

## EPA Human Studies Review Board (HSRB)

### September 13, 2018 Meeting Minutes

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

**Date and Time:** Thursday, September 13, 2018, 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 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> Liza Dawson, Ph.D. (HSRB Chair) Edward Gbur, Jr., Ph.D. (HSRB Vice-Chair) AJ Allen, Ph.D., M.D. Jennifer Cavallari, Sc.D., CIH Alesia Ferguson, Ph.D. Kyle L. Galbraith, Ph.D. Walter T. Klimecki, D.V.M., Ph.D. Randy Maddalena, Ph.D. Lindsay McNair, M.D. Ann Um, Ed.D.	<u>EPA staff members</u> Michelle Arling (OPP) Tom O’Farrell, Ph.D. (OSA)
<u>Members of the public, representatives of research sponsor and research team</u> Kurd Ali (EnDyna) Kevin Dunn (EnDyna)	

Tom O’Farrell provided an introduction to the meeting and outlined the Federal Advisory Committee Act (FACA) procedures and introduced new HSRB members: AJ Allen, Lisa Corey and Lindsay McNair.

The Board discussed the draft report from the July 25, 2018 HSRB Meeting regarding the protocol “Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings” which was circulated to the Board by email in advance of the call. The Board voted unanimously to accept the current draft of the report subject to adding the recommendations in bullet point form for both the science and ethics review. The HSRB’s recommendations include:

- All edits outlined in the EPA’s science and ethics review of the protocol should be incorporated.
- More explicit details should be included in the protocol on how the amount of permethrin initially loaded onto the fabric will be determined and how the residue will be measured.

- Include justification in the protocol for starting with the 100 washing level test rather than randomizing the order of the washing level tests.
- Include justification in the protocol as to why starting with the 100 washing level test does not eliminate the need for testing at fewer washing levels.
- Justify or remove the age limit for participation in the protocol.
- Clarification and additional information on the attractiveness phase should be provided in the protocol. Specifically, the protocol should explain clearly whether a subject's arm will be exposed to mosquitoes or whether there will be a physical barrier between the mosquitoes and the subject's arm.
- The protocol should make clear during the participant screenings that the mosquitoes used in the tests have been certified as disease free.
- A rationale for the participant's health insurance to be the primary provider of coverage should an injury occur during the test should be included in the protocol.

Ann Um, Lindsay McNair, and AJ Allen refrained from voting because they were not members of the HSRB for the July meeting. Liza Dawson refrained from voting because she did not attend the July meeting.

This concluded the Board's session for September 13, 2018 and the meeting was adjourned.

Respectfully submitted:



Thomas O'Farrell  
Designated Federal Officer  
Human Studies Review Board  
United States Environmental Protection Agency

Certified to be true by:



Edward Gbur, Jr, Ph.D.  
Co-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**

Liza Dawson, Ph.D.  
Research Ethics Team Leader  
Division of AIDS  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
Bethesda, MD

**Vice Chair**

Edward Gbur, Jr., Ph.D.  
Professor of Statistics  
Director, Agricultural Statistics Laboratory  
University of Arkansas  
Fayetteville, AR

**Members**

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

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

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

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

Kyle L. Galbraith, Ph.D.  
Patient Experience Coordinator  
Piedmont Athens Regional Medical Center  
Athens, GA

Walter T. Klimecki, D.V.M., Ph.D.  
Associate Professor  
Departments of Pharmacology and  
Toxicology  
The University of Arizona Health Sciences  
Tucson, AZ

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

Randy Maddalena, Ph.D.  
Physical Research Scientist  
Indoor Environment Group  
Lawrence Berkeley National Laboratory  
Berkeley, CA

Ann Um, Ed.D.  
CEO and Owner  
AMSTAT Consulting  
Bethesda, MD

**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-9980-61-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, July 25, 2018, from 1:00 pm to approximately 5:30 pm Eastern Time. A separate, subsequent teleconference meeting is planned for Thursday, September 13th, 2018, from 2:00 pm to approximately 3:30 pm Eastern Time for the HSRB to finalize its Final Report of the July 25, 2018 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

Wednesday, July 18, 2018, for the July 25, 2018 meeting and up to Noon Eastern Time on Thursday, September 6, 2018 for the September 13, 2018 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 by Noon Eastern Time on Wednesday, July 18, 2018, for the July 25, 2018 meeting and up to Noon Eastern Time on Thursday, September 6, 2018 for the September 13, 2018 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 July 25, 2018, EPA’s Human Studies Review Board will consider a study protocol titled “Laboratory evaluation of mosquito bite protection from permethrin-treated clothing after 0, 50, 75, and 100 washings” submitted by Pulcra Industries.

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 September 13, 2018, the HSRB will review and finalize their draft Final Report from the July 25, 2018 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

