EPA Human Studies Review Board (HSRB)
June 16, 2022 Meeting Minutes

June 16, 2022 EPA Human Studies Review Board Meeting Minutes

Committee Members: (See EPA HSRB Members List – Attachment A)
Date and Time: Thursday, June 16, 2022, 2:00 to 2:20 pm EDT.
Location: Via Zoom Meeting
Purpose: The HSRB provides advice, information and recommendations on issues related to scientific and ethical aspects of human subjects research.
HSRB Website: https://www.epa.gov/osa/human-studies-review-board

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Thursday, June 16, 2022:

A. Convene Public Meeting and Identification of Board Members

Tom Tracy, Designated Federal Officer, EPA Human Studies Review Board (HSRB), Office of the Science Advisor, Policy and Engagement (OSAPE)

Mr. Tom Tracy, Designated Federal Official (DFO) for the Human Studies Review Board (HSRB), called the meeting to order at 2:00 pm, EST. He noted upcoming membership changes effective August 31st. He introduced the meeting, outlined the Federal Advisory Committee Act (FACA) procedures, and performed a roll call of the meeting participants. The following members and observers were present:

HSRB members	Jennifer Cavallari, Sc.D., University of Connecticut (Chair) Alesia Ferguson, Ph.D., North Carolina A&T State University (Vice Chair) Mark Aulisio, Ph.D., Case Western University Philip Day, Ph.D., UMass Chan Medical School George Milliken, Ph.D., Milliken Consultants Julia Sharp, Ph.D., Colorado State University Albert J. Allen, M.D., Ph.D., Eli Lilly Eun Um, Ed.D., AMSTAT Consulting Lisa Corey, Ph.D., Intertox, Inc. Thomas Lewandowski, Ph.D., Gradient

EPA staff members	Michelle Arling, EPA, Office of Pesticide Programs (OPP) Tom Tracy, EPA, Office of Science Advisor, Policy and Engagement (OSAPE) Taylor Lass, EPA, OSAPE Monique Tadeo, EPA, Program in Human Research Ethics and Oversight (PHREO) Alexander Kliminsky, EPA, Office of Chemical Safety and Pollution Prevention (OCSPP) Timothy Dole, EPA, OPP
Members of the public, representatives of research sponsor and research team:	Afroditi Katsigiannakis, ICF, Contractor Support Julia Finver, ICF, Contractor Support

B. Meeting Administrative Procedures

Tom Tracy, Designated Federal Officer, EPA Human Studies Review Board (HSRB), Office of the Science Advisor, Policy and Engagement (OSAPE)

Mr. Tom Tracy reviewed Zoom Meeting platform tools and features and stated the purpose of the meeting was to review the paper by L. Rosenheck et al.[1] He noted minutes of the meeting and a report will be prepared, certified, and posted on the website within 90 days of June 16, 2022.

C. Meeting Process

Jennifer Cavallari, Sc.D., HSRB Chair

Dr. Jennifer Cavallari welcomed everyone to the EPA HSRB meeting and stated the purpose of the meeting was to confirm the meeting report from the April 27th HSRB meeting. Dr. Cavallari explained she would provide a high-level overview of changes in the report and then open the floor to comments from participants. She noted she would share her screen during the Board discussion to allow for review of the final draft of the report. HSRB members would vote on their agreement with the proposed responses to the charge questions through the "agree" and "disagree" functionalities within the Zoom Meeting platform.

D. Public Comments

Dr. Cavallari asked whether any members of the public had comments. There were none.

[1] Rosenheck, L. (2021) A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products; Scenario 2b: Measurement of Potential Dermal and Inhalation Exposure During Indoor Electrostatic Spraying of Sanitizers and Disinfectants. Sponsored by the Antimicrobial Exposure Assessment Task Force II. Study Number AEA14(2b), 645 pages. September 20, 2021. MRID 51707701.

E. Board Discussion and Decision on April 27, 2022, Meeting Final Report and Minutes

Jennifer Cavallari, Sc.D., HSRB Chair

Dr. Cavallari shared her screen and identified the six changes suggested by EPA. The first suggestion changed the microbial formulations text on page six from, "e.g., liquid concentrates, ready-to-use powders, etc." to "e.g., soluble concentrates, ready-to-use solutions, etc." A change on page seven added the clarifying sentence, "The surrogate chemical was one of the four quats, quat Didecyldimethylammonium chloride (DDAC), had respective concentrations from 36.3 to 145 ppm." The next suggestion added to page eight the sentence, "Lab spike recoveries were also used to adjust the residue concentration measured for the subjects." An edit to page nine changed the text from, "the highest residues were found on the hands (75% of dermal exposure)," to "80% of dermal exposure." After explaining each of these changes, Dr. Cavallari asked whether anyone had comments about the edits. There were no comments.

Dr. Cavallari next discussed proposed changes to page ten involving the sentence, "Use of the 12-inch wand extension that can be used on Victory Electrostatic Spray Study (ESS) seemed to reduce both dermal and inhalation exposures (creating more distance between the subject and the target compound), but there was not enough data to conclude a reduction of exposure with use of the wand extension." She asked whether there were any comments. Dr. Alesia Ferguson noted the language was contradictory. Dr. Cavallari clarified the text, changing, "but there was not enough data to conclude a reduction of exposure with use of the wand" to "but there was not enough data to conclude a statistically significant reduction of exposure with use of the wand extension."

She then reviewed the final editorial change, which resulted in the sentence, "If a specific estimate has a k-factor of three or less, the sample statistic will be accurate to within 3-fold the population estimate 95 percent of the time." Dr. Lisa Corey asked whether the sentence should read, "3-fold of the population estimate.…" Dr. Julia Sharp replied, noting the addition of the word "of" after "3-fold" was correct. Dr. Cavallari changed the sentence to, "If a specific estimate has a k-factor of three or less, the sample statistic will be accurate to within 3-fold of the population estimate 95 percent of the time."

Dr. Cavallari asked whether anyone had final comments or concerns about the final report. There were none. She motioned that the Board accept the April 27th, 2022, HSRB meeting final report, and the members unanimously agreed. She noted she would accept all the changes, finalize the report, and forward it to Mr. Tracy to review and upload onto the HSRB website.

F. Summary and Next Steps

Tom Tracy, Designated Federal Officer, EPA HSRB, OSAPE
Jennifer Cavallari, Sc.D., HSRB Chair

Dr. Cavallari asked Ms. Michelle Arling to share the July meeting date. Ms. Arling stated the HSRB would review the science and ethics of a patch test with an isothyazolinote at the next meeting on July 21st, 2022. She thanked Ms. Arling and asked whether Mr. Tracy had anything else to add. He reiterated there would be a change in Board membership after the meeting in July. Dr. George Milliken asked when participants would receive more information about the July meeting. Ms. Arling responded, stating information would be available by the end of the week or next Tuesday, June 21st, 2022.

G. Adjournment

The meeting adjourned at 2:18 pm, EST.

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Attachment A: HSRB Current Committee Membership

Name	Title	Affiliation
Jennifer Cavallari, ScD, CIH, Chair	Associate Professor	Division of Occupational and Environmental Medicine University of Connecticut Storrs, CT
Alesia Ferguson, Ph.D., Vice Chair	Associate Professor	Department of Built Environment North Carolina A&T State University Greensboro, NC
Janice Britt, Ph.D.	Managing Scientist	ToxStrategies Tallahassee, FL
George Milliken, Ph.D.	Statistical Consultant	Milliken Consultants Manhattan, KS
Mark Aulisio, Ph.D.	Professor	Case Western Research University Cleveland, OH
Thomas Lewandowski, Ph.D.	Principal	Gradient Seattle, WA
Julia Sharp, Ph.D.	Associate Professor	Colorado State University Fort Collins, CO
Albert J. Allen, M.D., Ph.D.	Senior Medical Fellow	Eli Lilly Indianapolis, IN
Lisa Corey, Ph.D.	Toxicologist	Intertox, Inc. Seattle, WA
Lindsay McNair, M.D.	Chief Medical Officer	WIRB-Copernicus Princeton, NJ
Eun Um, Ed.D.	President and CEO	AMSTAT Consulting San Jose, CA
Philip Day, Ph.D.	Assistant Professor	University of Massachusetts Chan Medical School Worcester, MA

Attachment B: Federal Registers Notice Announcing Meetings

ENVIRONMENTAL PROTECTION AGENCY

[FRL-10017-40-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of the 2022 public meetings of the Human Studies Review Board (HSRB). 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.

DATES: Four three-day virtual public meetings will be held on:

1. January 25-27, 2022;
2. April 26-28, 2022;
3. July 19-21, 2022; and
4. October 25-27, 2022.

Meetings will be held each day from 1 p.m. to 5:00 p.m. Eastern Time. For each meeting, separate subsequent follow-up meetings are planned for the HSRB to finalize reports from the three-day meetings. These meetings will be held from 2 p.m. to 4 p.m. Eastern time on the following dates: March 17, 2022; June 16, 2022; September 14, 2022; and December 14, 2022.

ADDRESSES: These meetings are open to the public and will be conducted entirely virtually and by telephone. For detailed access information and meeting materials please visit the HSRB Website: https://www.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), Tom Tracy, via phone/voicemail at: 919-541-4334; or via email at: tracy.tom@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App.2 section 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.

Meeting access: These meetings will be open to the public. The full agenda with access information and meeting materials will be available seven calendar days prior to the start of each meeting at the HSRB Website: https://www.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, Tom Tracy, 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 each 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. To pre-register to make oral comments, please contact the DFO, Tom Tracy, listed under **FOR FURTHER INFORMATION CONTACT**. Requests to present oral comments during the meetings will be accepted up to Noon Eastern Time, seven calendar days prior to each meeting date. 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 the meetings 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. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments prior to the meetings via email by Noon Eastern Time, seven calendar days prior to each meeting date. 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, Tom Tracy listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

Topics for discussion. The agenda and meeting materials will be available seven calendar days in advance of each meeting at https://www.epa.gov/osa/human-studies-review-board.

Meeting minutes and final reports. Minutes of these meetings, summarizing the topics discussed and recommendations made by the HSRB, will be released within 90 calendar days of each meeting. These minutes will be available at https://www.epa.gov/osa/human-studies-review-board. In addition, information regarding the HSRB's Final Reports, will be found at https://www.epa.gov/osa/human-studies-review-board or can be requested from Tom Tracy listed under **FOR FURTHER INFORMATION CONTACT**.

Dated:

Mary Ross, Director, Office of Science Advisor, Policy and Engagement.