EPA Human Studies Review Board (HSRB)
April 26-28, 2022 Meeting Minutes

Committee Members: (See EPA HSRB Members List – Attachment A)
Date and Time: Wednesday, April 27, 2022, 1:00 to 5:00 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, April 27, 2022:

A. Meeting Topic and Charge Questions

Topic: 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.

Charge to the Board - Science: Did the research summarized in "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" generate scientifically reliable data, useful for assessing the exposure of those who apply antimicrobial pesticides using electrostatic sprayers?

Discussants:
Lisa Corey and Alesia Ferguson, Science Review
Eun Um, Statistical Review

Charge to the Board - Ethics: Does the available information support a determination that the research was conducted in substantial compliance with the applicable requirements of 40 CFR part 26, subparts K-L?

Discussant:
Albert J. Allen, M.D., Ph.D., Ethics Review

B. Convene Public Meeting

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

The meeting was called to order at 1:00 pm EDT by Mr. Tom Tracy, Designated Federal Official (DFO) for the Human Studies Review Board (HSRB). Mr. Tracy 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 Texas Southwestern George Milliken, Ph.D., Kansas State University Tom Lewandowski, Ph.D., Gradient Julia Sharp, Ph.D., Colorado State University AJ Allen, M.D., Ph.D., Eli Lilly Company Eun Um, Ed.D., AMSTAT Consulting Lisa Corey, Ph.D., Intertox, Inc. Lindsay McNair, M.D., WIRB-Copernicus

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EPA staff members	Michelle Arling (EPA, OPP) Tom Tracy (EPA, OSAPE) Alexis Bryant (EPA, OSAPE) Andrew Byro (EPA, OPP) Richard Campbell (EPA, ORC) Timothy Dole (EPA, OPP) Elizabeth Donovan (EPA, OPP) Judy Facey (EPA, OPP) Alexander Kliminsky (EPA, OPP) Taylor Lass (EPA, OSAPE) Tim McMahon (EPA, OPP) Jacqueline Meadows (EPA) Sophie Nguyen (EPA OPP) Tina Pham (EPA, OPP) Monique Tadeo (EPA, PHREO)
Members of the public, representatives of research sponsor and research team:	Greg Baumann (Nisus Corp.) Eric Brown (Sevenson Environmental Services Inc.) Jeff Horsager (The Chemours Company) Leah Rosenheck (LR Risk Consulting, Inc.) Has Shah (American Chemistry Council) Afroditi Katsigiannakis (ICF, Contractor Support) Kathryn Van Artsdalen (ICF, Contractor Support) Parisa Shirzadi (ICF, Contractor Support) Jonathan Cohen (ICF)

Mr. Tom Tracy also covered Zoom Meeting platform tools and features, as this was the first HSRB meeting using Zoom. The purpose of the meeting was to review the study protocol by Rosenheck, L. (2021). Minutes of the meeting will be prepared and certified within 90 days of April 28, 2022 and will be available on the website.

C. Welcome and Introduction

Monique Tadeo, Human Subject Research Review Official and Director, Program in Human Research Ethics and Oversight (PHREO)

Dr. Monique Tadeo introduced herself to the group. She described her experiences prior to joining HSRB and then handed the meeting over to Dr. Jennifer Cavallari.

D. Welcome and Virtual Meeting Operations

Jennifer Cavallari, Sc.D., HSRB Chair

Dr. Jennifer Cavallari welcomed everyone to the meeting. She began with introductions and asked everyone to state their name, affiliation, and expertise. The members then introduced themselves. After introductions, Dr. Cavallari explained the agenda for the meeting.

E. Brief Update on Research Discussed at Last HSRB Meeting

Michelle Arling, J.D., Office of Pesticide Programs

Ms. Michelle Arling introduced herself and thanked everyone for reviewing the research and for attending the meeting. She briefly reviewed the types of research for the meeting in July. There will be a study on an isothiazolinone. There will also be studies on repellents and mosquitoes and some formaldehyde chamber studies for review to determine whether they would support a risk assessment on that chemical. They have also received a few protocols for efficacy-supported repellents. Dr. Cavallari asked a clarifying question about whether the isothiazolinone study is completed. Ms. Arling confirmed that it is a completed study. There is no protocol for it, and the HSRB was not involved. The chamber studies were pulled from public literature.

F. EPA Science Review Highlights

Alexander Kliminsky, Ph.D., Office of Pesticide Programs

Dr. Alexander Kliminsky presented dermal and inhalation monitoring for the Electrostatic Spray Study (ESS) exposure on behalf of EPA's completed science review of the AEATF II Scenario 2b. The purpose of the study was to capture the range of expected dermal and inhalation exposures for individuals working in janitorial industries while disinfecting and sanitizing surfaces with an antimicrobial product using various types of electrostatic sprayers, including carts, handheld sprayers, and backpack sprayers. The ESS clothing configuration includes long pants and long sleeves, no gloves, and no hat. However, hats were included in this study's sample design to account for drip down and spray drift but were not included as personal protective equipment (PPE) in the final recommended unit exposures (UEs) to account for full dermal exposure to the head.

Dr. Kliminsky described the study design. ESS monitoring was conducted in Orlando, Florida, at the Avanti Palms Resort and Conference Center. Spraying scenarios were monitored in meeting rooms, ballrooms, bathrooms, and guest rooms. Subjects treated horizontal and vertical surfaces in each room including tables, chairs, and beds, using ESS sprayers with which they were familiar. A total of 18 subjects participated. One pesticide product containing 4 quaternary ammonium active ingredients was used. DDAC was selected as the surrogate test chemical. Measured concentrations ranged from 215 to 860 ppm for total quats, and 36.3 to 145 ppm for DDAC. Sampling duration was based on volume rather than time so participants would not feel rushed in spraying time

Subjects wore two layers of outer and inner dermal dosimeters. Long pants and long shirts were used as whole-body dosimeters (WBD). Subjects did not wear gloves as per the pesticide label. Subjects wore a painter's cap with two gauze pads as an inner dosimeter. Subjects also wore two concurrent personal air samplers, one glass fiber filter filled with XAD2 sorbent to sample total inhalable particles as well as a disposable parallel particle impactor.

Dr. Kliminsky then described AEATF II responses to EPA and HSRB recommendations made during the protocol review to improve clarity and design. AEATF II made modifications to EPA's satisfaction. This included ensuring the volume and spray loads to be sprayed were explained to the subject and intervening if a subject applied ESS inconsistent with label instructions to ensure that subjects correctly expelled the totality of volume. The amount of experience needed in the study was also specified. The sprayer function was turned on for sprayers that had an on and off button separate from the on and off spray trigger. The OVS filters and sorbent media were combined for analysis because vapor exposures were not anticipated.

Dr. Kliminsky noted that there were no protocol amendments. There were six protocol deviations, with the most substantial change being the switch from C14-ADBAC to DDAC because previous studies indicated background contamination of ADBAC. There were five standard operating procedure (SOP) deviations and no laboratory deviations.

Dr. Kliminsky then shared quality assurance and quality control results. There was no background contamination in controls, although one outer WBD showed background contamination. However, Dr. Kliminsky explained that this concentration was less than 30 percent of the limits of quantification (LOQ), so it was considered acceptable. Mean method try-out recoveries ranged from 79 to 99 percent and mean method recoveries ranged from 78 percent to 94 percent. Mean concurrent laboratory recoveries for all matrices ranged from 86 percent for inner hat dosimeters to 100 percent for PVC filters. Mean field recoveries for all matrices ranged from 91 percent for OVS tubes to 98 percent for ball caps. Dr. Kliminsky noted that due to the high recovery rates in both the field and laboratory, EPA had high confidence in the study's values and results.

For the statistical analysis, Dr. Kliminsky explained that 15 of 108 outer WBD sections, 17 of 93 inner WBD sections, and 1 of 18 OVS tubes were below the LOQ. He noted that outer WBDs had higher LOQs than inner WBDs because outer WBDs were composed of thicker fabric, so it was harder to extract analytes from the material. In UE calculations, LOQ/2 was used for values below LOQ. Two statistical methods were used to estimate UEs, including an empirical random sample model and lognormal simple random sample model. Dr. Kliminsky also explained that there was minimal impact of samples below the LOQ for all exposure routes. Results indicated that exposure tends to increase with the amount of active ingredient handled.

Dr. Kliminsky then displayed a regression plot for inhalation (respirable) 8-hr total weight average (TWA) exposure, with a table showing UE for the AEATF II scenario. The results indicated that the respirable dose was less than the total inhalation, which was a good sign that the samples were collected appropriately, and the model was correct. Dr. Kliminsky then discussed a pie chart of total dermal exposure, which showed that hands had the greatest exposure at about 80 percent. The head also had a high exposure.

Dr. Kliminsky noted the study's limitations, which included assumptions that the results were nationally representative, represented all professional ESS users and building types, could be generalized to other low volatility chemicals, and could be extrapolated to higher treatment solution concentrations and larger amounts. Another limitation was that there was background ADBAC contamination, but this was resolved prior to the start of study by switching to DDAC as a surrogate compound. Finally, there was some indication for a difference between sprayer types. However, the structure of the study was not meant to evaluate the difference between sprayer types and the data did not necessitate this division. Dr. Kliminsky said that if companies want to submit data to differentiate the sprayer types, EPA is open to analyzing the data.

Dr. Kliminsky concluded that the study results were sufficiently sound to support estimates of dermal and inhalation unit exposures. He noted that the sample size was sufficient, and EPA did not recommend additional monitoring.

G. Board Questions of Clarification

Jennifer Cavallari, Sc.D., HSRB Chair

- **Alesia Ferguson:** First, this was a great study. I appreciate that EPA attempts to address our questions beforehand. You already answered some of the questions. In the future, we should be aware of the background contamination you discussed and not use ADBAC. UEs potentially apply to many compounds in the future, so I am not sure we are fully considering or measuring the possibilities of oral exposures in these scenarios.
    - **Alexander Kliminsky:** When referring to inhalation and ingestion, although there may be some exposure, it may be low. We do not have separate analytical techniques to analyze this issue.
    - **Timothy Dole:** For workers in industry, there are concerns for lead contamination and exposure. It is hard to measure exposure directly, but we can detect it in the workplace through biomonitoring. For antimicrobials, when they are inhaled, their effects are in the upper respiratory tract. Some have systemic effects but not as much as conventional products, of which many are neurotoxic. So that is why we have not focused on incidental oral exposure for workers in the past.
- **Lisa Corey:** You said wearing long pants and long sleeves is just general practice because it is the occupational environment. Do products generally have this recommendation? Is this the standard practice?
    - **Alexander Kliminsky:** Traditionally, when looking at labels, they say you should wear long sleeve pants, long sleeve shirts, usually chemical resistant boots, and often an apron. It is not personal protective equipment (PPE) per se, but it is universally assumed these items will be on the label.
    - **Timothy Dole:** The Pesticide Review Manual provides information about how to write labels. There is a chapter on precautions and PPE with a specific paragraph that says handlers must wear long pants, long sleeves, shoes, and socks for occupational uses and this must be on the label.
- **Lisa Corey:** Masks were being used for COVID precautions. How did that contribute to the results, particularly to measurements of total head exposure?
    - **Alexander Kliminsky:** There is a correction factor of 1.43 included now in the Science Review. There are edits that need to be made, and it should have included information on mask and goggles.
- **Lisa Corey:** There was variability in how subjects were applied to participate. This is a qualitative measurement of exposure. That is important. How does that information get used so it is not lost?
    - **Alexander Kliminsky:** It is primarily included in summaries in the document. It is used to crosscheck to make sure notes and numbers are correct.
- **Alesia Ferguson:** Can you show the UE equation again for dermal? You are going from exposure to dose in both the inhalation and dermal. Did you use percent absorption through the skin for the dermal equation, or were those just purely an exposure amount?
    - **Timothy Dole:** Dermal unit of exposure. How many pounds of AI will someone handle a day to figure out how much exposure per day? The dermal exposure factor for each chemical to calculate the dose.
    - **Alesia Ferguson:** The chart shows that most exposure is dermal. Oral can be more of a direct route than dermal.
    - **Timothy Dole:** We assess inhalation separately and usually have an endpoint. It is mostly

dermal exposure, though oral absorption may be greater. Oral exposure is probably through the hands.

- **Tom Lewandowski:** The report is mostly about hands. It is true that applied is not absorbed dose, so maybe make this clearer. To what extent do you think differences in viscosity or formulation might affect inhalable versus respirable differences?
    - **Timothy Dole:** We are dealing with small amounts of active ingredients in water.
    - **Tom Lewandowski:** So, would the aerosol and particle size be similar among different possible formulations in water?
    - **Timothy Dole:** Yes, they are in such dilute amounts, you are basically spraying a water solution.

H. EPA Ethics Review Highlights

Michelle Arling, J.D., Office of Pesticide Programs

Ms. Michelle Arling presented EPA's evaluation of the study's ethical conduct. The study was conducted according to an approved protocol and using materials approved by the Institutional Review Board (IRB). Ms. Arling explained that recruitment was conducted through English advertisements in newspapers and flyers distributed to pesticide sales managers, ESS manufactures and retailers, and hotels in the Orlando area. Interested subjects contacted the study director for more information and to review enrollment criteria. Potentially eligible subjects were invited for an in-person meeting at the study location. Ms. Arling explained that for the consent process, meetings were held virtually due to COVID-19. Materials were offered in English and Spanish. Subjects attended a consent meeting and had the opportunity to ask questions to confirm comprehension.

The respirator fit testing was performed by Safety Links, an independent company hired by the sponsor. Subjects completed an online medical questionnaire and were scheduled to attend an in-person respirator fit test in the hotel conference room. All subjects who consented were successfully fitted for a respirator or provided valid documentation of a fit test. Ms. Arling then described the demographics of the subjects. Study participants included 5 females and 17 males aged 24 to 70 years old. They had between 1 month to 3 years of ESS experience.

The test day procedures included a COVID-19 screening. Subjects wore a facemask, received a skin check, took a pregnancy test, washed their hands, changed into dosimeters and monitoring equipment, and were reminded about the study's purpose and provided with instructions. Ms. Arling described the study's safety precautions to reduce the risk to subjects. For PPE, subjects wore protective eyewear and respirators, as well as inner and outer dosimeters. COVID-related precautions included virtual consent meetings and medical evaluations, screenings at the start of testing days, and face masks. Medical professionals checked subjects for disqualifying skin conditions at each monitoring event. They were on-site for the duration of the study and periodically checked subjects for heat-related illnesses.

Subjects had the freedom to withdraw, and the study maintained the confidentiality of participants. No one withdrew, but one participant ended early without negative consequences. Participants were compensated for their time. Ms. Arling described oversight and approval of the study protocol by both EPA and the IRB. Ms. Arling concluded by stating the available information indicated that the ESS scenario was conducted in substantial compliance with subparts K and L of 40 CFR part 26. All subjects were at least 18 years old, and there were no pregnant or nursing women enrolled. Subjects were fully informed, and their consent was voluntary without coercion.

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I. Board Questions of Clarification

Jennifer Cavallari, Sc.D., HSRB Chair

There were no questions or comments.

J. Public Comments

No public comments.

K. Break

L. Board Discussion

Jennifer Cavallari, Sc.D., HSRB Chair

Dr. Jennifer Cavallari welcomed everyone back and held a quick roll call for the HSRB board.

- **Alesia Ferguson:** I will review the study. We noted that the study had an external company checking on them. We noted quite a few things about the study. Our questions were basically answered. The only thing is that the six protocol deviations were truly more than six. The third one was more than one. The third protocol deviation states that the direction of airflow was not mapped, and field fortifications were not analyzed. I have no more questions because they were all answered. My only guidance is to separate the third protocol deviation into individual deviations. A recommendation for EPA in the future is to not miss the opportunity in studies to document activities that could relate to oral exposure. That's it for me.
    - **Jennifer Cavallari:** Just to confirm, your recommendations are to document oral exposure routes, and for to separate protocol deviation three into individual deviations?
    - **Alesia Ferguson:** Correct.
- **Lisa Corey:** I want to reiterate that this was very well written. Going through the questions, there are some additional clarifications that could be included in the final document. My only additional recommendation is that there was a wonderful review about different sprayers. My suggestion would be to include whether there is anything known about new versus old sprayers. The reason for this is that new sprayers were purchased for this study. Maybe adding that into the discussion will be useful as well.
    - **Jennifer Cavallari:** I had a clarification, Alesia. Did you want to include a recommendation about DDAC and ADDBACK?
        - **Alesia Ferguson:** Yes. Recommend that they are aware of the issue. I am not suggesting EPA change the compound at all. Just make them aware.
        - **Leah Rosenheck:** I am the study director on this. You are right about the concern for background. In 2020, their usage started to skyrocket. We discovered that one of the reasons we had to switch. All the researchers knew not to have any quat disinfecting or cleaning wipes. We do background analyses on all the sample matrices we use in the studies.
        - **Alesia Ferguson:** Why don't we use the outcome if the other one is common in everything?
        - **Leah Rosenheck:** Both are quats. The product we used had 4 different ammonias. We try to use the one that has the highest percentage in formulation.
    - **Tom Lewandowski:** Just a super picky thing. I noticed in table 1 of EPAs summary documents, for the total inhalable dose, the footnote is the same for how you calculate the

inhaled dose. I thought having a footnote that describes how inhalable dose and real dose are different would be useful.

- **Jennifer Cavallari:** Based on what Lisa pointed out, thinking more long term, the idea that workers will wear long pants and sleeves when using these products is not what's typically occurring in the workplace. I would like to put that as a note for broader consideration.
- **Leah Rosenheck:** Even though this scenario was done with long clothes, the fact that we analyzed the interdosimeter, you can use the data from the inner and outer dosimeter to model the different scenarios.

- **Eun Um:** The study is great. Most key factors are less than 3. The assumption of independence was rejected, and the assumption of a low loop linearity was supported. My recommendation is to include other areas and states.
- **Jennifer Cavallari:** Now we can discuss the answer to the charge question. My draft response is as follows: "The HSRB concludes that the research summarized in the study AEA12: "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" provides scientifically reliable data, useful for assessing the exposure of individuals who apply antimicrobial pesticides using electrostatic sprayers." I will open it to the board for any recommendations.
  - **Alesia Ferguson:** I am fine with it worded as is. In this case, our recommendations don't affect the current data. I am fine with how simple it is now.
  - **Jennifer Cavallari:** We have a unanimous decision on this.
- **Philip Day:** Thank you to EPA for this thorough ethical consideration of this study. I agree with the EPA ethics review and don't have specific recommendations. Based on the study protocol, it appears the study was conducted according to appropriate ethical standards and an independent ethics review, more than one was conducted, subject selection was equitable. No pregnant, nursing, or lactating women were enrolled, and there was no intentional exposure to any human subject under 18.
  - **A.J. Allen:** In particular, this study came to us and prompted a lot of discussion about what to do around covid. We had questions about what to say about risk to staff and participants regarding SARS-COV-2. I appreciated the efforts made by the EPA and sponsor in the IRB to address these things. I had one concern for the future about the portion of the protocol having English only during the recruiting process. This was done to limit interactions between individuals during the process. It would make sense except the recruiting was done online and people called into a phone number. The visit for the consent process was also conducted online. There weren't any additional interactions that were mitigated via this step. I don't think there was any intent to have an inequitable distribution. If the meetings were in person, it would make sense.
    - **Leah Rosenheck:** I would like to jump in with that point. We changed the way we held our consent meetings. I did spend a lot of time trying to determine the best way to run this study during COVID. At that point, we wanted to move forward with the study. One of the reasons I wanted to stick with only English-speaking participants was because I did not want to bring our bilingual researcher in close contact with these individuals. Most of the Hispanic population in these locations spoke English, so we

did not think we would be changing the demographics by not advertising in Spanish.

- **A.J. Allen:** I do feel like it is important to recognize how much we did not know during that point in time. It would be good to keep in mind if we ever have another pandemic and must operate like this.

- **Jennifer Cavallari:** I would like to remind everyone of the charge question: "The available information supports the study "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" was conducted in substantial compliance with the requirements of 40 CFR part 26, subparts K-L." Are there any members of the board who want to change this response? I think that concludes the work we need to do at this meeting. I want to remind the leads to provide updated comments to help me write the final report.
    - **Tom Tracy:** I believe we have a follow-up meeting, and I will reconfirm that.
- **Jennifer Cavallari:** Thank you, everyone. I look forward to discussing the finalization of this report next time.

M. Adjournment

The meeting adjourned at 3:35 pm on April 27th, 2022.

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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 Bethesda, MD
Philip Day, Ph.D.	Assistant Professor	University of Texas, Southwestern Dallas, TX

Attachment B: Federal Registers Notice Announcing Meetings

EPA Human Studies Review Board (HSRB)
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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.