Draft Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
December 7, 2015 Public Meeting
Docket Number: EPA–HQ–ORD–2015–0588
HSRB Website: www2.epa.gov/osa/human-studies-review-board

Committee Members:	(See EPA HSRB Members—Attachment A)	
Date and Time:	Monday, December 7, 2015, 1:00–2:30 p.m. EST (See *Federal Register* Notice—Attachment B)	
Location:	Via Teleconference and Webinar	
Purpose:	The EPA HSRB provides advice, information and recommendations on issues related to the scientific and ethical aspects of human subjects research.	
Attendees:	Chair:	Liza Dawson, Ph.D.
	Vice Chair:	Edward Gbur, Jr., Ph.D.
	Board Members:	Kyle L. Galbraith, Ph.D. Jewell H. Halanych, M.D., M.Sc. Randy Maddalena, Ph.D. Kenneth Ramos, M.D., Ph.D., Pharm.B. Helen H. Suh, Ph.D. Jun Zhu, Ph.D.
Meeting Summary:	Meeting discussions generally followed the issues and general timing as presented in the Meeting Agenda (see Attachment C), unless noted otherwise.	

Convene Meeting and Identification of Board Members

Mr. Jim Downing (Designated Federal Officer [DFO], HSRB [or Board], Office of the Science Advisor [OSA], EPA [or Agency]) convened the meeting at 1:01 p.m. and conducted the roll call of the HSRB members. As their names were called, all Board members identified themselves and provided their titles and affiliations. A quorum of members was present. Mr. Downing introduced the HSRB Chair, Dr. Liza Dawson, and Vice Chair, Dr. Edward Gbur, Jr.

Meeting Administrative Procedures

Mr. Downing welcomed Board members, EPA colleagues and members of the public. He expressed appreciation on behalf of the Agency for the time and efforts of the Board members in preparing for the meeting deliberations.

Mr. Downing noted that in his role as DFO under the Federal Advisory Committee Act (FACA), he serves as liaison between the HSRB and EPA and is responsible for ensuring that all FACA requirements are met regarding the operations of the HSRB. Also in his role as DFO, he must work with appropriate Agency officials to ensure that all appropriate ethics regulations are satisfied. HSRB members have been briefed on federal conflict-of-interest laws and have completed a standard government financial disclosure report, which has been reviewed to ensure that all ethics requirements are met.

Mr. Downing stated that the purpose of this meeting was to review the decisions made by the Board at the October 19–20, 2015, HSRB meeting and to finalize the Board's draft final report from that meeting for submittal to the EPA Science Advisor and the Agency. Mr. Downing noted that the Board will allow adequate time for public comments. Copies of all meeting materials will be available at

www.regulations.gov under docket number EPA–HQ–ORD–2015–0588, and also available on the HSRB website at www2.epa.gov/osa/human-studies-review-board. Mr. Downing noted that a public comment period was scheduled on the agenda, during which each public remarks should be limited to 5 minutes, and that no individuals had preregistered to provide public comments.

In accordance with FACA requirements, meeting minutes, including a description of the matters discussed and conclusions reached by the Board, will be prepared and must be certified by the meeting Chair within 90 days. The approved minutes will be available at www.regulations.gov and on the HSRB website at www2.epa.gov/osa/human-studies-review-board. The HSRB also will revise the draft final report in response to the Board's discussion. The final report will be available at www.regulations.gov and on the HSRB website at www2.epa.gov/osa/human-studies-review-board.

Public Comments

Mr. Downing called for any comments from the meeting attendees. No public comments were presented to the Board. Mr. Downing then turned the meeting over to Dr. Dawson.

Meeting Process

Dr. Dawson indicated that the Board would discuss the draft final report and ascertain whether any changes were needed. The goal of this meeting's discussion was to ensure that the report reflects accurately what was discussed and the conclusions reached at the October 2015 meeting, as well as to raise any issues that require clarification or a change to the draft final report.

Dr. Dawson had identified issues that might require clarification with regard to the Board's recommendations. These had been communicated in an email to the Board members prior to this meeting. The first issue related to the first study that the Board had reviewed. Comments had been made about the statistical analysis that was performed on the data, and Dr. Dawson wanted to ensure that these comments were reflected accurately in the report. An additional recommendation was made about statistical analyses in future studies of this type. The second issue pertained to positive and negative controls in the second study that the Board had reviewed, including whether references existed in the peer-reviewed literature to support the study design. Questions also had been raised about pregnancy testing.

Dr. Dawson proposed first discussing the Board's recommendations regarding the first study, and then proceeding with the discussion of the Board's recommendations on the second study.

Board Discussion and Decision on the Final Report

Topic 1: A Completed Study from the U.S. Department of Agriculture Describing Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military

Science

Dr. Dawson stated that the statisticians on the Board had indicated that the statistical analysis was not optimal. The researchers had chosen a *t*-distribution to estimate confidence intervals. The Board statisticians recommended instead a generalized linear model (GLiM) as being more robust and appropriate for a study with this type of design. The statisticians had conducted a simulation comparing the *t*-distribution to the GLiM procedure, however, and determined that the conclusions drawn from the data would not have differed significantly had the GLiM been used, but they recommended that a GLiM be used in future studies of this type. Dr. Gbur added that the protocol originally had not described how the data would be analyzed. In the future, protocols should include the model that would be used to analyze the data. Although in this case, a more appropriate analysis would not have reached different conclusions, a precedent of using a *t*-distribution should not be established. All the Board members, including Drs. Suh and Jun Zhu, agreed with the recommendations on statistical analysis as they were stated in the draft final report.

Ms. Maureen Lydon, Human Research Ethics Review Officer, Office of Pesticide Programs (OPP), EPA, proposed a change to the text of page 3, paragraph 4, and sentence 2. No Board members dissented on the proposed change, and "Several of the deviations were minor changes in informed consent procedures" was changed to "There were minor changes in informed consent procedures."

Ms. Lydon also proposed an editorial change to page 3, paragraph 6, and sentence 2. No Board members dissented on the proposed change, and the word "treatment" was added before "ratio."

Ethics

No Board members dissented on the ethics recommendations in the draft final report.

Topic 2: HSRB review of the protocol for Testing of S.C. Johnson & Son, Inc. Personal Tick Repellent Products to Support Use of the EPA Repellency Awareness Graphic

Science

Dr. Dawson indicated that the protocol's provision for positive and negative controls had engendered considerable debate. The draft final report suggested that the scientific rationale for the lack of a positive control should be supported by peer-reviewed literature. Similarly, the adequacy of using an untreated arm as a negative control should be supported by the peer-reviewed literature. Subsequent to the October 2015 meeting, OPP had shared with the Board two studies from the published literature that used different study designs with somewhat differing results. Mr. William Jordan, Deputy Office Director for Programs, OPP, stated that EPA has issued guidelines for conducting laboratory-based tick repellency tests. He noted that the amount of published literature on tick repellency testing is limited because such tests are of greater relevance to the regulatory community than academia. Dr. Dawson replied that EPA's standards for rigor in testing protocols should be as stringent as those of the peer-reviewed literature. Dr. Suh suggested that the Board provide examples of sufficient justification of study design if a protocol is not based on the scientific literature. Dr. Gbur proposed that, in the future, inclusion of citations of other studies with similar design would help the Board review protocols. Dr. Dawson added that if a method other than that of published studies is chosen, a discussion of why the experimental design selected is preferable to that of existing studies should be provided. Such a discussion will help the field evolve. Dr. Kenneth Ramos agreed that standards evolve and asserted that study protocols need to be adjusted as knowledge accumulates. Past use of a particular experimental design, if it is faulty, is not sufficient justification for its continued use. Dr. Gbur observed that statistics evolves as well. Dr. Ramos expressed his surprise at the researchers' reluctance to embrace the improvement to their study design of including additional controls, which would increase the ability to interpret results.

Dr. Ramos clarified the basis for his objection to using an untreated arm for a negative control: Controlling for the vehicle used is needed for a true negative control. Regarding the nature of the negative control, Mr. Jordan responded that EPA is interested in the repellency properties of the entire mixture, rather than isolating the effects of the active ingredient. Dr. Dawson likened the study to field testing an already-approved and marketed product, as opposed to testing for the purpose of product development, when pinpointing the optimal formulation would be a high priority.

Dr. Ramos further clarified that a positive control is needed to account for factors other than the treatment that might affect the migratory behavior of the tick. Dr. Dawson suggested that a positive control could normalize across the variability of tick behavior between days (i.e., batches of "vigorous" vs. "sleepy" ticks). Dr. Randy Maddalena emphasized the need to prove that the tick is still active after being moved from the untreated to the treated arm. Dr. Dawson proposed releasing ticks simultaneously on both arms. Dr. Gbur stated that one of the tick repellency studies measured the time for the tick to begin moving, which might provide data on possible effects on the tick of moving between arms. A participant stated that ticks are "tough," and researchers would have institutional experience with whether moving them might affect their behavior.

The Board agreed to revise this section of its report on positive and negative controls to provide more detail, including (1) a recommendation that the study describe the strengths and weaknesses of previous studies' designs; (2) a request for more justification of why the study design chosen is the best suited for the purpose of the study; and (3) a note that as science continues to evolve, referencing previous studies will not be sufficient. Mr. Downing indicated that when a Board votes to approve a draft final report, the draft final report typically contains all the actual language for the Board's consideration. From the discussion, EPA has sufficient understanding of the Board's intent and waiting until January to finalize the report would not hold up anything. The Board could revise the section on positive and negative controls and vote to approve the revised final report at its next meeting. The Board decided unanimously to postpone voting to approve the draft final report, including the revised section on controls as discussed, until its next scheduled public meeting in January 2016.

Ms. Lydon proposed a change to the text in page 7, paragraph 2, and sentence 5. No Board members dissented on the proposed change, and the Board changed "marketed" to "registered."

Ms. Lydon suggested more accurate language for page 7, paragraph 4, and sentence 4. The Board agreed to change the sentence to read, "The effort to include Hispanic participants will consist of using Spanish-language advertising, using an online Spanish newspaper, and enrolling individuals who are bilingual and English speaking."

Ethics

Dr. Dawson stated that the issue of pregnancy testing had been discussed at length. One Board member had pointed out that the risk of an undetected pregnancy will be greater if pregnancy testing occurs 48 hours before female subjects participate in the study, rather than the day of participation. The study team preferred the 48-hour timing so as not to unduly extend the subjects' time commitment on the day of study participation. Most Board members were of the opinion that 48 hours was not unreasonable, particularly given that the use of the tick repellency product is already registered with no regulatory or safety concerns regarding its use during pregnancy, indicating that exposure to the product during pregnancy is not high risk. One option is to offer a choice of same-day pregnancy testing or 48-hour pregnancy testing with counseling on the steps subjects should take to avoid pregnancy in the interim. The text on page 10, paragraph 2, sentences 1–2, in the draft final report makes such counseling an option rather than a mandate by using "could" instead of "should." Dr. Kyle Galbraith expressed his opinion that based on the Board's previous discussion, the final report should use "should," rather than "could" in the indicated paragraph. He added that 40 C.F.R. 26 subpart L is inflexible in its prohibition against intentional exposure of pregnant women. Dr. Dawson noted that the proposed change would keep the option of conducting pregnancy testing at either time but make counseling mandatory. No Board members dissented on the proposed changes, and the Board changed "could" to "should" in both the first and second sentences.

Summary and Next Steps

Dr. Dawson indicated that she would make the changes to the draft final report that the Board had approved in this meeting. The version of the draft final report that will be circulated before the January 2016 meeting will contain those revisions.

Mr. Downing announced that the next HSRB meeting is scheduled for January 12–13, 2016, and the exact times will be posted in the *Federal Register*.

Adjournment

Mr. Downing thanked the HSRB members for their participation and adjourned the meeting at 2:31 p.m.

Respectfully submitted:

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

Certified to be true by:

Liza Dawson, Ph.D.
Chair
Human Studies Review Board
United States Environmental Protection Agency

NOTE AND DISCLAIMER: The minutes of this public 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.

Attachment A

EPA HUMAN STUDIES REVIEW BOARD MEMBERS

Chair

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

Vice Chair

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

Members

Gary L. Chadwick, Pharm.D., M.P.H., C.I.P.
Senior Consultant
HRP Consulting Group, Inc.
Fairport, NY

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

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

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

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

Members (continued)

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

Suzanne M. Rivera, Ph.D., M.S.W.
Associate Vice President for Research
Case Western Reserve University
Cleveland, OH

Helen H. Suh, Ph.D.
Associate Professor of Health Sciences
Northeastern University
Boston, MA

Jun Zhu, Ph.D.
Professor of Statistics and of Entomology
Department of Statistics
University of Wisconsin–Madison
Madison, WI

Attachment B

FEDERAL REGISTER NOTICE ANNOUNCING MEETING

[*Federal Register* Volume 80, Number 185 (Thursday, September 24, 2015)]
[Notices]
[Pages 57607–57608]
From the *Federal Register* Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2015–24342]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0588; FRL–9934–66–ORD]

Human Studies Review Board; Notification of a Public Meeting

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Office of the Science Advisor announces two separate public meetings of the Human Studies Review Board to advise the Agency on the ethical and scientific reviews of EPA research with human subjects.

DATES: A public virtual meeting will be held on October 19–20, 2015, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time each day. A separate teleconference meeting is planned for Monday, December 7, 2015, from 1:00 p.m. to approximately 2:30 p.m. for the HSRB to finalize its Final Report of the October 19–20, 2015 meeting.

ADDRESSES: Both of these meetings will be conducted entirely on the Internet using Adobe Connect. Registration is required to attend this meeting. Please visit the HSRB Web site: http://www.epa.gov/hsrb to register.

Comments: Submit your written comments, identified by Docket ID No. EPA–HQ–ORD–2015–0588, by one of the following methods:

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

Email: ORD.Docket@epa.gov.

Mail: The 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 WJC West, at 1301 Constitution Avenue NW, Washington, DC 20460. The 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 on the Web site at: http://www.epa.gov/epahome/dockets.htm.

Instructions: 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 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 comment and with any electronic storage media 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 member of the public who wishes to receive further information should contact Jim Downing on telephone number (202) 564–2468; fax number: (202) 564–2070; email address: downing.jim@epa.gov; or mailing address Environmental Protection Agency, Office of the Science Advisor, Mail code 8105R, 1200 Pennsylvania Avenue NW., Washington, DC 20460. General information concerning the EPA HSRB can be found on the EPA Web site at: http://www.epa.gov/hsrb.

SUPPLEMENTARY INFORMATION:

Meeting access: Access to these Internet meetings are open to all by following the information provided above.

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 Notice 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. This notice might also be of special interest to participants of studies involving human subjects, or representatives of study participants or experts on community engagement. The Agency has not attempted to describe all the specific entities that may have interest in human subjects research. If you have any questions regarding this notice, consult Jim Downing listed under **FOR FURTHER INFORMATION CONTACT.**

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

In addition to using regulations.gov, you may access this **Federal Register** document electronically through the EPA Internet 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 in http://www.regulations.gov or in hard copy at the ORD Docket, EPA Docket Center, in the Public Reading Room. The Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA WJC West, at 1301 Constitution Avenue NW, Washington, DC 20460. The 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.

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Updates to Public Reading Room access are available on the Web site (http://www.epa.gov/epahome/dockets.htm). The Agency's position paper(s), charge/questions to the HSRB, and the meeting agenda will be available by early October 2015. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and other related documents that are available electronically, from the regulations.gov Web site and the EPA HSRB Web site at http://www.epa.gov/hsrb/. For questions on document availability, or if you do not have access to the Internet, consult Jim Downing listed under **FOR FURTHER INFORMATION.**

C. What should I consider as I prepare my comments for the 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 that you used to support your views.
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 in these meetings by following the instructions in this section. To ensure proper receipt by the EPA, it is imperative that you identify Docket ID number EPA–HQ–ORD–2015–0588 in the subject line on the first page of your request.

1. *Oral comments.* Requests to present oral comments during either conference call will be accepted up to Noon Eastern Time on Wednesday, October 14, 2015, for the October 19–20 meeting and up to Noon Eastern Time on Wednesday, December 2, 2015, for the December 7, 2015 conference call. To the extent that time permits, interested persons who have not pre-registered may be permitted by the Chair of the HSRB to present oral comments during either call. Individuals or groups wishing to make brief oral comments to the HSRB on October 19 or 20, 2015, are strongly advised to submit their request (preferably via email) to Jim Downing, listed under **FOR FURTHER INFORMATION CONTACT** no later than noon, Eastern Time, Wednesday, October 14, 2015, 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. Individuals or groups wishing to make brief oral comments to the HSRB during the December 7, 2015 teleconference should submit their request by Noon Eastern Time on Wednesday, December 2, 2015. 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.* Submit your written comments prior to the meetings. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments by Noon Eastern Time on Wednesday, October 14, 2015, for the October 19–20 meeting, and by noon Eastern Time on Wednesday, December 2, 2015, for the December 7, 2015 teleconference. If you submit comments after these dates, those comments will be provided to the HSRB members, but you should recognize that the HSRB members may not have adequate time to consider your comments prior to their discussion. 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 agency 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 § 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 EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through the Agency's Science Advisor.

1. *Topics for discussion.* On Monday, October 19, 2015, EPA's Human Studies Review Board will consider scientific and ethical issues surrounding: A completed study from the U.S. Department of Agriculture Describing Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military. At the continuation of the October meeting on Tuesday, October 20, 2015, EPA's Human Studies Review Board will consider scientific and ethical issues surrounding: Protocol for Testing of S.C. Johnson Personal Tick Repellent Products to Support Use of EPA Repellency Awareness Graphic.

2. Then on Monday, December 7, 2015 the HSRB will finalize its Final Report for the October 19–20, 2015 meeting.

2. *Meeting minutes and reports.* Minutes of these meetings, 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's final meeting report, will be found at http://www.epa.gov/osa/hsrb/ or from the person listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: September 17, 2015.
Thomas A. Burke,
EPA Science Advisor.
[FR Doc. 2015–24342 Filed 9–23–15; 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

Monday, December 7, 2015
1:00 p.m. – 2:30 p.m. (Eastern Time)*

HSRB MEETING FOR REVIEW AND APPROVAL OF THE OCTOBER 19–20, 2015 HSRB MEETING FINAL REPORT

HSRB WEB SITE http://www.epa.gov/osa/hsrb/
Docket Telephone: (202) 566-1752
Docket Number: EPA–HQ–ORD–2015-0588

Meeting location via telephone/Internet only
Dial in number 866-299-3188; conference code 2025647189
https://epa.connectsolutions.com/hsrb

12:50 p.m. **HSRB members log in online and call in on the phone**

1:00 p.m. **Convene Meeting and Identification of Board Members**—Jim Downing (Designated Federal Officer, EPA HSRB)
1:05 p.m.* **Meeting Administrative Procedures**—Jim Downing, DFO
1:10 p.m. **Meeting Process—**Liza Dawson, Ph.D. (HSRB Chair)
1:15 p.m. **Public Comments**
1:20 p.m. **Board Discussion and Decision on Final Report—**Liza Dawson, Ph.D. (HSRB Chair)

The Board's response to EPA charge questions presented at the October 19–20, 2015 meeting.

Topic 1:

A Completed Study from the U.S. Department of Agriculture Describing Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military

Science

Charge to the Board:

Is the research reported in the completed study sufficiently sound, from a scientific perspective, to be used to evaluate the bite protection level of etofenprox-treated military clothing?

*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.

Ethics

Charge to the Board:

Does available information support a determination that the **Completed Study from the U.S. Department of Agriculture Describing Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military** was conducted in substantial compliance with subparts K and L of 40 CFR Part 26?

Topic 2:

HSRB review of the protocol for Testing of S.C. Johnson & Son, Inc. Personal Tick Repellent Products to Support Use of the EPA Repellency Awareness Graphic

Science

Charge to the Board

Is the protocol **Testing of S.C. Johnson & Son, Inc. Personal Tick Repellent Products to Support Use of the EPA Repellency Awareness Graphic** likely to generate scientifically reliable data, useful for estimating the complete protection time of various EPA-registered S.C. Johnson skin-applied repellents in laboratory studies using three species of tick populations?

Ethics

Charge to the Board

Is the research described in the protocol "Testing of S.C. Johnson Personal Tick Repellent Products to Support Their Use of the EPA Repellency Awareness Graphic" likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

2:25 p.m.* Summary and Next Steps—Liza Dawson, Ph.D. (HSRB Chair) and Jim Downing (DFO)

2:30 p.m.* Adjournment

*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.