

US ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD
April 24-26, 2018 PUBLIC MEETING AGENDA

Internet Virtual Meeting

The meeting will be conducted at the following website:

<https://epawebconferencing.acms.com/hsrb>

And on the phone: 202-991-0477 (access code: 7939251)

Tuesday, April 24, 2018

HSRB WEB SITE <http://www.epa.gov/osa/human-studies-review-board>

12:50 PM HSRB members login online

1:00 PM* Convene Public Meeting – Tom O’Farrell, Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor
Virtual Meeting Operations – Liza Dawson, Ph.D., HSRB Chair
Introduction of Board Members – Liza Dawson, Ph.D., HSRB Chair
Opening Remarks – Tom Sinks, Ph.D., Director, Office of the Science Advisor, EPA

1:20 PM Brief Update on Research Discussed at Last HSRB Meeting – Michelle Arling, Office of Pesticide Programs (OPP)

Topic: A protocol for laboratory-based testing of a tick repellent containing Oil of Lemon Eucalyptus

1:25 PM EPA Science Review Highlights – Clara Fuentes, OPP, Biopesticide and Pollution Prevention Division

1:55 PM Board Questions of Clarification – Liza Dawson, HSRB Chair

2:15 PM EPA Ethics Review Highlights - Michelle Arling, OPP

2:45 PM Board Questions of Clarification - Liza Dawson, HSRB Chair

3:00 PM Public Comments

3:05 PM Break

3:20 PM Board Discussion

Charge to the Board - Science:

- *Is the protocol “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” likely to generate scientifically reliable data, useful for estimating the amount of time the product tested repels ticks?*

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

Discussants – Walt Klimecki, Randy Maddalena, and consultant Kendra Lawrence, scientific review
Ed Gbur, statistical review

Charge to the Board – Ethics:

- *Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?*

Discussants – Liza Dawson, ethics review

5:15 PM* Adjourn

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And on the phone: 202-991-0477 (access code: 7939251)

Wednesday, April 25, 2018

HSRB WEB SITE <http://www.epa.gov/osa/human-studies-review-board>

12:50 PM HSRB members login online

1:00 PM* Convene Public Meeting – Tom O’Farrell, Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor
Virtual Meeting Operations – Liza Dawson, Ph.D., HSRB Chair
Introduction of Board Members – Liza Dawson, Ph.D., HSRB Chair

Topic: A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting

1:20 PM EPA Science Review Highlights – Timothy Leighton, OPP, Antimicrobials Division
1:55 PM Board Questions of Clarification – Liza Dawson, HSRB Chair
2:10 PM EPA Ethics Review Highlights – Michelle Arling, OPP
2:30 PM Board Questions of Clarification - Liza Dawson, HSRB Chair
2:40 PM Public Comments
2:45 PM Break
3:00 PM Board Discussion

Charge to the Board - Science:

- *Did the research in study AEA09 generate scientifically reliable data, useful for assessing the exposure of painters who apply paint containing antimicrobial pesticides using brushes and rollers?*

Discussants – Alesia Ferguson, and Jennifer Cavallari, scientific review
Ed Gbur, statistical review

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

Charge to the Board - Ethics:

- *Does the available information support a determination that the research was conducted in substantial compliance with the requirements of 40 CFR part 26, subpart Q?*

Discussants – Kyle Galbraith, ethics review

Topic: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure

4:30 PM EPA Science Review Highlights – Timothy Leighton, OPP, Antimicrobials Division

4:55 PM Board Questions of Clarification - Liza Dawson, HSRB Chair

5:05 PM EPA Ethics Review Highlights – Michelle Arling, OPP

5:20 PM Board Questions of Clarification - Liza Dawson, HSRB Chair

5:30 PM Adjourn

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]

**US ENVIRONMENTAL PROTECTION AGENCY
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Thursday, April 26, 2018

HSRB WEB SITE <http://www.epa.gov/osa/human-studies-review-board>

12:50 PM HSRB members login online

1:00 PM* Convene Public Meeting – Tom O’Farrell, Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor
Virtual Meeting Operations – Liza Dawson, Ph.D., HSRB Chair
Introduction of Board Members – Liza Dawson, Ph.D., HSRB Chair

Topic: Determination of Removal Efficiency of 1,2-Benzisothiazol-3(2H)-one (BIT) from Hand Surfaces Using an Isopropyl Alcohol/Water Wipe and Wash Procedure

1:20 PM Continuation – Summary of Wednesday discussion

1:30 PM Public Comments

1:35 PM Board Discussion

Charge to the Board - Science:

- *Did the research in study AEA08 generate scientifically reliable data, useful for establishing the efficiency of the hand wash procedure used to remove BIT-treated paint from the hands?*

Discussants – Alesia Ferguson, and Jennifer Cavallari, scientific review
Jun Zhu, statistical review

Charge to the Board - Ethics:

- *Does the available information support a determination that the research was conducted in substantial compliance with the requirements of 40 CFR part 26, subpart Q?*

Discussants – Kyle Galbraith, ethics review

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Topic: A published article titled “Assessing key safety concerns of a *Wolbachia*-based strategy to control dengue transmission by *Aedes* mosquitoes”

2:20 PM EPA Science Review Highlights – Eric Bohnenblust, Ph.D., OPP, Biopesticide and Pollution Prevention Division

2:50 PM Board Questions of Clarification – Liza Dawson, HSRB Chair

3:10 PM EPA Ethics Review Highlights – Michelle Arling, OPP

3:30 PM Board Questions of Clarification – Liza Dawson, HSRB Chair

3:40 PM Public Comments

3:55 PM Break

4:00 PM Board Discussion

Charge to the Board - Science:

- *Is the research described in the published article “Assessing key safety concerns of a *Wolbachia*-based strategy to control dengue transmission by *Aedes* mosquitoes” scientifically sound, providing reliable data for the purpose of contributing to a weight of evidence determination in EPA’s assessment of the risks to human health associated with releasing *Wolbachia*-infected mosquitoes?*

Discussants – Walt Klimecki, Randy Maddalena, and consultant Kendra Lawrence, scientific review
Jun Zhu, statistical review

Charge to the Board - Ethics:

- *Does the available information support a determination that the research was conducted in substantial compliance with the requirements of 40 CFR part 26, subpart Q?*

Discussants – Liza Dawson, ethics review

5:15 PM* Adjourn

*Agenda times are approximate and subject to change depending upon the discussion. [All times shown are Eastern time zone.]