

**US ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD  
January 14, 2015 PUBLIC MEETING AGENDA**

**Internet Virtual Meeting**

The meeting will be conducted at the following website:

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

Wednesday, January 14, 2015

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

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

**Docket Number: EPA-HQ-ORD-2014-0882**

**9:50 AM HSRB members login online**

**10:00 AM\*** **Convene Public Meeting** – Jim Downing, Designated Federal Officer, EPA Human Studies Review Board, Office of the Science Advisor  
**Virtual Meeting operations** –Rebecca Parkin, Ph.D., MPH, HSRB Chair  
**Introduction of Board Members** –Rebecca Parkin, Ph.D., MPH, HSRB Chair  
**Opening Remarks** – Toby Schonfeld, Ph.D., Human Subjects Research Review Official, EPA

**Session 1: Review and Approval of the HSRB Final Report of the November 5, 2014 Meeting**

**10:15 AM Public Comments**

**10:20 AM Board Discussion of Draft Final Report**

**Session 2: A published report: Ezratty, Veronique et al. (2014) Repeated Nitrogen Dioxide Exposures and Eosinophilic airway Inflammation in Asthmatics: A Randomized Crossover Study. *Environmental Health Perspectives*. Volume 122, Number 8, August 2014. (MRID 49519201)**

**10:40 AM EPA Science Review Highlights** – LT Jonathan Leshin, Ph.D. (OPP, EPA)

**10:50 AM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff

**11:05 AM EPA Ethics Review Highlights** - Ms. Kelly Sherman (OPP, EPA)

**11:15 AM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), and EPA staff

**11:30 AM Public Comments**

**11:35 AM Board Discussion**

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

Charge to the Board - Science:

- Is this study scientifically sound, providing reliable data?
- If so, is this study adequate for quantitative use in support of an inhalation risk assessment for the use of nitrogen dioxide as a medical equipment sterilant?

**Discussants:** Randy Maddalena, Ph.D. (George Fernandez, statistics)

Charge to the Board - Ethics:

- Does the study meet the applicable requirements of 40 CFR part 26 subpart Q?

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

**12:45 PM Lunch**

**1:30 PM Reconvene – roll call**

**Session 3: A published report: Spak, C.J. et al. (1989) Tissue Response of Gastric Mucosa after Ingestion of Fluoride. Karolinska Institute, Huddinge University Hospital, Huddinge, Sweden. *British Medical Journal*. 298:1686-7. (MRID 49489101)**

**1:35 PM EPA Science Review Highlights – Jaime D’Agostino, Ph.D., (Health Effects Division, OPP, EPA)**

**1:45 PM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff**

**2:00 PM EPA Ethics Review Highlights - Ms. Kelly Sherman (OPP, EPA)**

**2:10 PM Board Questions of Clarification – Rebecca Parkin, Ph.D., MPH (HSRB Chair), and EPA staff**

**2:25 PM Public Comments**

**2:35 PM Board Discussion**

Charge to the Board - Science:

- Is this study scientifically sound, providing reliable data?
- If so, is this study adequate for quantitative use in support of an acute dietary risk assessment for fluoride?

**Discussants:** Ken Ramos, M.D., Ph.D. (Ed Gbur, Ph.D., statistics)

Charge to the Board - Ethics:

- Does the study meet the applicable requirements of 40 CFR part 26 subpart Q?

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**Discussant:** Jewel Halanych, M.D., M. Sc.

**Session 4:** A published report: **Hansson, T. and Roos, B. (1987). The Effect of Fluoride and Calcium on Spinal Bone Mineral Content: A Controlled, Prospective (3 years) study. Sahlgren's Hospital, University of Gothenberg, Sweden. *Calcified Tissue International*. 40:315-317. (MRID 49489102)**

**3:25 PM EPA Science Review Highlights** – Jaime D'Agostino, Ph.D., (Health Effects Division, OPP, EPA)

**3:30 PM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff

**3:45 PM EPA Ethics Review Highlights** - Ms. Kelly Sherman (OPP, EPA)

**3:55 PM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), and EPA staff

**4:10 PM Public Comments**

**4:15 PM Board Discussion**

Charge to the Board - Science:

- Is this study scientifically sound, providing reliable data?
- If so, is this study adequate for qualitative use in support of an acute dietary risk assessment for fluoride?

**Discussants:** Will Pependorf, Ph. D. (Jun Zhu, Ph.D., statistics)

Charge to the Board - Ethics:

- Does the study meet the applicable requirements of 40 CFR part 26 subpart Q?

**Discussant:** Suzanne Rivera, Ph.D., M.S.W.

**5:00 PM\* Adjourn**

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