

**US ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD  
APRIL 2015 PUBLIC MEETING AGENDA**

**Environmental Protection Agency Conference Center**  
Lobby Level - One Potomac Yard (South Bldg.)  
2777 S. Crystal Drive, Arlington, VA 22202

Wednesday, April 22, 2015

**HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>**

**Docket Telephone: (202) 566 1752**

**Docket Number: EPA-HQ-ORD-2015-0145**

**Webcast of the HSRB Meeting**

The Webcast of the meeting is at the following website:

<https://epa.connectsolutions.com/hsrb>

**1:00 PM\***     **Convene Public Meeting** – Jim Downing, Designated Federal Officer, EPA  
Human Studies Review Board, Office of the Science Advisor  
**Introduction of Board Members** –Liza Dawson, Ph.D., HSRB Chair  
**Welcome** – Thomas A. Burke, PhD, MPH, Science Advisor, EPA

**Session 1:   Completed Study and Monograph Report for Backpack and Handgun  
Application of Liquid Spray in Utility Rights of Way (Agricultural Handlers  
Exposure Task Force)**

**1:20 PM**     **EPA Science Review** – Mr. Mathew Crowley, (Health Effects Division, OPP,  
EPA)

**2:05PM**     **Board Questions of Clarification** – Liza Dawson, Ph.D., (HSRB Chair), EPA, and  
Principal Investigator/Sponsor

**2:30 PM**     **EPA Ethics Review** - Ms. Kelly Sherman (OPP, EPA)

**2:45 PM**     **Board Questions of Clarification** – Liza Dawson, Ph.D., (HSRB Chair), EPA,  
Principal Investigator/Sponsor

**3:00 PM**     **Break**

**3:15 PM**     **Public Comments**

**3:25 PM**     **Board Discussion**

Charge to the Board - Science:

1.     Was the research reported in the Agricultural Handler Exposure Task Force (AHETF) completed monograph reports and associated field study report for AHE400 faithful to the design and objectives of the protocol, SOPs, and governing documents?
  
2.     Has the Agency adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating exposure of those who apply liquid pesticide sprays to utilities rights-of-way using backpack or handgun spray equipment?

**Discussant:** William Pependorf, Ph.D. (George Fernandez, Ph.D., statistics)

\*Agenda times are approximate and subject to change depending upon the discussion.

Charge to the Board - Ethics:

3. Does available information support a determination that the studies were conducted in substantial compliance with subparts K and L of 40 CFR Part 26?

**Discussant:** Elizabeth Heitman, Ph.D.

**4:50 PM Adjourn**

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**9:00 AM\***    **Convene Public Meeting** – Jim Downing, Designated Federal Officer, EPA  
Human Studies Review Board, Office of the Science Advisor  
**Introduction of Board Members** – Liza Dawson, Ph.D., HSRB Chair  
**Follow-up on Previous Day’s Discussion** – Ms. Kelly Sherman, OPP, Office of  
Chemical Safety and Pollution Prevention, EPA

**Session 1: Protocol for Field Testing of skin applied mosquito repellent products (SC  
Johnson)**

**9:10 AM**    **EPA Science Review** – Mr. Kevin Sweeney, (Registration Division, OPP, EPA)

**9:30 AM**    **Board Questions of Clarification** – Liza Dawson, Ph.D., (HSRB Chair), EPA, and  
Principal Investigator/Sponsor

**10:00 AM**   **EPA Ethics Review** - Ms. Kelly Sherman (OPP, EPA)

**10:20 AM**   **Board Questions of Clarification** – Liza Dawson, Ph.D., (HSRB Chair), EPA, and  
Principal Investigator/Sponsor

**10:45 AM**   **Public Comments**

**10:55 PM**   **Break**

**11:05 AM**   **Board Discussion**

If the SCJ study proposal is revised as suggested in EPA’s science and ethics reviews and if the research is performed as described:

Charge to the Board - Science:

- Is this research is likely to generate scientifically reliable data, useful for assessing the efficacy of these insect repellent pesticide products?

**Discussant:** Randy Maddalena, Ph.D. (Jun Zhu, Ph.D., statistics)

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Charge to the Board - Ethics:

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

**Discussant:** Gary Chadwick, Pharm.D., M.P.H, C.I.P.

**12:05 PM   Adjourn**

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