

EPA Human Studies Review Board (HSRB)

September 17, 2020 Meeting Minutes

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

Date and Time: Tuesday, September 17, 2020, 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:

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| <u>HSRB members</u> Jennifer Cavallari, Sc.D., (Chair) Alesia Ferguson, Ph.D., (Vice-Chair) Mark Aulizio, Ph.D. AJ Allen, Ph.D., M.D. Ann Um, Ed.D. Lisa Corey, Ph.D. Julia Sharp, Ph.D. Thomas Lewandowski, Ph.D. | <u>EPA staff members</u> Michelle Arling (OPP) Clara Fuentes (OPP) Tom Tracy (OSAPE) Tom O’Farrell (OSAPE) |
| <u>Members of the public, representatives of research sponsor and research team</u> Brian Lange (Lange Research and Consulting) Leah Rosenheck (LR Risk Consulting) Has Shah (ACC) | |

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 July 2020 meeting report that was comprised of the review of “A Single Group Trial to Determine the Complete Protection Time of an Insect Repellent Formulation Containing 30% Citriodiol ® (Oil of Lemon Eucalyptus) against three species of ticks” by Citrefine and “A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products along with Study Addendum: Addition of Electrostatic Sprayers (AEA14)” by the AEATF.

There were no public comments.

Jen Cavallari introduced the first item of discussion, the edits requested by the EPA to the Citriodiol Insect Repellent Study. The changes were minor and all were accepted without further discussion. The second item of discussion was the exposure study on handheld pressurized

sprayer equipment and antimicrobials. Dr. Cavallari suggested removing wording in parentheses that stated the study focuses on manual spraying versus automated spraying for fixed nozzles (Summary of Study Protocol section) Dr. Lisa Corey suggested removing the last part of the parenthesis “from fixed nozzles” and Dr. Cavallari agreed. Dr. Cavallari said the study addendum presented data on the margins of exposure MOE which all exceeded the target level of concern of 10 in which reportedly indicated acceptable risk (Summary of Study Protocol section) and asked if the public will know what it means or it needs clarification. Dr. Corey suggested to put in a footnote of a definition of margin of exposure and Dr. Cavallari agreed. Dr. Cavallari asked about editing the statement suggesting the use of the Durbin-Watson statistical method (Statistical Review section). Dr. Ann Um said the statement can be removed in its entirety. The Board, except Dr. Alesia Ferguson who abstained, voted in favor of the finalization of the report for the July 2020 HSRB meeting, pending small grammatical changes and edits.

This concluded the Board’s September 17, 2020 meeting and Dr. O’Farrell adjourned the meeting.

Respectfully submitted:

11/9/2020

X Thomas O’Farrell, 11/9/20

Thomas O’Farrell

Signed by: THOMAS O’FARRELL

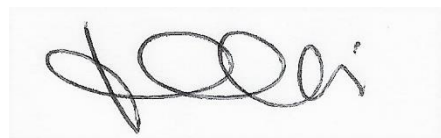
Thomas O’Farrell, Ph.D.

Designated Federal Officer

Human Studies Review Board

United States Environmental Protection Agency

Certified to be true by:



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

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-10010-72-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 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 two-day virtual public meeting will be held on Tuesday, July 21, 2020 and Wednesday, July 22, 2020, both from 1:00 p.m. to approximately 5:30 p.m. Eastern Time. A separate, subsequent teleconference meeting is planned for Thursday, September 17, 2020, from 2:00 p.m. to approximately 3:30 p.m. Eastern Time for the HSRB to finalize its Report of the July 21 and 22, 2020 meeting.

ADDRESSES: All of these meetings will be conducted entirely virtually and by telephone. For detailed access information 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 address at: ofarrell.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

Meeting access: These meetings will be open to the public. The full agenda with access information and meeting materials will be available 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 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, July 14, 2020, for the July 21 and 22, 2020 meeting and up to Noon Eastern Time on Thursday, September 10, 2020 for the September 17, 2020 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 by Noon Eastern Time on Tuesday, July 14, 2020, for the July 21 and 22, 2020 meeting and by Noon Eastern Time on Thursday, September 10, 2020 for the September 17, 2020 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 21, 2020, the HSRB will review a completed study from Citrefine International Limited titled "A single group trial to determine the complete protection time of an insect repellent formulation containing 30% Citriodiol® (Oil of Lemon Eucalyptus) against three species of ticks". On July 22, 2020, the HSRB will review a protocol from the Antimicrobial Exposure Assessment Task Force II titled "A Study for Measurement of Potential Dermal and Inhalation Exposure During Pressurized Hand-Wand Spraying of Antimicrobial Products".

The agenda and meeting materials for this topic will be seven calendar days available in advance of the meeting at <https://www.epa.gov/osa/human-studies-review-board>.

On September 17, 2020, the HSRB will review and finalize their draft Final Report from the July 21 and 22, 2020 meeting. The agenda and the draft report will be available seven calendar days prior to the 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 Report, 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