

EPA Human Studies Review Board (HSRB)

March 15, 2018 Meeting Minutes

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

Date and Time: Thursday, March 15, 2018, 2:00 to 2:35 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> Liza Dawson, Ph.D. (HSRB Chair) 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. Jun Zhu, Ph.D.	<u>EPA staff members</u> Michelle Arling (EPA)
<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.

The Board discussed the question of changing the format of the minutes that will be prepared from each HSRB meeting. In the past, very lengthy and detailed minutes were prepared which reflected all the detailed conversations that took place over the course of the HSRB meeting. The chair and the DFO are proposing a new format for the minutes which will be more succinct, giving an overview of main points from the meeting. This will be accompanied by a transcript of each HSRB meeting which is a verbatim transcript prepared by the meeting contractor, using the recording of the meeting.

The Chair asked for comments, concerns or questions about this new approach. Members of the Board stated that they appreciate having a chance to correct any errors in the minutes, and also appreciate having access to the transcript and recording in case it is needed. It is not always routinely needed, but important to have these materials as a backup.

Mr. O'Farrell stated that the meeting transcript and recording will be sent out to the Board a few days after each HSRB meeting, and the minutes will be prepared and shared with the Board after that. The Board indicated their agreement with the plan.

Liza Dawson called for public comments and there were none.

The Board discussed the report from the January 2018 HSRB meeting. The Board had a number of considerations for the study team to think about for both studies, some relatively minor changes. These considerations were not reviewed on the call, as they were discussed in detail at the last HSRB meeting. The chair noted that the most significant comments were with regard to statistical analysis on the Fabric Repellency Study. The completed study received a favorable review. Board members indicated that they had no additional comments for the report. The Board voted unanimously to approve the draft report.

Tom O'Farrell announced that the next HSRB meeting will be April 24-26, 2018 and adjourned the meeting at 2:25 pm.

Respectfully submitted:

 5/24/18

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

Certified to be true by:



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

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
FEDERAL REGISTER NOTICE ANNOUNCING MEETING
ENVIRONMENTAL PROTECTION AGENCY

[FRL-9972-41-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, January 23, 2018 and Wednesday, January 24, 2018, from 1:00 pm to approximately 5:30 pm Eastern Time on both dates. A separate, subsequent teleconference meeting is planned for Thursday, March 15, 2018, from 2:00 pm to approximately 3:30 pm Eastern Time for the HSRB to finalize its Final Report of the January 23 and 24, 2018 meeting and review other possible topics.

ADDRESSES: Both 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, January 16, 2018, for the January 23 and 24, 2018 meeting and up to Noon Eastern Time on Tuesday, March 8, 2018 for the March 15, 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, January 16, 2018, for the January 23 and 24, 2018 meeting and up to Noon Eastern Time on Tuesday, March 8, 2018 for the March 15, 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 January 23 and 24, 2018, EPA's Human Studies Review Board will consider two topics: 1) A completed study and monograph report titled "Agricultural Handler Exposure during Open Pour Loading of Granules" by the Agricultural Handlers Exposure Task Force, and 2) a study protocol titled "Laboratory Evaluation of Bite Protection From Repellent-Impregnated Fabrics" by Pinebelt Industries.

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 15, 2018, the HSRB will review and finalize their draft Final Report from the January 23 and 24, 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

