

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN SUBJECTS REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE/WEBINAR
MEETING AGENDA

Wednesday, October 11, 2023
1:00pm – 4:00pm (Eastern Time*)

Internet Virtual Meeting

The meeting will be conducted at the following website:

Join Zoom Meeting

<https://us02web.zoom.us/j/87847807160>

Meeting ID: 878 4780 7160

Commented [CM1]: Has been updated

HSRB WEBSITE <https://www.epa.gov/osa/human-studies-review-board>

- 12:50 PM** HSRB members login online and call in on the phone
- 1:00 PM** Convene Meeting and Introduction of Members – Tom Tracy (Designated Federal Officer, EPA HSRB)
- 1:05 PM** Introduction of EPA Staff – Michelle Arling (Office of Pesticide Programs)
- 1:10 PM** Update from EPA Human Subject Research Review Official - Monique E. Tadeo
- 1:15 PM** Opening Remarks and Meeting Process – Lisa Corey (HSRB Co-Chair)
Julia Sharp (HSRB Co-Chair)
- 1:20 PM** Updates from OPP – Michelle Arling (Office of Pesticide Programs)
- Topic: Flyvholm, MA, Hall, BM, Agner, T, Tiedemann, E, Greenhill, P, Vanderveken, W, Freeberg, FE and T Menné. (1997). Threshold for Occluded Formaldehyde Patch Test in Formaldehyde-Sensitive Patients. Contact Dermatitis. 36: 26-33.**
- 1:25 PM** EPA Science Review Highlights – Colleen Rossmeisl, OPP Antimicrobials Division
- 1:40 PM** Board Questions of Clarification
- 1:50 PM** EPA Ethics Review Highlights – Michelle Arling, OPP

2:00 PM Board Questions of Clarification

2:10 PM Public Comments

2:15 PM Break

2:30 PM Board Discussion

Charge to the Board – Science:

- *Is the research described in the published study “Flyvholm, MA, Hall, BM, Agner, T, Tiedemann, E, Greenhill, P, Vanderveken, W, Freeberg, FE and T Menné. (1997). Threshold for Occluded Formaldehyde Patch Test in Formaldehyde-Sensitive Patients. Contact Dermatitis. 36: 26-33” scientifically sound, providing reliable data for consideration as part of endpoint selection and derivation of a point of departure for elicitation of dermal sensitization from dermal exposure?*

Discussants

David Williams, Ph.D., Science Review

Weiyang Jiang, Ph.D., Science Review

Sinziana Seicean, Ph.D., Statistical Review

Commented [CM2]: These are the discussants for day 1. Different from day 2.

Charge to the Board – Ethics:

- Does available information support a determination that the conduct of the research was not fundamentally unethical?
- Does available information support a determination that the research was not deficient relative to the ethical standards prevailing at the time the research was conducted or conducted in a way that placed participants at increased risk of harm or impaired their informed consent?

Discussant

Philip Day, Ph.D., Ethics Review

Commented [CM3]: These are the discussants for day 1. Different from day 2.

4:00 PM Adjournment – Tom Tracy, DFO

*Note that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Tom Tracy at tracy.tom@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
HUMAN SUBJECTS REVIEW BOARD (HSRB)
PUBLIC TELECONFERENCE/WEBINAR
MEETING AGENDA

Thursday, October 12, 2023
1:00pm – 4:00pm (Eastern Time*)

Internet Virtual Meeting

The meeting will be conducted at the following website:

Join Zoom Meeting

<https://us02web.zoom.us/j/87847807160>

Meeting ID: 878 4780 7160

Commented [CM4]: Has been updated

HSRB WEBSITE <https://www.epa.gov/osa/human-studies-review-board>

- 12:50 PM** HSRB members login online and call in on the phone
- 1:00 PM** Convene Meeting and Introduction of Members – Tom Tracy (Designated Federal Officer, EPA HSRB)
- 1:05 PM** Opening Remarks and Meeting Process – Lisa Corey (HSRB Co-Chair)
Julia Sharp (HSRB Co-Chair)
- 1:15 PM** Updates from OPP – Michelle Arling (Office of Pesticide Programs)
- Topic:** Fischer, T; Andersen, K; Bengtsson, U; Frosch, P; Gunnarsson, Y; Kreilgård, B; Menné, T; Shaw, S; Svensson, L; Wilkinson, J. (1995). Clinical Standardization of the TRUE Test™ Formaldehyde Patch. In Exogenous Dermatology: Advances in Skin-Related Allergology, Bioengineering, Pharmacology and Toxicology. Current Problems in Dermatology, Edited by Surber C and Elsner P. Volume 22:24-30. Basel: S Karger, AG.
- 1:20 PM** EPA Science Review Highlights – Colleen Rossmeisl, OPP Antimicrobials Division
- 1:35 PM** Board Questions of Clarification
- 1:45 PM** EPA Ethics Review Highlights – Michelle Arling, OPP
- 1:55 PM** Board Questions of Clarification

2:05 PM Public Comments

2:15 PM Break

2:30 PM Board Discussion

Charge to the Board – Science:

- *Is the research described in the published study “Fischer, T; Andersen, K; Bengtsson, U; Frosch, P; Gunnarsson, Y; Kreilgård, B; Menné, T; Shaw, S; Svensson, L; Wilkinson, J. (1995). Clinical Standardization of the TRUE Test™ Formaldehyde Patch. In Exogenous Dermatology: Advances in Skin-Related Allergology, Bioengineering, Pharmacology and Toxicology. Current Problems in Dermatology” scientifically sound, providing reliable data for consideration as part of endpoint selection and derivation of a point of departure for elicitation of dermal sensitization from dermal exposure?*

Discussants

Srikumaran Melethil, Ph.D. Science Review
Chad Cross, Ph.D., Statistics

Charge to the Board – Ethics:

Does available information support a determination that the conduct of the research was not fundamentally unethical?

Does available information support a determination that the research was not deficient relative to the ethical standards prevailing at the time the research was conducted or conducted in a way that placed participants at increased risk of harm or impaired their informed consent?

Discussant

Joseph Tuminello, Ph.D., Ethics Review

4:00 PM Adjournment – Tom Tracy, DFO

*Note that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Tom Tracy at tracy.tom@epa.gov

Commented [AM(5)]: Confirm this accurate - same on day 1 and 2?

Commented [CM6R5]: This is for day 2

Commented [AM(7)]: Confirm this accurate - same on day 1 and 2?

Commented [CM8R7]: This is for day 2.