

**EPA Human Studies Review Board (HSRB)  
November 6, 2024 Meeting Minutes**

**Committee Members:** See Appendix A: HSRB Current Committee Membership.

**Date and Time:** Wednesday, November 6, 2024, 1:00 to 1:30 p.m. ET

**Location:** Via Zoom

**Purpose:** The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subject research.

**HSRB Website:** <https://www.epa.gov/osa/human-studies-review-board>

**Table of Contents**

Wednesday, November 6, 2024.....	1
A. Meeting Topics and Charge Questions.....	1
B. Convene Meeting and Introduction of Members.....	1
C. Meeting Administrative Procedures .....	2
D. Introduction of EPA Staff.....	2
E. Updates from EPA HSRB Review Official.....	2
F. Opening Remarks and Meeting Process .....	3
G. Public Comment .....	3
H. Review and Finalize HSRB Report .....	3
I. Adjournment.....	4
Attachment A: HSRB Current Committee Membership.....	A-1
Attachment B: Federal Register Notice Announcing Meetings .....	B-1

**Wednesday, November 6, 2024**

**A. Meeting Topics and Charge Questions**

**Topic:** Thouvenin, I, Bouneb, F, Mercier, T. Operator dermal exposure and individual protection provided by personal protective equipment during application using a backpack sprayer in vineyards. *Journal of Consumer Protection and Food Safety*. (2016) 11:325-336. DOI: 10.1007/s00003-016-1049-z

**Charge to the Board – Science:** Does the research described in the published study “Operator dermal exposure and protective factors provided by personal protective equipment during foliar application using backpack sprayer in vineyards” (I. Thouvenin, et al., 2016) provide scientifically reliable data for assessing the exposure of workers mixing, loading, and/or applying liquid solutions using motorized handheld fogger/mister equipment?

**Charge to the Board – Ethics:**

- Does available information support a determination that the conduct of the research was not fundamentally unethical?
- Does available information support a determination that the research was not deficient relative to the ethical standards prevailing at the time the research was conducted or conducted in a way that placed participants at increased risk of harm or impaired their informed consent?

**B. Convene Meeting and Introduction of Members**

*Tom Tracy, designated federal official (DFO), EPA HSRB, Office of Science Advisor, Policy, and Engagement (OSAPE)*

*Emily Sokol, DFO, EPA HSRB, OSAPE*

Mr. Tom Tracy and Ms. Emily Sokol, the DFOs for HSRB, called the meeting to order at 1:00 p.m. ET. Mr. Tracy thanked Ms. Sokol for joining the HSRB team. They introduced the meeting, outlined the Federal Advisory Committee Act procedures, and performed a roll call of meeting participants. Dr. Julia Sharp welcomed new HSRB members to introduce themselves to the group. The following members and observers were present:

<b>HSRB members</b>
Julia Sharp, Ph.D., Co-Chair (National Institute of Standards and Technology) Philip Day, Ph.D. (University of Massachusetts, Chan Medical School) Albert J. Allen, M.D., Ph.D. (Consulting Specialist) Chad Cross, PhD, MFT, PStat® (University of Nevada, Las Vegas) Nicole Deming, J.D., M.A. (Case Western Reserve University, School of Medicine) Weiyang Jiang, Ph.D. (California Environmental Protection Agency) Thomas Lewandowski, Ph.D., (Gradient) George Milliken, Ph.D. (Milliken Associates, Inc.) Joseph Tuminello, Ph.D. (McNeese State University) David Williams, Ph.D. (Oregon State University)

**EPA Human Studies Review Board (HSRB)  
November 6, 2024 Meeting Minutes**

<b>EPA staff members</b>
Tom Tracy (EPA, OSAPE) Emily Sokol (EPA, OSAPE) Michelle Arling (EPA, Office of Pesticide Programs [OPP]) Matthew Crowley (EPA, OPP) Brent Davis (EPA, OPP) Thomas Moriarty (EPA, OPP) Monique Perron (EPA, OPP) John Reall (EPA, ORAU) Mira Shwadron (EPA, ORAU) Monique Tadeo (EPA, Program in Human Research Ethics and Oversight [PHREO])
<b>Members of the public, representatives of research sponsor, and research team</b>
Gretchen Bruce, DABT (Intertox, Inc.) Richard Feinn, Ph.D., M.A. (Qinnipiac University) Thomas Gillam-Shaffer, MPH (Michigan Public Health Institute/State of Michigan Partnership) Afroditi Katsigiannakis (ICF, Contractor Support) Katie Lenae (ICF, Contractor Support) Abri Segal (ICF, Contractor Support) Mary Lundin (ICF, Contractor Support)

**C. Meeting Administrative Procedures**

*Tom Tracy, DFO, EPA HSRB, OSAPE*

*Emily Sokol, DFO, EPA HSRB, OSAPE*

Mr. Tom Tracy and Ms. Emily Sokol reviewed the Zoom platform tools and features and stated the purpose of the meeting was to review and discuss the HSRB report on the paper by Isabell Thouvenin et al., (2016) “Operator dermal exposure and individual protection provided by personal protective equipment during application using a backpack sprayer in vineyards.” Ms. Sokol noted that the minutes of the meeting and a report will be prepared, certified, and posted on the website within 90 days of November 6, 2024.

**D. Introduction of EPA Staff**

*Michelle Arling, J.D., OPP*

Ms. Michelle Arling introduced herself and the members of the EPA OPP staff to the Board.

**E. Updates from EPA HSRB Review Official**

*Monique E. Tadeo, HSRB Review Official, PHREO*

Ms. Monique Tadeo introduced herself and shared that there were no updates for the HSRB subject research review.

**EPA Human Studies Review Board (HSRB)  
November 6, 2024 Meeting Minutes**

**F. Opening Remarks and Meeting Process**

*Julia Sharp, Ph.D., HSRB Co-Chair*

*Michelle Arling, J.D., OPP*

Dr. Julia Sharp welcomed the Board and reviewed the meeting's logistical procedures. She then invited Ms. Arling to share any updates on the OPP and the next meeting. Ms. Arling reported that there were no OPP updates. For the next meeting, the OPP plans to present a protocol review for a skin-applied repellent, which is currently being drafted. She confirmed that the OPP will notify the Board once this task is complete and reiterated that it would be the only topic.

**G. Public Comment**

Dr. Sharp stated that there were no public comments for the present meeting.

**H. Review and Finalize HSRB Report**

*Julia Sharp, Ph.D., HSRB Co-Chair*

*Philip Day, Ph.D., HSRB Co-Chair*

Dr. Sharp shared that this meeting's main task was to review, finalize, and approve the October HSRB report. She shared the draft report on her screen and thanked the reviewers for drafting it. She reviewed the report's contents and shared any changes or comments that were made. Dr. Sharp noted that the word "dermal" was added to the HSRB response for the science charge to the Board, which was approved in October. She also noted that the EPA suggested adding the word "handled" to the last sentence of the first paragraph in the Science Review section of the report. Dr. Sharp mentioned there has been some back and forth over the HSRB recommendations. She read the Recommendations section to the group and shared that commenters suggested deleting everything from the first paragraph except for the first sentence. She then gave Dr. David Williams the opportunity to discuss the recommendation before having a broader discussion with the group.

- **David Williams:** The second part of the first bullet asks for information beyond the scope of the EPA's review of Thouvenin et al., (2016). It would be nice to have information on systemic toxicology and other routes of exposure. However, these topics are not the focus of the charge, and we need to limit ourselves to dermal exposure for the purpose of this report. The EPA is aware that information on systemic toxicity and other routes of exposure would be desirable to incorporate into future analysis, but that topic is not the purpose of this report. Therefore, the HSRB should limit the first sentence.
- **Weiyang Jiang:** There is also an agriculture handler task force database. I am wondering whether this study will be used as a stand-alone study or will it be treated as part of a meta-analysis to be incorporated into a larger database to derive unit exposure values.
  - **Matthew Crowley:** One reason we are looking at this study is because while there is a lot of data that has been provided over a couple of decades by the agricultural handler exposure task force, they did not provide data for this

**EPA Human Studies Review Board (HSRB)  
November 6, 2024 Meeting Minutes**

scenario. This scenario is not that common in United States agriculture, but there are times we need to consider the use of pesticides with this equipment and setting. At this time, we have no intention to incorporate this study into a meta-analysis. The study will serve as a stand-alone study because even though the study sample size is relatively low, the exposure stands out separately from other kinds of handheld equipment. If there is future data that looks at similar equipment or setting, we would go through a similar process to decide if the data should be combined or kept as another stand-alone study.

- **Weiying Jiang:** Does stand-alone mean fogger and handler?
- **Matthew Crowley:** Yes.

The HSRB Board did not have additional comments on the recommendations.

Dr. Sharp shared a comment from the HSRB report comments section suggesting changing “I find” to “the HSRB finds.”

- **Monique E. Tadeo:** On the first page of the report, the letter is addressed to Christopher Frey, who is no longer at the Agency. The letter should be addressed to me.
  - **Julia Sharp:** ICF and Ms. Sokol will address this error.

Dr. Sharp asked members to show their approval of the report. The Board approved unanimously. Dr. Sharp shared that the next steps were for her and Dr. Philip Day to finalize the report and to send it to Ms. Sokol, who will work with ICF to finalize it. Once finalized, the report would be published on the website with the other materials for the meeting.

#### I. Adjournment

Ms. Sokol announced that the next meeting will be held January 29–31, 2025. She thanked the HSRB, and the meeting concluded.

The meeting adjourned at 1:30 p.m. EDT.

**EPA Human Studies Review Board (HSRB)  
November 6, 2024 Meeting Minutes**

**Attachment A: HSRB Current Committee Membership**

<b>Name</b>	<b>Title</b>	<b>Affiliation</b>
Julia Sharp, Ph.D.	Mathematical Statistician	National Institute of Standards and Technology Fort Collins, CO
Philip Day, Ph.D.	Assistant Professor	University of Massachusetts, Chan Medical School Worcester, MA
Albert J. Allen, M.D., Ph.D.	Consulting Specialist	Self-employed
Chad Cross, Ph.D., MFT, PStat®	Professor, Faculty in Residence	University of Nevada Las Vegas, NV
Nicole Deming, J.D., M.A.	Assistant Dean, Faculty Affairs and Human Resources	Case Western Reserve University, School of Medicine Cleveland, OH
Weiyang Jiang, Ph.D.	Staff Toxicologist	California Environmental Protection Agency Sacramento, CA
Thomas Lewandowski, Ph.D.	Principal	Gradient Seattle, WA
Srikumaran Melethil, Ph.D., J.D.	Professor Emeritus	University of Missouri-Kansas City Kansas City, MO
George Milliken, Ph.D.	President	Milliken Consultants Manhattan, KS
Sinziana Seicean-Boose, M.D., Ph.D., M.P.H., LLC	Assistant Professor	Case Western Reserve University Cleveland, OH
Joseph Tuminello, Ph.D.	Assistant Professor	McNeese State University Lake Charles, LA
David Williams, Ph.D.	Distinguished Professor	Oregon State University Corvallis, OR

**EPA Human Studies Review Board (HSRB)  
November 6, 2024 Meeting Minutes**

**Attachment B: Federal Register Notice Announcing Meetings**

**ENVIRONMENTAL PROTECTION AGENCY**

**[FRL-10408-01-ORD]**

**Human Studies Review Board Meetings—2024**

**AGENCY:** Environmental Protection Agency

**ACTION:** Notice of public meeting

**SUMMARY:** The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of the upcoming 2024 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), in the Office of Chemical Safety and Pollution Prevention (OCSPP), to be used for regulatory purposes. EPA is announcing this meeting with less than 15 calendar days' public notice.

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

1. January 9–11, 2024
2. April 10–12, 2024
3. July 9–11, 2024
4. October 9–11, 2024

Meetings will be held each day from 1 p.m. to 5 p.m. eastern time. For each meeting, separate subsequent follow-up one-day meetings are planned for the HSRB to finalize reports from the primary three-day meetings listed above. These meetings will be held from 1 p.m. to 5 p.m. eastern time on the following dates: February 14, 2024; May 15, 2024; August 21, 2024; and November 6, 2024.

**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](mailto: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 OPP in the OCSPP to be used for regulatory purposes.

**EPA Human Studies Review Board (HSRB)**  
**November 6, 2024 Meeting Minutes**

*Meeting access:* These meetings will be open to the public. The full agenda with access information and meeting materials will be available 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.

### **Public Participation**

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

1. *Oral comments.* To preregister 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 preregistered 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.