

EPA Human Studies Review Board (HSRB)

June 17, 2021 Meeting Minutes

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

Date and Time: Thursday, June 17, 2021, 2:00 to 3:30 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.

The 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> Jennifer Cavallari, Sc.D., (Chair) Alesia Ferguson, Ph.D., (Vice-Chair) AJ Allen, Ph.D., M.D. Janice Britt, Ph.D. Ann Um, Ed.D. Lisa Corey, Ph.D. Julia Sharp, Ph.D. Philip Day, Ph.D. Lindsay McNair, M.D. George Milliken, Ph.D.	<u>EPA staff members</u> Michelle Arling (OPP) Tom O’Farrell (OSAPE) Clara Fuentes (OPP) Helen Hull-Sanders (OPP)
<u>Members of the public, representatives of research sponsor and research team</u> Dana Lateulere (Bergeson and Campbell, P.C.)	

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

The purpose of the meeting was to review the final version of the April 20 and 21, 2021 meeting report that was comprised of the review of the protocols “Field Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray Against Mosquitoes” and “Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray with Ticks under Laboratory Conditions” by Mimikai.

There were no public comments.

Dr. Jennifer Cavallari reviewed the report with the Board. Dr. Cavallari said the Board had suggested on page 33 to clarify how long of a pause will be considered for a second mosquito landing to be confirming of the first landing. Dr. Julia Sharp said that there should not be a reason for pause based on EPA’s recommendations to the study protocol. There was no

further discussion of the report. The Board voted in favor of the finalization of the report, pending small grammatical edits, for the April 20 and 21, 2021 HSRB meeting.

Dr. O'Farrell said that the next HSRB meeting is scheduled for July 20-21, 2021, where the HSRB will be reviewing two journal articles. This concluded the Board's June 17, 2021 meeting and Dr. O'Farrell adjourned the meeting.

Respectfully submitted:

8/9/2021

X Thomas O'Farrell

Thomas O'Farrell

Signed by: THOMAS O'FARRELL

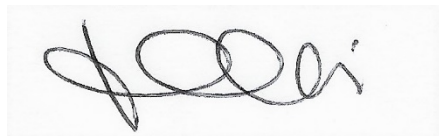
Thomas O'Farrell, Ph.D.

Designated Federal Officer

Human Studies Review Board

United States Environmental Protection Agency

Certified to be true by:

A handwritten signature in black ink, appearing to read "Jennifer Cavallari", is written over a light gray rectangular background.

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
Department of Public Health Science
University of Connecticut School of Medicine
Farmington, 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

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

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

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

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

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

Thomas Lewandowski, Ph.D.
Principal
Gradient
Seattle, WA

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

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

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-10017-40-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development announces the 2021 public meetings dates of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects.

DATES: Four three-day virtual public meetings will be held on:

1. January 26-28, 2021;
2. April 20-22, 2021;
3. July 20-22, 2021; and
4. October 19-21, 2021.

Meetings will be held each day from 1 p.m. to 5:30 p.m. Eastern Time. Separate, subsequent teleconference meetings are planned for the HSRB to finalize its Reports of the three-day meetings that proceed these dates on March 18, 2021; June 17, 2021; September 16, 2021; and December 14, 2021; all from 2 p.m. to approximately 3:30 p.m. Eastern Time.

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), Thomas O’Farrell at the following telephone number: (202) 564-8451 or by email at: ofarrell.thomas@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, 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 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, Thomas O'Farrell, 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, Thomas O'Farrell 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 Thomas O'Farrell listed under **FOR FURTHER INFORMATION CONTACT**.

Dated:

Jennifer Orme-Zavaleta,
EPA Science Advisor.