a lung evaluation (simple test of blowing into a tube) and completing a questionnaire about asthma.

Mr. Dole (EPA) responded that OSHA requires the completion of a questionnaire (basic screening questions) with a health professional to determine if the increased burden of wearing a respirator would lead to adverse health effects. Breathing spirometry tests are sometimes performed to make this determination, but are not required.

Dr. Dawson summarized that medical evaluation would consist of a screening questionnaire to determine the potential effects of wearing a respirator, which could reasonably be incorporated into this study. She suggested considering study feasibility and what is protective for the subject.

Dr. Klimecki commented that the issue rests on whether or not wearing a respirator is required to meet an OSHA standard that protects the study subjects. If required, then respirators should be worn, despite the overhead.

Dr. Dawson asserted that everyone was in agreement that the study should be consistent with OSHA standards, but she needed to understand what these standards are. Dr. Dawson also solicited comments from the group about the decision to go forward with the Board's proposed recommendations or refine the recommendations prior to finalization.

Dr. Ferguson agreed with Dr. Klimecki's concern and stated she would feel uncomfortable not recommending respirator use, fit testing, and medical clearance; if these worker safety and health procedures are needed for study subjects, then they should be included in the study. Dr. Ferguson recommended keeping the Board's recommendations as they were in the draft report.

Board Vote on Draft Recommendations

Dr. Dawson proposed a show of hands on finalizing the draft report as currently written or redrafting the recommendations. Dr. Dawson noted that the Board recommendations were consistent with EPA's approach. Dr. Dawson then asked the group if there were any more issues before the vote.

Mr. O'Farrell asked if the two comments in Section 7 were resolved (regarding residues on gloves) on the previous mark-up copy of the draft report. Dr. Dawson and Dr. Ferguson stated that these issues were resolved.

Dr. Dawson then asked for vote to finalize the Board's report by a show of hands through the webinar, and all Board members agreed.

Adjournment

Dr. Dawson thanked the Board members for their efforts and turned the meeting over to Mr. O'Farrell. Mr. O'Farrell announced that the Agenda for the December meeting was completed.

Mr. O'Farrell announced that the next HSRB meeting is scheduled for January 23 and 24, 2018. The times and agenda for this meeting will be posted on the HSRB website.

Mr. O'Farrell thanked the HSRB members for their participation and adjourned the meeting at 3:12 p.m. EDT.

Respectfully submitted:

Thomas O'Farrell
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:

Liza Dawson, Ph.D.
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public 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.

Attachment A
EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

Liza Dawson, Ph.D.
Research Ethics Team Leader
Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD

Vice Chair

Edward Gbur, Jr., Ph.D.
Professor of Statistics
Director, Agricultural Statistics Laboratory
University of Arkansas
Fayetteville, AR

Members

Jennifer Cavallari, Sc.D., CIH
Assistant Professor
Division of Occupational and Environmental Medicine
University of Connecticut
Storrs, CT

Alesia Ferguson, Ph.D.
Associate Professor
Department of Environmental and Occupational Health
University of Arkansas
Little Rock, AR

Kyle L. Galbraith, Ph.D.
Human Subjects Protection
Carle Foundation Hospital
Urbana, IL

Walter T. Klimecki, D.V.M., Ph.D.
Associate Professor
Departments of Pharmacology and Toxicology
The University of Arizona Health Sciences
Tucson, AZ

Randy Maddalena, Ph.D.
Physical Research Scientist
Indoor Environment Group
Lawrence Berkeley National Laboratory
Berkeley, CA

Jun Zhu, Ph.D.
Professor of Statistics and of Entomology
Department of Statistics
University of Wisconsin–Madison
Madison, WI

Consultants to the Board

Kendra L. Lawrence, Ph.D., BCE, PMP
Health Sciences Product Manager
U.S. Army Medical Materiel Development Activity
Fort Detrick, MD

Attachment B
***FEDERAL REGISTER* NOTICE ANNOUNCING MEETING**

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9968-88-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of the Science Advisor announces two separate public meetings of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects.

DATES: A virtual public meeting will be held on Wednesday, October 25, 2017 and Thursday, October 26, 2017, from 1:00 pm to approximately 5:00 pm Eastern Time on both dates. A separate, subsequent teleconference meeting is planned for Tuesday, December 12, 2017, from 2:00 pm to approximately 3:30 pm Eastern Time for the HSRB to finalize its Final Report of the October 25 and 26, 2017 meeting and review other possible topics.

ADDRESSES: Both of these meetings will be conducted entirely by telephone and on the Internet using Adobe Connect. For detailed access information visit the HSRB Website: http://www2.epa.gov/osa/human-studies-review-board

FOR FURTHER INFORMATION, CONTACT: Any member of the public who wishes to receive further information should contact the HSRB Designated Federal Official (DFO), Thomas O'Farrell on telephone number (202) 564-8451; fax number: (202) 564-2070; email address: ofarrell.thomas@epa.gov; or mailing address: Environmental Protection Agency, Office

of the Science Advisor, Mail code 8105R, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Meeting access: These meetings will be open to the public. The full Agenda and meeting materials will be available at the HSRB Website: http://www2.epa.gov/osa/human-studies-review-board . For questions on document availability, or if you do not have access to the Internet, consult with the DFO, Thomas O'Farrell, listed under FOR FURTHER INFORMATION, CONTACT.

Special accommodations. For information on access or services for individuals with disabilities, or to request accommodation of a disability, please contact the DFO listed under FOR FURTHER INFORMATION, CONTACT at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

How May I Participate in this Meeting?

The HSRB encourages the public's input. You may participate in these meetings by following the instructions in this section.

1. Oral comments. Requests to present oral comments during either meeting will be accepted up to Noon Eastern Time on Wednesday, October 18, 2017, for the October 25 and 26, 2017 meeting and up to Noon Eastern Time on Tuesday, December 5, 2017 for the December 12, 2017 meeting. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments during either meeting at the designated time on the agenda. Oral comments before the HSRB are generally limited to five

minutes per individual or organization. If additional time is available, further public comments may be possible.

2. Written comments. Submit your written comments prior to the meetings. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments by Noon Eastern Time on Wednesday, October 18, 2017, for the October 25 and 26, 2017 meeting and up to Noon Eastern Time on Tuesday, December 5, 2017 for the December 12, 2017 meeting. If you submit comments after these dates, those comments will be provided to the HSRB members, but you should recognize that the HSRB members may not have adequate time to consider your comments prior to their discussion. You should submit your comments to the DFO, Thomas O'Farrell listed under FOR FURTHER INFORMATION, CONTACT. There is no limit on the length of written comments for consideration by the HSRB.

Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 § 9. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of third-party human subjects research that are submitted to the Office of Pesticide Programs (OPP) to be used for regulatory purposes.

Topic for discussion. On October 25 and 26, 2017, EPA's Human Studies Review Board will finalize the draft Final Report from the July 26, 2017 meeting and consider two topics: the Antimicrobial Exposure Assessment Task Force II Airless Sprayer Study Protocol and Pinebelt Laboratory Evaluation of Bite Protection from Repellent-Impregnated Fabrics Study Protocol. The Agenda and meeting materials for this topic will be available in advance of the meeting at http://www2.epa.gov/osa/human-studies-review-board.

On December 12, 2017, the HSRB will review and finalize their draft Final Report from the October 25 and 26, 2017 meeting, in addition to other topics that may come before the Board. The HSRB may also discuss planning for future HSRB meetings. The agenda and the draft report will be available prior to the meeting at http://www2.epa.gov/osa/human-studies-review-board.

Meeting minutes and final reports. Minutes of these meetings, summarizing the matters discussed and recommendations made by the HSRB, will be released within 90 calendar days of the meeting. These minutes will be available at http://www2.epa.gov/osa/human-studies-review-board. In addition, information regarding the HSRB's Final Report, will be found at http://www2.epa.gov/osa/human-studies-review-board or from Thomas O'Farrell listed under FOR FURTHER INFORMATION, CONTACT.

Date: _____

_____
Robert J. Kavlock, Ph.D.
EPA Science Advisor