

**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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