

EPA Human Studies Review Board (HSRB)

March 17, 2020 Meeting Minutes

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

Date and Time: Tuesday, March 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.

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) Mark Aulisio, Ph.D. Janice Britt, Ph.D. AJ Allen, Ph.D., M.D. Ann Um, Ed.D. Lisa Corey, Ph.D. George Milliken, Ph.D. Julia Sharp, Ph.D. Lindsay McNair, M.D.	<u>EPA staff members</u> Michelle Arling (EPA, OPP) Jeff Dawson (EPA, OPP) Tom O’Farrell (OSAPE)
<u>Members of the public, representatives of research sponsor and research team</u> Mike Krolski (AHETF) Steve McEuen (AHETF) Jeff Holmsen (AHETF) David Johnson (Johnson Management & Consulting) Kevin Dunn Kurd Ali	

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. Dr. O’Farrell announced that there will be no HSRB meetings in April or June. He also announced that Beth Roxland will no longer be serving on the HSRB but that Dr. Thomas Lewandowski is a full member of the Board and will be able to participate in the July meeting.

The purpose of the meeting was to review the final version of the HSRB January 2020 meeting report regarding the topic *Agricultural Handler Exposure Taskforce Study Report in*

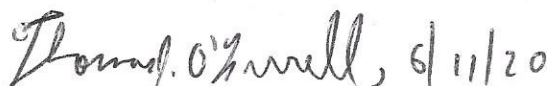
Monograph AHE500 and 1022, Determination of Dermal Inhalation Exposure to Workers during Closed System Loading of Liquids in Returnable and Non-Returnable Containers/Mechanical Transfer of Liquids.

There were no public comments.

Dr. Jennifer Cavallari clarified a point about data from AHE500 being combined with two earlier studies, AHE13 and AHE501. Dr. Cavallari also clarified that gloves were required always when handling the product and protective eyewear was required when the label of any product being handled required eyewear. The Board unanimously voted to approve of the final report in its current form subject to minor editorial changes.

This concluded the Board's session for March 17, 2020 and the meeting was adjourned.

Respectfully submitted:

 Thomas O'Farrell, 6/11/20

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

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

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

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

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

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-10004-35-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of the Science Advisor, Policy, and Engagement 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 Thursday, January 30, 2020 from 1:00 pm to approximately 5:30 pm Eastern Time. A separate, subsequent teleconference meeting is planned for Tuesday, March 17th, 2020, from 2:00 pm to approximately 3:30 pm Eastern Time for the HSRB to finalize its Report of the January 30, 2020 meeting and review other possible topics.

ADDRESSES: All of these meetings will be conducted entirely by telephone and on the Internet. 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 with access information 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 Thursday, January 23, 2020, for the January 30, 2020 meeting and up to Noon Eastern Time on Tuesday, March 10, 2020 for the March 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 or fax by Noon Eastern Time on Thursday, January 23, 2020, for the January 30, 2020 meeting and by Noon Eastern Time on Tuesday, March 10, 2020 for the March 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 January 30, 2020, the HSRB will consider a study titled "Determination of Dermal and Inhalation Exposure to Workers during Closed System Loading of Liquids in Returnable and Non-Returnable Containers" and a report titled "Agricultural Handler Scenario Monograph: Mechanical Transfer of Liquids", both submitted by the Agricultural Handlers Exposure Task Force.

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 March 17, 2020, the HSRB will review and finalize their draft Final Report from the January 30, 2020 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: _____

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