

**EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes**

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

Date and Time: Thursday, September 16, 2021, 2:00 to 3:30 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>

Table of Contents

Thursday, September 16, 2021:	2
A. Convene Meeting and Identification of Board Members and Meeting Administrative Procedures.....	2
B. Meeting Process.....	2
C. Public Comments.....	2
D. Board Discussion and Decision on July 20 and 21, 2021 Meeting Final Report and Minutes	3
E. Summary and Next Steps	4
Attachment A: HSRB Current Committee Membership	6
Attachment B: Federal Registers Notice Announcing Meetings.....	7

**EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes**

Thursday, September 16, 2021:

A. Convene Meeting and Identification of Board Members and Meeting Administrative Procedures

Tom O'Farrell, Ph.D., Designated Federal Officer, EPA Human Studies Review Board (HSRB), Office of the Science Advisor, Policy and Engagement (OSAPE)

Meeting was called to order at 2:00 pm EDT by Dr. Tom O'Farrell, Designated Federal Official (DFO) for the Human Studies Review Board (HSRB). Dr. O'Farrell noted that he would be leaving his position as the DFO for HSRB, and that Mr. Tom Tracy would take over in October 2021.

Dr. O'Farrell introduced the meeting, outlined the Federal Advisory Committee Act (FACA) procedures, and took roll 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 Janice Britt, Ph.D., ToxStrategies Philip Day, Ph.D., University of Massachusetts George Milliken, Ph.D., Milliken Consultants Thomas Lewandowski, Ph.D., Gradient Julia Sharp, Ph.D., Colorado State University Eun Um, Ed.D., AMSTAT Consulting Lisa Corey, Ph.D., Intertox, Inc. Lindsay McNair, M.D., WIRB-Copernicus
EPA staff members	Michelle Arling (EPA, OPP) Tom Tracy (EPA, OSAPE) Tom O'Farrell (EPA, OSAPE) Taylor Lass (EPA, OSAPE) Jeremy Leonard (EPA, OPP) Shalu Shelat (EPA, OPP) Brian Van Deusen (EPA, OPP)
Members of the public, representatives of research sponsor and research team:	Steven Black (ICF, Contractor Support) Afroditi Katsigiannakis (ICF, Contractor Support) Kevin Dunn (EnDyna, Contractor Support)

B. Meeting Process

Jennifer Cavallari, Sc.D, HSRB Chair

Dr. Jennifer Cavallari next covered the features of Zoom that are important for meeting participation.

C. Public Comments

There was a call for public comments, but there were none.

EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes

D. Board Discussion and Decision on July 20 and 21, 2021 Meeting Final Report and Minutes

Jennifer Cavallari, Sc.D., HSRB Chair

Dr. Cavallari outlined several items that needed to be addressed before finalizing the meeting report, as outlined below. Dr. Julia Sharp left a comment, as she was unclear of the phrasing “non-guideline study” (p. 6). EPA staff made updates and Dr. Sharp reviewed and confirmed agreement. Dr. Cavallari updated and revised the statistical review section to include limitations such as “subjects were in groups of three in a chamber” with no additional grouping data (p. 8). In the recommendations section, the second recommendation was removed and agreed upon. Dr. Sharp noted that due to it being a controlled study, her recommendation would be to include all the model terms whether they are fixed or nonsignificant, including interactions (p. 10). Dr. George Milliken agreed with Dr. Sharp, noting that it is a standard operating procedure. Dr. Jeremy Leonard noted that the recommendation was sufficiently clear.

Dr. Tom Lewandowski noted that describing that “the acrolein was only 90% pure” makes it unclear what the remaining 10% is (p. 16). Dr. Leonard provided additional details, noting that the data sheet provided clarification noting that the impurities are less than 10% water and cyclic dimer. As the dimer is derived from acrolein, even in the presence of a stabilizer, all potential toxicity can be considered as coming from acrolein only. Considering this clarification, Dr. Lewandowski agreed to remove the comment. Regarding the Chemical Sensitivity and Perceived Stress Questionnaires, Dr. Leonard suggested removing “no conclusions are made about these findings” since the discussion section mentions that the responders did not report more stress, affective reactions or behavioral disruptions by odorous pungent compounds when compared to non-responders, and that the values of responders on the questionnaires was within the range of the general population (p. 16). The Board members agreed to delete the bullet point. Dr. Milliken noted that while the bullet point discussing Figure 4 mentioned that it is not stated “how the lines shown in the graph were obtained,” the method they use to obtain those lines is described (p. 16). Dr. Cavallari removed that section of the comment but noted that the interpretation of the figure remains challenging, and therefore left the first section of the comment.

Dr. Lewandowski commented on the discrepancies on if subjects rated the exposure as “clearly irritating” and the description of “clearly irritating” was inconsistent with what was discussed in the article (p.17). Dr. Lewandowski suggested that EPA should further clarify what is meant by the classification “58% rated it as clearly irritating” to avoid confusion conflation regarding the Borg scale. Dr. Leonard interpreted the statements differently, explaining that “clearly irritating” is not a magnitude on the Borg CR-100 and rather is a subjective assignment relative to almost no reaction at all from the non-responders, but noted that EPA should still provide clarification. Dr. Alesia Ferguson noted that the authors might have overstated their findings. Dr. Milliken provided updates to the review of the statistical analysis (p. 18-20). These updates included (1) separating persons into responders and non-responders to design a study powered on a specific number of responders, noting that the model used to analyze the data did not take into account the possibility of blocking of responders into groups that were tested together, and (2) being careful in interpretation as the decisions in the study are based on the data of 15 responders. No board members had additional edits based on these comments and recommendations.

When reviewing the overall charge question, Dr. Milliken stated that there was a misspelling of the word “than” which was then corrected (p. 23). Dr. Ferguson noted that the first sentence of the overall charge question is unclear and that the commas should be rearranged to clarify the sentence. Changes were

**EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes**

made to the first sentence to state, “with respect to the weight of the evidence provided by Claeson et al, given the limitations in the study design and data analysis as previously noted, the HSRB believes this study...” Dr. Sharp suggested that the word “believes” be changed to “recommends,” to which the group agreed and made the change. No additional comments were made to the final charge question. No additional points were made on the rest of the final report.

The group voted and agreed on the final acceptance of the July 2021 meeting report, except for minor editorial edits.

E. Summary and Next Steps

Tom O’Farrell, Ph.D., Designated Federal Officer, EPA Human Studies Review Board (HSRB), Office of the Science Advisor, Policy and Engagement (OSAPE)

Jennifer Cavallari, Sc.D., HSRB Chair

Ms. Michelle Arling previewed the October 21st meeting, which will focus on a study from the Antimicrobial Exposure Assessment Task Force that examines immersion activities for sanitizing hard surfaces. Dr. Cavallari thanked Dr. O’Farrell for his time as DFO and thanked all participants for joining. Dr. O’Farrell thanked everyone for their attendance and reminded everyone to send him their confidential disclosure forms. He noted that the next meeting would be on October 21, 2021, and that Mr. Tracy would be the DFO at that meeting.

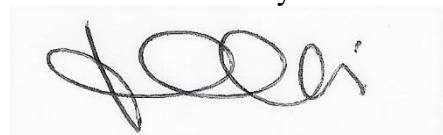
The meeting adjourned at 3:30 pm EDT.

Respectfully submitted:

X *Thomas O’Farrell*

Thomas O’Farrell, Ph.D.
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:



Jennifer Cavallari, Sc.D.
Chair
Human Studies Review Board
United States Environmental Protection Agency

EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes

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.

**EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes**

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 Bethesda, MD
Philip Day, Ph.D.	Assistant Professor	UMass Chan Medical School Worcester, MA

**EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes**

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.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development announces the 2021 public meetings dates of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects.

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

1. January 26-28, 2021;
2. April 20-22, 2021;
3. July 20-22, 2021; and
4. October 19-21, 2021.

Meetings will be held each day from 1 p.m. to 5:30 p.m. Eastern Time. Separate, subsequent teleconference meetings are planned for the HSRB to finalize its Reports of the three-day meetings that proceed these dates on March 18, 2021; June 17, 2021; September 16, 2021; and December 14, 2021; all from 2 p.m. to approximately 3:30 p.m. Eastern Time.

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>.

EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes

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 at the following telephone number: (202) 564-8451 or by email at: ofarrell.thomas@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, 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 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, Thomas O’Farrell, listed under **FOR FURTHER INFORMATION CONTACT**. Requests to present oral

EPA Human Studies Review Board (HSRB)
September 16, 2021 Meeting Minutes

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, Thomas O'Farrell 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 Thomas O'Farrell listed under **FOR FURTHER INFORMATION CONTACT**.

Dated:

Jennifer Orme-Zavaleta,
EPA Science Advisor.