

**US ENVIRONMENTAL PROTECTION AGENCY  
HUMAN STUDIES REVIEW BOARD  
JUNE 2014 PUBLIC MEETING AGENDA**

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

Wednesday, June 11, 2014

**HSRB WEB SITE <http://www.epa.gov/osa/hsrb/>**  
**Docket Telephone: (202) 566 1752**  
**Docket Number: EPA-HQ-ORD-2014-0411**

**10:30 AM\***    **Convene Public Meeting** – Jim Downing, Designated Federal Officer, EPA  
Human Studies Review Board, Office of the Science Advisor  
**Introduction of Board Members** –Rebecca Parkin, Ph.D., MPH, HSRB Chair  
**Opening Remarks** – Toby Schonfeld, Ph.D., Human Subjects Research Review  
Official, EPA  
**Welcome** – Mr. Jack Housinger, Director, Office of Pesticide Programs (OPP),  
Office of Chemical Safety and Pollution Prevention, EPA

**Session 1:**    **A published report by *Paul et al* (1988) of an intentional exposure human  
study measuring the effects of small increases of dietary iodine on thyroid function.**

**10:45 AM**    **EPA Science Review** – Jonathan Leshin, Ph.D. (OPP, EPA)  
**11:00 AM**    **Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair),  
EPA staff  
**11:15 AM**    **EPA Ethics Review** - Ms. Kelly Sherman (OPP, EPA)  
**11:25 AM**    **Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair),  
EPA staff  
**11:35 AM**    **Public Comments**  
**11:40 AM**    **Board Discussion**

Charge to the Board - Science:

- Was the research reported in the published report by *Paul et al* (1988) faithful to the design and objectives of the protocol and governing documents of AEATF?
- Has EPA adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating the exposure?

Charge to the Board - Ethics:

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

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

**Session 2: A published report by Gardner et al (1988) of an intentional exposure human study measuring the effects of low dose oral iodide supplementation on thyroid function.**

**12:05 PM EPA Science Review** – Jonathan Leshin, Ph.D. (OPP, EPA)

**12:20 PM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff

**12:30 PM EPA Ethics Review** - Ms. Kelly Sherman (OPP, EPA)

**12:40 PM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), and EPA staff

**12:50 PM Public Comments**

**12:55 PM Board Discussion**

Charge to the Board - Science:

- Was the research reported in the published report by *Gardner et al* (1988) faithful to the design and objectives of the protocol and governing documents of AEATF?
- Has EPA adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating the exposure?

Charge to the Board - Ethics:

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

**1:20 PM Lunch**

**Session 3: A published report by Lemar et al (1995) of an intentional exposure human study measuring the effects of chronic tetraglycine hydroperiodide water purification tablet use on thyroid function.**

**2:00 PM EPA Science Review** – Jonathan Leshin, Ph.D. (OPP, EPA)

**2:15 PM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff

**2:25 PM EPA Ethics Review** - Ms. Kelly Sherman (OPP, EPA)

**2:35 PM Board Questions of Clarification** – Rebecca Parkin, Ph.D., MPH (HSRB Chair), EPA staff

**2:45 PM Public Comments**

**2:50 PM Board Discussion**

Charge to the Board - Science:

- Was the research reported in the published report by *Lemar et al* (1995) faithful to the design and objectives of the protocol and governing documents of AEATF?
- Has EPA adequately characterized, from a scientific perspective, the limitations on these data that should be considered when using the data in estimating the exposure?

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

Charge to the Board - Ethics:

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

**3:20 PM Discussion of HSRB Work Group on Return of Individual Research Results Report**

**4:00 PM\* Adjourn**

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