

## EPA Human Studies Review Board (HSRB)

### December 10, 2019 Meeting Minutes

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

**Date and Time:** Tuesday, December 10, 2019, 2:00 to 4:00 pm EST.

**Locations:** Via teleconference and webinar

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

Meeting was called to order at 2:00 p.m. by Dr. Tom O’Farrell, designated federal official (DFO) for the HSRB. Roll was taken and the following members and observers were present:

<u>HSRB members</u> Jennifer Cavallari, Sc.D. (HSRB Chair) Alesia Ferguson, Ph.D. (HSRB Vice-Chair) Albert (AJ) Allen, Ph.D., M.D. Lisa Corey, Ph.D. Mark Aulisio, Ph.D. Ann Um, Ed.D. Julia Sharp, Ph.D. George Milliken, Ph.D. Beth Roxland	<u>EPA staff members</u> Michelle Arling (OPP) Clara Fuentes (OPP) Shannon Borges (OPP) Tom O’Farrell, Ph.D. (OSAPE)
<u>Members of the public, representatives of research sponsor and research team</u> Has Shaw (ACC) Brian Lange (Lange Research and Consulting) Emma Weeks (University of Florida) Alexandra Hiscox (ARCTEC)	

Dr. O’Farrell provided an introduction to the meeting and outlined the Federal Advisory Committee Act (FACA) procedures.

Dr. O’Farrell called for public comments and Emma Weeks (University of Florida) and Alexandra Hiscox (ARCTEC ) gave public comments.

The Board first discussed the draft report from the October 23, 2019 HSRB Meeting regarding the study “Field Evaluation of Two Topically Applied Insect Products Containing IR353 Against Mosquitoes in Florida” which was circulated to the Board by email in advance of the call. Dr. Alesia Ferguson asked about getting clarification for how the current method of finding the dose of the agent applied to

subjects was derived and was concerned if it was accurate. Ms. Michelle Arling said that there are earlier documents that describe how this method was arrived at. Dr. Ferguson said that the HSRB comment regarding determining dose could be removed if these background documents are cited in EPA's final report. The Board then discussed their comment about EPA providing the sponsor with better guidance regarding landing pressure criteria and when a study should be stopped. After discussion, the Board decided not to change this recommendation further in the report. Regarding a subject that was exposed to poison ivy during the study, the Board asked whether the IRB recommended changing the consent form to include the possibility of poison ivy exposure after the study was completed. Ms. Arling confirmed that the incident was reported to the IRB after the study finished and the recommendation to change the consent form was after the study finished.

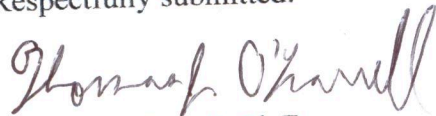
There was no discussion of the part of the report pertaining to the study discussed on October 24, 2019, "Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing An Antimicrobial Using An Airless Sprayer".

The Board voted unanimously to accept the current draft of the report subject to minor editorial changes.

The next HSRB meeting is scheduled for January 30, 20120.

This concluded the Board's session for December 10, 2019 and the meeting was adjourned.

Respectfully submitted:



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

**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.

**Attachment A**  
**EPA HUMAN STUDIES REVIEW BOARD MEMBERS**

**Chair**

Jennifer Cavallari, Sc.D., CIH  
Associate Professor  
Division of Occupational and Environmental Medicine  
University of Connecticut  
Storrs, CT

**Vice Chair**

Alesia Ferguson, Ph.D.  
Associate Professor  
Department of Built Environment  
North Carolina A&T University  
Greensboro, NC

**Members**

Janice Britt, Ph.D.  
Managing Scientist  
ToxStrategies, Inc.  
Tallahassee, FL

Lisa Corey, Ph.D.  
Toxicologist  
Intertox, Inc.  
Seattle, WA

George Milliken, Ph.D.  
Consultant  
Milliken Consultants  
Manhattan, KS

Beth Roxland  
Senior Consultant  
Roxland Consultants  
New York, NY

Mark Aulisio, Ph.D.  
Professor  
Case Western Reserve University  
Cleveland, OH

Albert J. Allen, M.D., Ph.D.  
Senior Medical Fellow  
Eli Lilly  
Indianapolis, IN

Eun Um, Ed.D.,  
President and CEO  
AMSTAT Consulting  
Bethesda, MD

Julia Sharp, Ph.D.  
Associate Professor  
Colorado State University  
Fort Collins, CO

Lindsay McNair, M.D., Ph.D.  
Chief Medical Officer  
WIRB-Copernicus  
Princeton, NJ

**Consultants to the Board**

Kendra L. Lawrence, Ph.D., BCE, PMP  
Health Sciences Product Manager  
U.S. Army Medical Materiel Development Activity  
Fort Detrick, MD

**Attachment B**  
**Federal Registers Notice Announcing Meetings**

**ENVIRONMENTAL PROTECTION AGENCY**

[FRL-10001-03-ORD]

**Human Studies Review Board; Notification of Public Meetings**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

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**SUMMARY:** The Environmental Protection Agency (EPA), Office of the Science Advisor announces two separate public meetings of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects.

**DATES:** A virtual public meeting will be held on Wednesday, October 23, 2019 and Thursday, October 24, 2019 from 1:00 pm to approximately 5:30 pm Eastern Time on both dates. A separate, subsequent teleconference meeting is planned for Tuesday, December 10th, 2019, from 2:00 pm to approximately 3:30 pm Eastern Time for the HSRB to finalize its Report of the October 23 and 24, 2019 meeting and review other possible topics.

**ADDRESSES:** All of these meetings will be conducted entirely by telephone and on the Internet using Adobe Connect. For detailed access information visit the HSRB Website:

<http://www2.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), Thomas O'Farrell on telephone number (202) 564-8451; fax number: (202) 564-2070; email address: ofarrell.thomas@epa.gov; or mailing address: Environmental Protection Agency, Office

of the Science Advisor, Mail code 8105R, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

#### **SUPPLEMENTARY INFORMATION:**

**Meeting access:** These meetings will be open to the public. The full Agenda and meeting materials will be available at the HSRB Website: <http://www2.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 the 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 comments during the meeting will be accepted up to Noon Eastern Time on Tuesday, October 15, 2019, for the October 23 and 24, 2019 meeting and up to Noon Eastern Time on Tuesday, December 3, 2019 for the December 10, 2019 meeting. 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 either meeting 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.** Submit your written comments prior to the meetings. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments via email or Fax by Noon Eastern Time on Tuesday, October 15, 2019, for the October 23 and 24, 2019 meeting and by Noon Eastern Time on Tuesday, December 3, 2019 for the December 10, 2019 meeting. 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.

### **Background**

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

**Topic for discussion.** On October 23, 2019, the Human Studies Review Board will consider a study report submitted by LivFul, Inc. titled "Field Evaluation of Two Topically Applied Insect Repellent Products Containing IR3535 Against Mosquitoes in Florida". On October 24, 2019, the Human Studies Review Board will consider a study submitted by the Antimicrobial Exposure Assessment Task Force (AEATF II) titled "A Study for Measurement of Potential Dermal and



Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer” (AEA10).

The Agenda and meeting materials for this topic will be available in advance of the meeting at <http://www2.epa.gov/osa/human-studies-review-board>.

On December 10, 2019, the HSRB will review and finalize their draft Final Report from the October 23 and 24, 2019 meeting, in addition to other topics that may come before the Board. The HSRB may also discuss planning for future HSRB meetings. The agenda and the draft report will be available prior to the meeting at <http://www2.epa.gov/osa/human-studies-review-board>.

**Meeting minutes and final reports.** Minutes of these meetings, summarizing the matters discussed and recommendations made by the HSRB, will be released within 90 calendar days of the meeting. These minutes will be available at <http://www2.epa.gov/osa/human-studies-review-board>. In addition, information regarding the HSRB’s Final Report, will be found at <http://www2.epa.gov/osa/human-studies-review-board> or from Thomas O’Farrell listed under FOR FURTHER INFORMATION, CONTACT.

Date: \_\_\_\_\_

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Jennifer Orme-Zavaleta, Ph.D.  
EPA Science Advisor

