

EPA Human Studies Review Board (HSRB)

December 13, 2018 Meeting Minutes

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

Date and Time: Thursday, December 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 Dr. 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) AJ Allen, Ph.D., M.D. Lisa Corey, Ph.D. Jennifer Cavallari, Sc.D., CIH Kyle L. Galbraith, Ph.D. Walter T. Klimecki, D.V.M., Ph.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> Has Shah (American Chemistry Council) Brian Lange (Lange Research and Consulting) Greg Baumann (Nicis Corp.) Tim Curtis (Pilot Chemical) Kurd Ali (EnDyna) Kevin Dunn (EnDyna)	

Dr. O’Farrell provided an introduction to the meeting and outlined the Federal Advisory Committee Act (FACA) procedures. Dr. O’Farrell announced that Dr. Liza Dawson would be leaving the HSRB after this meeting and thanked her for service to the Board. Dr. O’Farrell announced that Dr. Jennifer Cavallari will be the new Chair of the HSRB.

Ms. Michelle Arling informed the Board that the EPA issued a notice of proposed rule making to harmonize the EPA specific human studies rule with the revised common rule. Ms. Arling encouraged Board members to look at the notice and provide comments formally, through regulations.gov, by Feb. 4, 2019.

Dr. Dawson called for public comments and there were none.

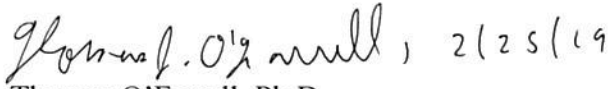
The Board discussed the draft report from the October 23, 2018 HSRB Meeting regarding the protocol "A Study for Measurement of Potential Dermal and Inhalation Exposure During Antimicrobial Applications Involving Immersion, Dip and Soak" which was circulated to the Board by email in advance of the call. Dr. Dawson asked Dr. Ann Um if the statistics comments were adequate in the final report. Dr. Um indicated that the comments were adequate.

The Board voted unanimously to accept the current draft of the report subject to minor edits.

Dr. O'Farrell announced that there will be no HSRB meetings in January or March 2019. The next HSRB meeting will likely be in April 2019.

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

Respectfully submitted:


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

Certified to be true by:

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Liza Dawson, Ph.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

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-9984-60-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency.

ACTION: Notice.

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, October 23, 2018, from 1:00 pm to approximately 5:30 pm Eastern Time. A separate, subsequent teleconference meeting is planned for Thursday, December 13th, 2018, from 2:00 pm to approximately 3:30 pm Eastern Time for the HSRB to finalize its Report of the October 23, 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 Tuesday, October 16, 2018, for the October 23, 2018 meeting and up to Noon Eastern Time on Thursday,

December 6, 2018 for the December 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 via email or Fax by Noon Eastern Time on Tuesday, October 16, 2018, for the October 23, 2018 meeting and by Noon Eastern Time on Thursday, December 6, 2018 for the December 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 October 23, 2018, the Human Studies Review Board will consider a protocol titled “A Study for Measurement of Potential Dermal and Inhalation Exposure During Antimicrobial Applications Involving Immersion, Dip, and Soak” submitted by the Antimicrobial Exposure Assessment 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 December 13, 2018, the HSRB will review and finalize their draft Final Report from the October 23, 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: _____

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