EPA Human Studies Review Board (HSRB)
September 14, 2022 Meeting Minutes

September 14, 2022 EPA Human Studies Review Board Meeting Minutes

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

Date and Time: Wednesday, September 14, 2022, 2:00 to 4:00 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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Wednesday, September 14, 2021:

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 p.m. EST. He introduced the meeting agenda, outlined the Federal Advisory Committee Act (FACA) procedures, and asked for HSRB members to introduce themselves. The following members and observers were present:

HSRB members	Julia Sharp, Ph.D., Colorado State University (Co-Chair) Lisa Corey, Ph.D., Intertox, Inc. (Co-Chair) Philip Day, Ph.D., University of Massachusetts, Chan Medical School George Milliken, Ph.D., Milliken Consultants Albert J. Allen, M.D., Ph.D., Eli Lilly (retired) Eun Um, Ed.D., AMSTAT Consulting 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 Lexie Burns, EPA, OSAPE Elizabeth Donovan, EPA, OPP
Members of the public, representatives of research sponsor and research team	

B. Meeting Administrative Procedures

Tom Tracy, Designated Federal Officer

Mr. Tom Tracy noted a quorum was reached although with less members than at some of the previous meetings, and that there will be up to seven new board members in October. He noted the absence of contractor ICF during the meeting due to temporary contract issues but confirmed the meeting would be recorded and meeting minutes completed and uploaded to the public website. Next, Mr. Tracy asked members to introduce themselves.

C. Meeting Process

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

Dr. Julia Sharp welcomed everyone to the EPA HSRB meeting and stated the purpose of the meeting was to discuss the draft final report from the July 21st HSRB meeting. Dr. Sharp mentioned that there was a comment from EPA which would be considered. This would be followed by closing comments and then adjournment.

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D. Public Comments

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

E. Board Discussion and Decision on July 21, 2022, Meeting Final Report and Minutes

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

Dr. Sharp shared her screen and presented a comment from EPA for the group to discuss before moving to the final report discussion.

- **Julia Sharp:** In the last meeting there was a recommendation that EPA consider the results of the BIT study only in the context of its use in paints. The EPA wants further clarification on this to determine if the HSRB is recommending that EPA only apply the BIT study to paint users because of the Rhoplex vehicle. Michelle or Lisa, could you remind us of who made that comment and where it might occur in the report?
    - **Michelle Arling:** I'm happy to provide background on this matter. In the meeting we had comments around limiting the use of the study we presented to only to assess the risks of BIT when used as a paint preservative. However, we couldn't find it in the report and didn't know if that was an omission or if there was more around it that we should consider and we wanted to check in before the report was finalized.
    - **Lisa Corey:** I don't specifically recall that recommendation, although I know we discussed it, and there's a recommendation to discuss how Rhoplex could affect bioavailability, but I don't recall it being a limitation that needed to be specified in the report that it could only be used for paints. Our current recommendation includes the provision of additional information about the effects of the vehicle and how it might interact with the test substance to increase or decrease bioavailability. The inclusion of this information in the final report would provide enough context for its use. We don't need to limit it to just paint.
    - **Elizabeth Donovan:** Thank you for that. If I recall correctly from the meeting, it came up when we clarified that Rhoplex AC-64 vehicle is a polymer that is used in paints and that is what triggered the follow up comment but if it's not a limitation of the study and if capturing the uncertainties as noted in the report is sufficient, then I think it is clear.

Next, Dr. Sharp apologized for sending the report at the last minute and asked if there were any other comments to discuss. All members unanimously responded that there were no other comments.

Dr. Sharp then moved on to the next item which was to approve the final report. All other members were instructed to use the reactions button in the Zoom meeting interface (green check to agree, red X to not agree) in response to approving the final report as written, without considering any edits. Dr. Sharp waited for everyone to provide their reaction and announced the approval of the final report in its current form. She thanked everyone for their help and went on to thank Dr. Thomas Lewandowski, Dr. Lisa Corey, Dr. Philip Day and Dr. George Milliken for their contribution to the review and reports.

F. Summary and Next Steps

Tom Tracy, Designated Federal Officer, EPA HSRB, OSAPE
Julia Sharp, Ph.D., HSRB Co-Chair

Dr. Sharp asked Ms. Michelle Arling and Mr. Tracy to share updates on what to expect from the meeting in October. Ms. Arling stated EPA plans to present two studies involving formaldehyde exposure in chambers as well as at least one insect repellent study involving mosquitos and may bring

another study involving repellent tested against ticks. The materials would be finalized and sent by the last week of September. Dr. Sharp and Ms. Arling confirmed that these discussions would take place over three days in October (25th, 26th, 27th). Dr. Philip Day readdressed Ms. Arling to confirm the number of studies, which was confirmed as definitely three, but maybe four studies.

G. Adjournment

The meeting adjourned at 2:30 pm EST.

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Attachment A: HSRB Current Committee Membership

Name	Title	Affiliation
George Milliken, Ph.D.	Statistical Consultant	Milliken Consultants Manhattan, KS
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
Eun Um, Ed.D.	President and CEO	AMSTAT Consulting San Jose, CA
Philip Day, Ph.D.	Assistant Professor	University of Texas, Southwestern Dallas, TX

Attachment B: Federal Register 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

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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**.

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Dated:

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