

**EPA Human Studies Review Board (HSRB)**

**June 14, 2018 Meeting Minutes**

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

**Date and Time:** Thursday, June 14, 2018, 2:00 to 3:00 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> Edward Gbur, Jr., Ph.D. (HSRB Vice-Chair) Jennifer Cavallari, Sc.D., CIH Alesia Ferguson, Ph.D. Kyle L. Galbraith, Ph.D. Randy Maddalena, Ph.D.	<u>EPA staff members</u> Michelle Arling (EPA, OPP) Timothy Leighton (EPA, OPP) Tim Dole (EPA, OPP) Alicia Denning (EPA, OPP) Eric Bohnenblust (EPA, OPP) Wiebke Striegel (EPA, OPP) Clara Fuentes (EPA, OPP)
<u>Members of the public, representatives of research sponsor and research team</u> Kurd Ali (Endyna, meeting support contractor)	

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

Ed Gbur called for public comments and there were none.

The Board discussed the report from the April 24-26, 2018 HSRB meeting. The Chair asked if there were comments on the content in the report regarding the “Protocol for laboratory-Based Testing of a Tick Repellent Containing Oil of Eucalyptus” and the “Study of Removal Efficiency of BIT from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure” and there were no significant comments.

The Board discussed the portion of the report concerning the “Study for Measurement of Potential Dermal Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting” and Randy Maddalena said he would send some edits to address some redundancy in this section.

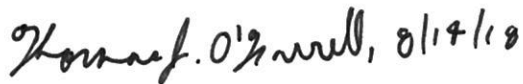
The Board next discussed the journal article “Assessing Key Safety Concerns of a Wolbachia-based Strategy to Control Dengue Transmission by Aedes Mosquitos”. The Board considered whether the

response to the charge question should state that not enough data was provided in the article to determine whether the study was scientifically sound but decided not to qualify the response to the charge.

The Board voted unanimously to approve the current version of the draft report subject to the addition of OPP's comments and minor editorial changes.

Tom O'Farrell announced that the next HSRB meeting will be July 25, 2018 and adjourned the meeting at approximately 3 pm.

Respectfully submitted:



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

Certified to be true by:



Ed Gbur, Ph.D.  
Vice 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**

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

Alesia Ferguson, Ph.D.  
Associate Professor  
Department of Environmental and  
Occupational Health  
University of Arkansas  
Little Rock, AR

Kyle L. Galbraith, Ph.D.  
Human Subjects Protection  
Carle Foundation Hospital  
Urbana, IL

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

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

Jun Zhu, Ph.D.  
Professor of Statistics and of Entomology  
Department of Statistics  
University of Wisconsin–Madison  
Madison, WI

**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**  
**ENVIRONMENTAL PROTECTION AGENCY**

[FRL-9976-38-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 Tuesday, April 24, 2018, Wednesday, April 25, 2018, and Thursday, April 26, 2018 from 1:00 pm to approximately 5:30 pm Eastern Time on all dates. A separate, subsequent teleconference meeting is planned for Thursday, June 14, 2018, from 2:00 pm to approximately 3:30 pm Eastern Time for the HSRB to finalize its Final Report of the April 24-26, 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 either meeting will be accepted up to Noon Eastern Time on Tuesday, April 17, 2018, for the April 24-26, 2018 meeting and up to Noon Eastern Time on Thursday, June 7, 2018 for the June 14, 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 Tuesday, April 17, 2018, for the April 24-26, 2018 meeting and up to Noon Eastern Time on Thursday, June 7, 2018 for the June 14, 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 April 24-26, 2018, EPA's Human Studies Review Board will consider four topics: 1) A protocol for laboratory-based testing of a tick repellent containing Oil of Lemon Eucalyptus, submitted by ARCTEC (Arthropod Control Product Centre) and by sponsored by Citrefine International, 2) a published article titled "Assessing key safety concerns of a *Wolbachia*-based strategy to control dengue transmission by *Aedes* mosquitoes", authored by Jean Popovici, Luciano A Moriera, Anne Poinsignon, Inaki Iturbe-Ormaetxe, Darlene McNaughton, and Scott O'Neill, 3) a completed study submitted by the Antimicrobial Exposure Assessment Task Force: "Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one

(BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure”, and 4) a completed study submitted by the Antimicrobial Exposure Assessment Task Force: “A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting”.

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

On June 14, 2018, the HSRB will review and finalize their draft Final Report from the April 24-26, 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