Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
August 15, 2014 Public Teleconference/Webinar Meeting
Docket Number: EPA–HQ–ORD–2014-0564
HSRB Website: http://www.epa.gov/osa/hsrb

Committee Members: (See EPA HSRB Members list—Attachment A)

Date and Time:	Friday, August 15, 2014, 2:00 p.m. – 3:30 p.m. EDT (See *Federal Register* Notice—Attachment B)	
Location:	Via Teleconference and Webinar	
Purpose:	The EPA Human Studies Review Board provides advice, information and recommendations on issues related to the scientific and ethical aspects of human subjects research.	
Attendees:	Chair:	Rebecca Parkin, Ph.D., M.P.H.
	Board Members:	Liza Dawson, Ph.D. George C.J. Fernandez, Ph.D. Kyle L. Galbraith, Ph.D. Edward Gbur, Jr., Ph.D. Sidney Green, Jr., Ph.D., Fellow, ATS John C. Kissel, Ph.D. Randy Maddalena, Ph.D. William J. Popendorf, Ph.D. Kenneth Ramos, M.D., Ph.D., Pharm.B. Leonard Ritter, Ph.D., ATS Linda J. Young, Ph.D.
Meeting Summary:	Meeting discussions generally followed the issues and general timing as presented in the meeting Agenda (Attachment C), unless noted otherwise in these minutes.	

COMMENCEMENT OF PUBLIC MEETING AND IDENTIFICATION OF BOARD MEMBERS

Mr. Jim Downing, Designated Federal Officer (DFO) of the HSRB, commenced the teleconference/webinar meeting and welcomed Board members on behalf of EPA. He noted that the Agency appreciates the Board members' time and diligence in preparing for the meeting and during the deliberations. He also welcomed EPA colleagues and members of the public. The purpose of this teleconference/webinar meeting is to review the decisions made by the Board at the June 11, 2014 HSRB meeting and to finalize the Board's report from that meeting.

Mr. Downing called roll to determine which members were present on the call; a quorum of members was present. The members introduced themselves with their names and affiliations.

MEETING ADMINISTRATIVE PROCEDURES

As DFO, Mr. Downing, serves as the liaison between the HSRB and EPA and ensures that Federal Advisory Committee Act (FACA) provisions are met with regard to the operations of the HSRB. He also works with the appropriate officials to ensure that all applicable ethics regulations are satisfied. Each Board member has been briefed on the provisions of the federal conflict of interest laws and has filed a standard government financial disclosure form that has been reviewed to ensure that all ethics disclosure requirements have been met.

At the teleconference/webinar meeting, the Board will review the draft final report from the June 2014 HSRB meeting and will finalize the report for submission to EPA's Science Advisor. Mr. Downing reminded participants that meeting times listed on the agenda would be approximate, and that participants should state their names before speaking to ensure proper attribution. Copies of the meeting materials, supporting documents and public comments will be available at *http://www.regulations.gov* under docket number EPA-HQ-ORD-2014-0564, and most are available on the HSRB website at *http://www.epa.gov/osa/hsrb*. At the appropriate time, members of the public may provide public comments; these must be limited to 5 minutes. No individuals preregistered to provide public comments. The draft final report will be displayed, reviewed and modified on the website at *https://epa.connectsolutions.com/hsrbtele* during the teleconference/webinar. Mr. Downing encouraged the participants to log in to the webinar, which will enable the Board to follow along as revisions to the draft document are made in real time during the deliberations.

According to FACA requirements, meeting minutes will be prepared, including descriptions of the topics discussed and conclusions reached by the Board. These minutes will be reviewed and certified by the Chair within 30 days of the meeting and posted at *http://www.regulations.gov* and on the HSRB website. Mr. Downing expressed appreciation to the Board members for their participation and eagerness to finalize the report from the June 2014 meeting. Mr. Downing turned the meeting over to the HSRB Chair, Dr. Rebecca Parkin.

MEETING PROCESS

Dr. Parkin, HSRB Chair, thanked all of the Board members for their diligent work at the June 2014 meeting and their efforts in developing the draft meeting report and preparing for the teleconference/webinar. She reiterated Mr. Downing's request for the Board members to log in to the webinar. Dr. Parkin explained that Mr. Downing will edit the document in real time in response to Board members' comments.

She expressed confidence that the Board would finalize the report and expedite its progress toward public access. Dr. Parkin described the meeting process, explaining that she would lead the discussion sequentially through each section of the report to ensure that all issues are covered. After Dr. Parkin announces a section, the Board members will have an opportunity

to offer comments about that particular section. The Board will address the draft cover letter at the end of the discussion.

PUBLIC COMMENTS

Mr. Downing noted that there were no preregistered public comments, and no public participants had identified themselves on the teleconference line. He invited participants to comment publicly on the draft June 2014 HSRB meeting report. No public comments were presented to the Board.

BOARD DISCUSSION AND DECISION ON THE FINAL REPORT

Dr. Parkin directed the participants to the draft report Introduction. She asked the Board members to contribute any concerns or suggested revisions. In response to a question, Dr. Parkin confirmed that the version under review by the Board is labeled August 13, 2014, with Dr. Sidney Green's revision incorporated. Hearing no comments on the Introduction, Dr. Parkin moved sequentially through the Review Process paragraphs to solicit comments. Hearing no comments on the Review Process section, Dr. Parkin directed the Board members to the Paul *et al.* report.

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

Moving on to the Paul *et al*. report, Dr. Parkin asked if there were any Board member concerns about the Overview of the Study as written. Dr. Randy Maddalena noted that the units specifying the dosages of the sodium iodide were incorrect as written in the Board's report. The Board members discussed the correct way to represent the sodium iodide doses. After referring to the original article and debating the appropriate language, the Board members decided to rephrase the sentences about the sodium iodide doses as follows:

> "While maintaining their usual diets over a 14-day period, the female participants took sodium iodide dissolved in water at one of three dosages (250, 500 or 1,500 µg per day) along with 5 mg/day ascorbic acid. In the same manner the male participants received only the 1,500 µg per day dose."

All of the Board members were in agreement with regard to the revised sentences, and they all approved of Dr. Green's revision.

Dr. Parkin called for comments within the Science section, including the Charge to the Board and Board Response to the Charge. She noted that the HSRB Recommendation points capture the Board decisions during the June 2014 meeting. The HSRB Detailed Recommendations and Rationale were built on the contributions from the lead discussants, with minor formatting modifications. Dr. Parkin noted that the recommendations now address the issue that reliable data do not necessarily generate reliable conclusions. She solicited additional comments for the Science section.

A participant suggested modifying the quoted phrase in item 1 to read, "some of the women were studied at two dose levels at least one year apart" to ensure that the phrase was captured verbatim from the Paul *et al.* report.

An HSRB member referenced the question regarding the Paul *et al.* study's inclusion of data from repeat study participants in item 1 in response to the question, "Is this study scientifically sound, providing reliable data?" The issue is that 36 observations were recorded from 32 participants, and the origin of the additional four measurements is unclear to the Board members. Dr. Parkin asked how the paragraph should be reworded to address the Board members' concern. Drs. Linda Young, George Fernandez, William Popendorf and Edward Gbur discussed how to capture the Board's concern within the report. Dr. Parkin noted that the treatment issue is separate from the confusion about Table 1 in the Paul *et al*. report. Several Board members expressed reluctance to include the Board's assumptions about the data within the HSRB report. To lend clarity to the HSRB Detailed Recommendations and Rationale section, a participant suggested removing the sentence beginning with "Furthermore…" from point 1. Dr. Young suggested language to insert after the first sentence in point 2 that would read, "For example, it is unclear how the total sample size of 32 can be reconciled with the values in column N of Table 1." The participants also agreed to modify point 2 to read, "(1) the duplicate assay values used in the study were treated as subsamples (not as true replications)."

Dr. Parkin called for comments or suggested revisions within the Ethics section of the HSRB report. No comments were offered in the Charge to the Board, Board Response to the Charge, HSRB Recommendation, and HSRB's Detailed Recommendation and Rationale sections. Dr. Parkin concluded that the Board was in agreement with the Ethics section of the Paul *et al.* review within the HSRB report.

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

Dr. Parkin solicited comments for the Overview of the Study section for the Gardner *et al.* review. Hearing none, she read the HSRB Recommendations for the Science section aloud:

- The Board concurred that the study is scientifically sound, providing reliable data. However, the lack of details in the analytic methods and less than robust statistical analysis weakened the HSRB's ability to evaluate all aspects of the study's scientific soundness. Thus, the Board did not find clear and convincing evidence that this study's data are not reliable.
- The HSRB concluded that this study is relevant for quantitative use in support of an assessment of the oral risk of exposure to iodine. However, the hormone levels and changes in T4 observed in this study should be viewed as qualitative in nature. In contrast, the changes in thyroid function are sufficiently reliable to be used in a weight-of-evidence analysis.

Dr. Leonard Ritter suggested removing the word "thus" from the first bullet point of the recommendations. Dr. Gbur commented that the lack of details about the analytic methods might be an issue. Dr. Parkin reminded the participants that the HSRB report reflects the decisions voted by the Board at the June 2014 meeting. Dr. Young suggested changing the wording of the

last sentence in the first bullet to read: "The Board did not find clear and convincing evidence that the conclusions drawn from this study are not reliable" to assuage the members' concern about the reliability of the data versus the reliability of the conclusions. Several Board members expressed reluctance to use a double negative in the sentence, but Mr. Downing noted that such language has been used in previous reports.

A HSRB member questioned the meaning of the phrase "this study is relevant for quantitative use" in the second bullet. He expressed caution in endorsing wording that is unclear. Dr. Young explained that EPA uses data for qualitative and quantitative purposes in a weight-of-evidence approach. Dr. Fernandez asked for clarification of the term "weight-of-evidence." Dr. Parkin clarified that weight-of-evidence is an approach used by EPA. It is not a statistical term. The term is used in the HSRB report for consistency with EPA's charge question. A participant elaborated that EPA uses the term "weight-of-evidence approach" interchangeably with "weight-of-evidence analysis" and "weight-of-evidence evaluation." According to draft EPA guidance, "a weight-of-evidence evaluation is a process where potentially relevant studies are judged in a professional manner for quality." Even when data are not quantitatively useful, they might provide qualitative information on the nature of toxicity or exposure.

Dr. Parkin proceeded through the HSRB Detailed Recommendations and Rationale within the Science section. Hearing no comments, Dr. Parkin concluded that the Board was satisfied with the Gardner *et al.* Science section of the HSRB report with the proposed changes. The Board members also approved of the Gardner *et al.* Ethics section of the HSRB report with no changes.

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

Dr. Parkin directed the Board members to the Lemar *et al.* article. There were no comments offered on the Overview of the Study. Dr. Parkin read the three HSRB Recommendations:

Subject to the limitations noted below, the Board concluded that:

- The study is scientifically sound and provides reliable data.
- This study would be relevant in a weight-of-evidence approach for establishing the reversibility of high dose iodine exposure.
- This study would be relevant in a weight-of-evidence approach for establishing that there are no sustained adverse effects from high dose iodine exposure.

Dr. Parkin asked for any comments or revisions to the recommendations, and none were offered. She then proceeded through the HSRB Detailed Recommendations and Rationale. A participant suggested that the quoted phrase be modified to include hyphens: "Student-Newman-Keuls." There were no further edits suggested within the Science section. Mr. Downing affirmed that he would check pagination when he prepares the final version of the HSRB report.

Dr. Parkin proceeded through the Ethics section of the HSRB report. Dr. Kyle Galbraith noticed a discrepancy in the spelling of the Fitzsimons Army Medical Center, and the text was corrected.

Dr. Liza Dawson noted that the U.S. Department of Defense (DoD) version of the Common Rule has a different regulatory citation. Drs. Dawson and Galbraith affirmed that the correct citation for DoD's Common Rule is "Title 32 part 219." Dr. Parkin suggested that the citation follow the year that the rule was adopted by the DoD to increase clarity. The changes were made within the HSRB report. Board members offered no additional comments within the Ethics section.

HSRB Work Group on Return of Individual Research Results Report

Dr. Parkin directed the Board members to review the Overview, Discussion and Board Consensus on the HSRB Work Group on Return of Individual Research Results Report section. In response to a question, she clarified that "Appendix A" refers to the appendix of the Work Group Report, which is available on the HSRB website. Hearing no further comments, Dr. Parkin concluded that the Board approved the consensus statement as written.

References and Cover Letter

Dr. Parkin proceeded to the HSRB report references. A participant noted inconsistencies in the journal titles within the reference list. Dr. Parkin asserted that the references would be reviewed for consistency with EPA's traditional format.

Dr. Parkin solicited any revisions or clarifications to the cover letter. She explained that any changes made to the recommendations during the HSRB's deliberations would be reflected in the cover letter. Several Board members noted that their contact information was incorrect in the HSRB report. Mr. Downing asserted that all contact information would be corrected in the final draft. Hearing no additional comments or revision requests to the HSRB report, Dr. Parkin turned the meeting to Mr. Downing.

SUMMARY AND NEXT STEPS

Mr. Downing announced that the next HSRB meeting is scheduled for November 5, 2014. The meeting will be conducted virtually, and further details will be provided in the coming months.

Mr. Downing announced that this is the final meeting for HSRB Chair, Dr. Parkin. He acknowledged her stellar service on the HSRB as a member, Vice Chair and Chair. Mr. Downing said that the Agency is indebted to Dr. Parkin for her service, which started in October 2007. Dr. Parkin's steady guidance of the Board and dutiful service will always be remembered. Mr. Downing also acknowledged the final meeting of Dr. Young. He thanked her for her contributions to the HSRB, noting the particular strength of statistical expertise that she brought to the Board. Mr. Downing explained that EPA staff have commented about the much-improved statistical power of current studies, which is attributable to Dr. Young's input.

Mr. Downing described the new compensation system for the HSRB members. He requested that all members submit their time sheets every 2 weeks to Ms. Lu-Ann Kleibacker (EPA). In response to a question, Mr. Downing agreed to distribute a calendar of time sheet deadlines through the end of the year.

ADJOURNMENT

Dr. Parkin thanked the Board members for their participation. The teleconference/ webinar meeting was adjourned by Mr. Downing at 3:30 p.m.

Respectfully submitted:

Jim Downing
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:

Rebecca Parkin, Ph.D., M.P.H.
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public teleconference/webinar meeting reflect diverse ideas and suggestions offered by Board members during the course of deliberations within the meeting. Such ideas, suggestions and deliberations do not necessarily reflect definitive consensus advice from the Board members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final report prepared and transmitted to the EPA Science Advisor following the public meeting.

Attachments

Attachment A	HSRB Members
Attachment B	*Federal Register* Notice Announcing Meeting
Attachment C	Meeting Agenda

Attachment A

EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

Rebecca Parkin, Ph.D., M.P.H.
Professorial Lecturer, EOH and
Epidemiology and Biostatistics
Milken Institute School of Public Health
The George Washington University
Washington, D.C.

Vice Chair

Jewell H. Halanych, M.D., M.Sc.
Assistant Professor
Internal Medicine Residency Program
University of Alabama at Birmingham
Montgomery, AL

Members

Liza Dawson, Ph.D.
Research Ethics Team Leader
Division of AIDS, National Institutes of
Health
National Institute of Allergy and Infectious
Diseases
Bethesda, MD

George C.J. Fernandez, Ph.D.
Statistical Training Specialist
SAS Institute, Statistical Training and
Technical Services
Sparks, NV

Kyle L. Galbraith, Ph.D.
Human Subjects Protection
Carle Foundation Hospital
Urbana, IL

Members (continued)

Edward Gbur, Jr., Ph.D.
Professor
Agricultural Statistics Laboratory
University of Arkansas
Fayetteville, AR

Sidney Green, Jr., Ph.D., Fellow, ATS
Retired
Department of Pharmacology
Howard University College of Medicine
Silver Spring, MD

Elizabeth Heitman, Ph.D.
Associate Professor of Medical Ethics
Center for Biomedical Bioethics and Society
Vanderbilt University Medical Center
Nashville, TN

John C. Kissel, Ph.D.
Department of Environmental
and Occupational Health Sciences
School of Public Health
University of Washington
Seattle, WA

Randy Maddalena, Ph.D.
Physical Research Scientist
Indoor Environment
Lawrence Berkeley National Laboratory
Berkeley, CA

William J. Popendorf, Ph.D.
Professor Emeritus
Department of Biology
Utah State University
Logan, UT

Members (continued)

Kenneth Ramos, M.D., Ph.D., Pharm.B.
Associate Vice President
Precision Health Sciences
Professor of Medicine
Arizona Health Sciences Center
Tucson, AZ

Leonard Ritter, Ph.D., ATS
Professor Emeritus (Toxicology)
School of Environmental Sciences
University of Guelph
Guelph, ON, Canada

Linda J. Young, Ph.D.
Chief Mathematical Statistician and Director
USDA National Agricultural Statistics Service
Research and Development Division
Fairfax, VA

Attachment B

FEDERAL REGISTER NOTICE ANNOUNCING MEETING

[*Federal Register* Volume 79, Number 148 (Friday, August 1, 2014)]
[Notices]
[Pages 44769-44771]
From the *Federal Register* Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2014–18221]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2014–0564; FRL-9914–72– ORD]

Human Studies Review Board; Notification of a Public Webinar/Teleconference

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Office of the Science Advisor announces a public Webinar/ teleconference of the Human Studies Review Board (HSRB) to discuss its draft report on the HSRB meeting held August 15, 2014.

DATES: The Webinar/teleconference will be held on Friday, August 15, 2014,

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from approximately 2:00 p.m. to approximately 3:30 p.m. Eastern Time. Comments may be submitted on or before Friday, August 8, 2014. Information regarding the HSRB final meeting report will be found at http://www.epa.gov/osa/hsrb and http://www.regulations.gov or from the persons listed under **FOR FURTHER INFORMATION CONTACT**.

Webcast: This meeting may be webcast. Please refer to the HSRB Web site http://www.epa.gov/osa/hsrb for information on how to access the webcast. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

ADDRESSES: Submit your written comments, identified by Docket ID No. EPA–HQ–ORD–2014–0564, by one of the following methods:

Internet: http://www.regulations.gov: Follow the Web site instructions for submitting comments.

Email: ORD.Docket@epa.gov.

Mail: Environmental Protection Agency, EPA Docket Center EPA/DC, ORD Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

Hand Delivery: The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue NW., Washington,

DC 20460. The Reading Room's hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding Federal holidays. Please call (202) 566–1744 or email the ORD Docket at ord.docket@epa.gov for instructions. Updates to Public Reading Room access are available online at http://www.epa.gov/epahome/dockets.htm.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2014–0564. The Agency's policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or email. The http://www.regulations.gov Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through http://www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comments and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment.
Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Any members of the public who wish to receive further information about this Webinar/Teleconference should contact Jim Downing at telephone number (202) 564–2468; fax (202) 564–2070; email address downing.jim@epa.gov; mailing address Environmental Protection Agency, Office of the Science Advisor, Mail Code 8105R, 1200 Pennsylvania Avenue NW., Washington, DC 20460. General information concerning the HSRB can be found on the EPA Web site at http://www.epa.gov/osa/hsrb.

SUPPLEMENTARY INFORMATION:

Location: The meeting will take place via the Internet and telephone only. Access information can be found on the HSRB Web site: http://www.epa.gov/osa/hsrb/ or by contacting the persons listed under the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

Meeting access: For detailed information on access or services for individuals with disabilities, please contact Jim Downing at least ten business days prior to the meeting using the information under **FOR FURTHER INFORMATION CONTACT**, so that appropriate arrangements can be made.

Procedures for providing public input: Interested members of the public may submit relevant written or oral comments for the HSRB to consider during the advisory process. Additional information concerning submission of relevant written or oral comments is provided in Section I, "Public Meeting," under subsection D, "How may I participate in this meeting?" of this notice.

I. Public Meeting

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of particular interest to persons who conduct or assess human studies, especially studies on substances regulated by the EPA, or to persons who are, or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act. Since other entities may also be interested, the EPA has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I access electronic copies of this document and other related information?

You may use http://www.regulations.gov, or you may access this Federal Register document via the EPA's internet site under the Federal Register listings at http://www.epa.gov/fedrgstr.

Docket: All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at http://www.regulations.gov or in hard copy at the ORD Docket, EPA/DC Public Reading Room. The EPA/DC Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Avenue NW., Washington, DC 20460; its hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time, Monday through Friday, excluding federal holidays. Please call (202) 566–1744, or email the ORD Docket at ord.docket@epa.gov for instructions. Updates regarding the Public Reading Room access are available at http://www.epa.gov/epahome/dockets.htm.

C. What should I consider as I prepare my comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data used that support your views.

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4. Provide specific examples to illustrate your concerns and suggest alternatives.
5. To ensure proper receipt by the EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and Federal Register citation.

D. How may I participate in this meeting?

You may participate by providing comments in this meeting by following the instructions in this section. To ensure proper receipt of your comments by the EPA, it is imperative that you identify Docket ID No. EPA–HQ–ORD– 2014–0564 in the subject line on the first page of your request.

1. *Oral comments.* Requests to present oral comments will be accepted up to and including Friday, August 8, 2014. To the extent that time permits, interested persons who have not preregistered may be permitted by the Chair of the HSRB to present oral comments during the meeting. Each individual or group wishing to make brief oral comments to the HSRB is strongly advised to submit their request (preferably via email) to Jim Downing under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, Friday, August 8, 2014, in order to be included on the meeting agenda and to provide sufficient time for the HSRB Chair and HSRB Designated Federal Official to review the meeting agenda to provide an appropriate public comment period. The request should identify the name of the individual making the presentation and the organization (if any) the individual will represent. Oral comments before the HSRB are generally limited to five minutes per individual or organization. Please note that this includes all individuals appearing either as part of, or on behalf of, an organization. While it is our intent to hear a full range of oral comments on the science and ethics issues under discussion, it is not our intent to permit organizations to expand the time limitations by having numerous individuals sign up separately to speak on their behalf. If additional time is available, further public comments may be possible.

2. *Written comments.* Please submit written comments prior to the meeting. For the HSRB to have the best opportunity to review and consider your comments as it deliberates on its report, you should submit

your comments at least five business days prior to the beginning of this teleconference. If you submit comments after this date, those comments will be provided to the Board members, but you should recognize that the Board members may not have adequate time to consider those comments prior to making a decision. Thus, if you plan to submit written comments, the Agency strongly encourages you to submit such comments no later than noon, Eastern Time, Friday, August 8, 2014. You should submit your comments using the instructions in Section I, under subsection C, "What should I consider as I prepare my comments for the EPA?" In addition, the EPA also requests that persons submitting comments directly to the docket also provide a copy of their comments to Jim Downing listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

E. Background

The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act 5 U.S.C. App. 2 Section 9. The HSRB provides advice, information, and recommendations to the EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) Research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen the EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through the EPA Science Advisor.

1. *Topics for Discussion.* The HSRB will be reviewing its draft report from the June 11, 2014 HSRB meeting. The HSRB may also discuss planning for future HSRB meetings. Background on the June 11, 2014 HSRB meeting can be found at the HSRB Web site: http://www.epa.gov/osa/hsrb. The June 11, 2014 meeting draft report is available. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from regulations.gov and the HSRB Web site at http://www.epa.gov/osa/hsrb. For questions on document availability or if you do not have internet access, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

2. *Meeting minutes and reports.* Minutes of the meeting, summarizing the matters discussed and recommendations, if any, made by the advisory committee regarding such matters, will be released within 90 calendar days of the meeting. Such minutes will be available at http://www.epa.gov/osa/hsrb/ and http://www.regulations.gov. In addition, information regarding the HSRB final meeting report will be found at http://www.epa.gov/osa/hsrb and http://www.regulations.gov or from the persons listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: July 28, 2014.
Robert Kavlock,
Interim Science Advisor.
[FR Doc. 2014–18221 Filed 7–31–14; 8:45 am]
BILLING CODE 6560–50–P

Attachment C

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

Friday, August 15, 2014
2:00 pm - 3:00 pm (Eastern Time)*

HSRB MEETING FOR REVIEW AND APPROVAL OF THE JUNE 11, 2014 HSRB MEETING FINAL REPORT

HSRB WEB SITE http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566 1752
Docket Number: EPA–HQ–ORD–2014-0564

2:00 PM	**Convene Meeting and Identification of Board Members** – Jim Downing (Designated Federal Officer, EPA HSRB, OSA)
2:05 PM*	**Meeting Administrative Procedures** – Jim Downing, DFO
2:10 PM	**Meeting Process** – Rebecca Parkin, Ph.D., MPH (HSRB Chair)
2:15 PM	**Public Comments**
2:20 PM	**Board Discussion and Decision on Final Report** – Rebecca Parkin, Ph.D., MPH (HSRB Chair)

The Board's response to EPA charge questions presented at the June 11, 2014 meeting.

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

Charge to the Board – Science

- Is this study scientifically sound, providing reliable data?
- If so, is this study relevant for quantitative use in support of an assessment of the oral risk of exposure to iodine?

Charge to the Board – Ethics

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

*Note that agenda times are approximate. For further information, please contact the Designated Federal Officer for this meeting, Jim Downing via telephone: (202) 564-2468 or email: downing.jim@epa.gov

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

Charge to the Board – Science

- Is this study scientifically sound, providing reliable data?
- If so, is this study relevant for quantitative use in support of an assessment of the oral risk of exposure to iodine?

Charge to the Board – Ethics

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

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

Charge to the Board – Science

- Is this study scientifically sound, providing reliable data?
- If so, is this study relevant to establish the reversibility of high dose iodine exposure?
- Also, is this study sufficient to establish that there are no sustained adverse effects from high dose iodine exposure?

Charge to the Board – Ethics

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

2:45 PM* **HSRB Work Group on Return of Individual Research Results Report**

2:55 PM* **Summary and Next Steps** – Rebecca Parkin, Ph.D., MPH (HSRB Chair) and Jim Downing (DFO)

3:00 PM* **Adjournment**

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