

US ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD  
July 20, 2021 PUBLIC MEETING AGENDA

**Internet Virtual Meeting**

The meeting will be conducted at the following website:

<https://us02web.zoom.us/j/89727943343?pwd=RGFSbjVTLzF0b1N5TUtKOVpiU0Rpdz09>

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

**12:50 PM HSRB members login (webinar and teleconference line)**

**1:00 PM\* Convene Public Meeting** – Tom O’Farrell, Ph.D., Designated Federal Officer, EPA Human Studies Review Board (HSRB), Office of the Science Advisor, Policy and Engagement (OSAPE)

**Welcome and Virtual Meeting Operations** – Jennifer Cavallari, Sc.D., HSRB Chair

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

**Topic:** Dwivedi, A. et al. *Acute effects of acrolein in human volunteers during controlled exposure. Inhalation Toxicology. Volume 27, Issue 14. pp. 810-821. December 4, 2015.*

**1:25 PM EPA Overview** – Jeremy Leonard, Ph.D., OPP

**1:40 PM EPA Science Review Highlights** – Jeremy Leonard, Ph.D., OPP

**2:05 PM Board Questions of Clarification** – Jennifer Cavallari, HSRB Chair

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

**2:35 PM Board Questions of Clarification** – Jennifer Cavallari, HSRB Chair

**2:45 PM Public Comments**

**2:50 PM Break**

**3:10 PM Board Discussion**

**Charge to the Board - Science:**

*Is the research described in the published article “Acute effects of acrolein in human volunteers during controlled exposure” scientifically sound, providing reliable data?*

**Discussants** – Janice Britt, Ph.D., and Lisa Corey, Ph.D.  
Julia Sharp, Ph.D., statistical review

**Charge to the Board - Ethics:**

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

**Discussant** – Lindsay McNair, M.D., ethics review

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

**5:15 PM\* Adjourn**

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**Welcome and Virtual Meeting Operations** – Jennifer Cavallari, Sc.D., HSRB Chair

**Topic:** Claeson, A-S and Lind, N. Human exposure to acrolein: Time-dependence and individual variation in eye irritation. *Environmental Toxicology and Pharmacology*. Volume 45. pp. 20-27. May 13, 2016.

**1:20 PM EPA Science Review Highlights** – Jeremy Leonard, Ph.D., OPP  
**1:45 PM Board Questions of Clarification** – Jennifer Cavallari, HSRB Chair  
**1:55 PM EPA Ethics Review Highlights** – Michelle Arling, OPP  
**2:20 PM Board Questions of Clarification** – Jennifer Cavallari, HSRB Chair  
**2:30 PM Public Comments**  
**2:35 PM Break**  
**2:50 PM Board Discussion**

**Charge to the Board - Science:**

*Is the research described in the published article “Human exposure to acrolein: Time dependence and individual variation in eye irritation” scientifically sound, providing reliable data?*

**Discussants** – Alesia Ferguson, Ph.D., and Thomas Lewandowski, Ph.D. scientific review  
George Milliken, Ph.D., statistical review

**Charge to the Board - Ethics:**

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

**Discussant** – Philip Day, Ph.D., ethics review

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**Overall Charge:**

*When considered together, do the studies described in Claeson et al. and Dwivedi et al. provide a scientific weight of evidence in support of the existing short-term to intermediate-term inhalation point of departure of 0.09 ppm based on eye irritation in risk assessments?*

**5:15 PM\* Adjourn**

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