Minutes of the
United States Environmental Protection Agency (EPA)
Human Studies Review Board (HSRB)
December 13, 2016, Public Meeting
HSRB Website: www.epa.gov/osa/human-studies-review-board

Committee Members:	(See EPA HSRB Members List—Attachment A)	
Date and Time:	Tuesday, December 13, 2016, 2:00–4:00 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:		Jennifer Cavallari, Sc.D., CIH Gary Chadwick, Pharm.D., M.P.H., CIP Alesia Ferguson, Ph.D. Kyle L. Galbraith, Ph.D. Jewell H. Halanych, M.D., M.Sc. Walter T. Klimecki, D.V.M., Ph.D. Randy Maddalena, Ph.D. Suzanne M. Rivera, Ph.D., M.S.W. Jun Zhu, Ph.D.
	Consultant to the Board: Kendra L. Lawrence, Ph.D., BCE, PMP	
Meeting Summary:	Meeting discussions generally followed the issues and timing as presented in the Meeting Agenda unless noted otherwise.	

Introduction of Board Members and Convening of the Public Meeting

Mr. Jim Downing, Designated Federal Officer (DFO), HSRB (or Board), Office of the Science Advisor, EPA (or Agency), convened the meeting at 2:00 p.m. and welcomed Board members, EPA colleagues and members of the public. Mr. Downing conducted a roll call of the Board members, then asked the members to introduce themselves, providing their names, affiliations and areas of expertise. This meeting will be a review and discussion of the topic, Mosquito Repellency Testing, and will finalize the report from the October 19–20, 2016 meeting. Mr. Downing expressed the Agency's appreciation to the Board members for their time and efforts preparing for the meeting, and for their deliberations in developing the final report.

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 provisions are met regarding the operations of the HSRB. One of his critical responsibilities is to work with appropriate Agency officials to ensure that all appropriate ethics regulations are satisfied. HSRB members were briefed on provisions of the federal ethics and conflict-of-interest laws and have completed

government financial disclosure reports, which have been reviewed to ensure that all ethics requirements are satisfied.

Mr. Downing informed the Board members that they would review the final report from the October 2016 meeting and finalize the report for submission to the Science Advisor and to the Agency. He noted that agenda times are approximate and that adequate time will be allowed for Agency presentations, public comments and the Board's deliberations. Mr. Downing also told the audience that the public would be allowed to comment at the appropriate time, and that public comments should be limited to 5 minutes. He noted that no individuals had pre-registered to provide public comments.

In accordance with FACA requirements, meeting minutes, including a description of the matters discussed and decisions reached by the Board, will be prepared and must be certified by the meeting Chair within 90 calendar days. The approved minutes will be available on the HSRB website.

Meeting Administrative Procedures

Because this meeting was conducted as a teleconference, Mr. Downing reminded participants to keep their telephones on mute when not speaking and, when speaking, to unmute their phones and identify themselves by name. The mosquito repellency testing presentation and the Final Report, he added, would be displayed via the Web conferencing site as the Board worked through the documents. Mr. Downing turned the meeting over to Dr. Ed Gbur, HSRB Vice Chair, to discuss the meeting process. The HSRB Chair, Dr. Liza Dawson was delayed in attending the meeting.

Meeting Process

Dr. Dawson, HSRB Chair, assumed charge of the meeting from the Vice Chair. She described the process for the meeting and noted the two items on the agenda: Board Discussion and Recommendations on Mosquito Repellency Testing; and Board Discussion and Decision on the October 19–20, 2016 Final Report. The Board was provided with the Background Paper from the Office of Pesticide Programs (OPP), EPA, on mosquito repellency testing and the draft HSRB October 2016 Final Report prior to the meeting. OPP will present their proposal and HSRB science and ethics discussants will present their comments, which will be followed by a Board discussion; recommendations will be formalized for EPA. Following will be a review of the HSRB October 2016 Final Report to address any substantive content issues. Editorial changes can be noted, but will not be discussed at this meeting. Dr. Dawson reviewed the guidelines for participation in the virtual meeting. She asked members to use the hand-raising feature to request to speak and the approval/disapproval feature for voting.

Topic: Mosquito Repellency Testing

Dr. Dawson described OPP's internal draft proposal to the HSRB on testing insect repellency in field studies. The Board has reviewed these types of studies previously, but new information on the Zika virus has prompted EPA to request further review of the topic. Mr. Downing introduced Michelle Arling, the new Ethics Reviewer in OPP, to present EPA's proposal. Ms. Arling pointed out that OPP's Registration Division handles the Agency's repellency testing issues and that members of its staff will join her for the presentation. They will present background information and provide an overview of the mosquito repellency testing process.

Dr. Eric Bohnenblust, OPP, provided a background for EPA's new concerns on field testing. Given the increased attention to the hazards associated with the Zika virus and the ramifications it could have on repellency field testing, EPA has thought to engage in conducting an assessment of the field testing process to address questions registrants may have regarding protocols. The HSRB has been asked

to provide recommendations on how best to address these issues. He then detailed EPA's requirements for mosquito repellency testing. The Agency, under the Federal Insecticide, Fungicide and Rodenticide Act, requires data to support efficacy of pesticide products against public health pests (e.g., mosquitoes and ticks) to ensure consumer safety in the use of these products. Mosquito repellents are the primary products that involve human subjects, and the HSRB reviews the completed studies and product testing protocols. EPA requires field testing for skin-applied repellents as it more closely aligns with real-world conditions and is the best method to demonstrate efficacy in those products. Arm-and-cage laboratory testing is the required method for fabric-treated clothing (e.g., permethrin-treated military uniforms). Dr. Bohnenblust noted that with skin-applied repellents, efficacy is measured by landing with intent to bite, which is quantified as protection time.

To raise public awareness to the health protectiveness of mosquito and tick repellents applied to the skin, EPA developed the Repellency Awareness Program and Repellency Awareness Graphic. Product labeling through this graphic clearly communicates to the consumer the estimated number of hours mosquitoes or ticks are repelled by the product. Dr. Bohnenblust highlighted the differences between laboratory and field studies. Laboratory studies are conducted on treated fabrics in a controlled laboratory setting utilizing caged, disease-free, laboratory-bred mosquitos. Efficacy is measured by the number of bites a human subject receives, and bite protection is the endpoint measure. Field studies are performed for skin-applied repellents (e.g., N,N-diethyl-meta-toluamide, or DEET) and spatial repellents worn by people (e.g., clip-on products) utilizing wild-bred mosquitos (e.g., mosquito pressure in the field). Efficacy is measured by the number of landings with intent to bite a human subject receives, and the endpoint measure is protection time.

Dr. Bohnenblust discussed EPA's concern for the Zika virus and transmission risks in mosquito repellency field studies and provided the science viewpoints. The local mosquito-borne Zika virus transmission reports in the continental United States, mostly due to the *Aedes* species mosquito, is a public health concern. The risks to subjects of contracting the Zika virus while participating in mosquito repellency field studies is a concern to the public and is one that EPA should address. He reiterated EPA's stance that field testing for skin-applied repellents represents the real-world conditions and provides the highest level of confidence that the efficacy claim on the product label is accurate. Dr. Bohnenblust emphasized the need to rely on field tests for efficacy testing and determination of protection time because EPA does not have a validated laboratory protocol by which results can be translated to reliable field efficacy protection time. EPA recognizes the need to balance the requirement for performing field testing with the risks of contracting the Zika virus, which include taking necessary precautions such as limiting testing to locations that do not have *Aedes* species mosquito populations and acquiring data on vector-borne diseases.

Ms. Arling presented EPA's ethics viewpoints. Given the increased awareness to the hazards of contracting the Zika virus in the United States, EPA is evaluating the public health benefits of conducting efficacy testing in human subjects with the potential health risks to those subjects for contracting the Zika virus. To address this issue, the Agency will incorporate adequate controls (e.g., exclusion criteria and consent forms) into future study protocols to provide participants with adequate information about the risks of Zika virus to allow for informed consent.

EPA proposes the following questions to the HSRB:

1. Does the HSRB agree with OPP's proposed approach from both the scientific and ethical perspectives?
2. Are there additional issues the Agency should consider?

Public Comments

Mr. Downing indicated that no requests to provide public comments had been received by EPA in advance of the meeting. Dr. Dawson then called for comments from members of the public participating via teleconference. Hearing none, Dr. Dawson proceeded to the next item on the agenda: Board discussion and recommendations on mosquito repellency testing.

Board Discussion and Recommendations on Mosquito Repellency Testing

Science Discussant

Dr. Dawson asked science discussant Dr. Kendra Lawrence to provide her comments. Dr. Lawrence noted that OPP in its proposal stated that the Zika virus in natural *Aedes* species mosquito populations was in limited distribution within the United States, substantial monitoring efforts are ongoing, and the measurement endpoint in repellent studies is mosquito landings and not bites. She pointed out the existing efforts of the OPP to provide guidance for conducting mosquito repellency field studies that ensure minimal risks to the participants. After clearly stating in its proposal that the risk of subjects contracting the Zika virus in repellent field studies is low and could be avoided by testing in areas where the Zika virus has not been detected in the local mosquito population, Dr. Lawrence questioned the scientific basis for OPP to propose additional participant exclusion criteria, OPP Limitation 2, as a limitation on performing field studies. Suggesting that male study participants who plan on becoming fathers and women who intend to become pregnant be excluded from the study is too restrictive, and obtaining representative enrollments of the local populations would be challenging, especially given the percentages of unplanned pregnancies. These criteria do not align with the Centers for Disease Control and Prevention (CDC) recommendations for Zika virus prevention. Some other options to consider for enrolling participants include imposing travel restrictions to endemic countries, similar to CDC's guidelines, and including details on the consent form regarding allowable activities during the study (e.g., sexual).

Dr. Lawrence agreed that field testing is the most appropriate and effective means of providing accurate data for repellency testing and for ensuring consumer safety. However, the details regarding ongoing monitoring for Zika transmission and the responsibility of the study sponsor in these iterations are unclear. She recommended including in OPP Limitation 1 that the risk would be low if field tests were conducted in areas where no competent vectors to the Zika virus are present. Dr. Lawrence explained that "OPPTS 810.3700: Insect Repellents to be Applied to Human Skin" provides the necessary guidance to study sponsors on monitoring testing sites for vector-bone diseases, which would include monitoring for the Zika virus; she suggested that OPP reevaluate making any additional changes.

Ethics Discussant

Dr. Dawson asked ethics discussant Dr. Suzanne Rivera to provide her comments. Dr. Rivera agreed with EPA and Dr. Lawrence regarding the need to continue field testing of skin repellents, as it represents the real-world scenario. Protection from pathogens that can be contracted from insect bites is an important public health issue. The efforts of EPA and the HSRB are ongoing to evaluate the risks-to health-benefit ratio and the ethical considerations for performing human subjects research. The benefit of knowing how well these products work and under what conditions can justify exposing participants to some risk. EPA has the responsibility to mitigate these risks as much as possible.

Without prior knowledge or review of current guidelines, Dr. Rivera could not determine whether the increased confirmations and documentations of Zika virus transmissions for the study sponsors in OPP Limitation 1 were justified. She suggested that this question would be best addressed in the scientific assessments. OPP's proposal did not include information on geographic locations to avoid when

conducting field testing. Maps are readily available on the Internet that depict Zika cautionary areas of travel; these areas will be high-risk areas for field testing. Regarding OPP Limitation 2, the reference to participants who "intend" to become pregnant should be removed from the exclusion criteria, given the high unintended pregnancy rates in the United States. She suggested establishing criteria for Zika virus transmissions and pregnancy risks during field testing that was similar to the guidance used in other products that pose risks to pregnancy. For example, EPA could make it a requirement to use two methods of birth control and it also would be the participant's responsibility to use extra precautions.

Dr. Dawson solicited comments on the science and ethics assessments from the Board members.

An HSRB member pointed out the exclusivity of OPP's proposal to concentrate on the Zika virus in isolation from other vector-borne diseases and suggested establishing an integrated plan (e.g., arbor virus focus team) or long-term strategy to assess and manage these types of risks versus focusing on the current hot topic. The potential exists for participants to contract these diseases after the study and considerations should be given to performing post-study surveillance tests. The protocol could include antibody titer testing at the end of the study.

A consultant to the HSRB pointed out that OPP's current guidance of performing weekly testing 1 month prior to the field site being used has adequately minimized risks to vector-borne diseases. Imposing limitations to conduct studies in locales where no virus or competent vectors present have been detected should preclude having additional participant exclusion criteria. Any update to EPA guidance on repellency field testing should address all potential risks.

The HSRB Chair asked about testing the efficacy of repellency products against mosquito species of competent vectors and whether similar species would have the same response. An HSRB consultant responded that there is no evidence to suggest a species-specific response to repellents. The repellency awareness graphic will indicate a protection from mosquitos, not a species of mosquito, to suggest that EPA is already collecting these data.

One HSRB member observed that OPP's proposal indicated a discussion of the generic topic and asked whether the HSRB should give EPA a generic response that would include referring study sponsors to the CDC for general information on vector-borne diseases and provide specific recommendations for the Zika virus. The HSRB Chair clarified that the proposal is asking for a general response with specific recommendations on the Zika virus.

Regarding EPA not having a validated laboratory protocol for which results can be translated to reliable field efficacy protection time, an HSRB member wondered whether EPA had consulted with expert laboratories to develop a repellent efficacy test that could model the field test. An HSRB consultant agreed that a validated test might be feasible, but deciding on who would assume the cost for assay development would be an issue to resolve. In addition, the mosquito population diversity would have to be reconciled; the availability of different species of laboratory-bred mosquitos could be a limiting factor. EPA replied that the Agency has considered the possibility of having a validated laboratory protocol that recapitulates the field test, but there are not many promising contenders in the pipeline. Laboratories in the academic settings have protocols for laboratory testing, but their protocols have not been validated against a field study. Regarding cost, EPA explained that the company registering the repellent would be responsible for assay development.

One HSRB member emphasized that if field testing were not justified, then ethically, cost levied to the sponsor would have no ceiling; however, if the HSRB is affirming with EPA that field testing of skin repellents is justified, then EPA is expecting the added risks due to the Zika virus to be evaluated. This would fall into the category of mitigating the new known risk to the research. Providing advice on pregnancy risks should be included in the HSRB's recommendations.

The HSRB Chair posed a question to the members: If field testing is needed and is ethically permissible, what are the conditions that should be placed on the field testing?

An HSRB consultant agreed that field testing is needed and ethical, but there is no scientific basis for the study sponsor to confirm and document 48 hours prior to each testing day that Zika virus has not been detected, when the monitoring guidelines are provided in EPA OPPTS 810.3700. In addition, counseling on safe sex should be included in the criteria for pregnancy risks from exposure to the Zika virus.

Another HSRB member agreed that field testing is needed and ethical, and noted that the Zika virus is sexually transmitted, which is different from the other vector-borne diseases. A specialized blue ribbon task force to monitor the ongoing hazards to field test subjects is what is needed, one HSRB member added.

The HSRB Chair offered that the focus should be on identifying the depth and breadth of the evidence that local transmissions of Zika or other pathogens are not present. The justification for conducting field studies, in general, is that local vector-borne disease transmissions through mosquito bites should be nonexistent per the most recent data. In summary, Board members agree with EPA that field testing is needed, the public health imperative should be addressed, and field studies should be conducted in locations of non-active transmissions. More details on the monitoring schedules and data required to confirm that there is no disease transmission are needed. Given that the locations are free of disease transmission, are precautionary measures still needed? A contingency plan should be in place to address concerns that might arise after the study ends and new data are presented.

Dr. Dawson solicited new comments on the distilled deliberations thus far from the Board members.

Noting that the precaution regarding the Zika virus is related to the sexual transmission of the virus, one HSRB member suggested that this fact be clearly stated in the participant exclusion criteria. Protected sex, dual-barrier and time-based relations are secondary precautions and if participants discover that they or their partners are pregnant after the study has ended and before the precautionary time period expires, then participants should contact the study sponsor for disease testing.

The HSRB Chair commented that the field studies have the advantage of being short duration, which limits the risk to exposure, and any outbreaks that occur after the study ends would entail contacting participants for testing. No other mitigations would be needed if participants tested negative.

An HSRB member asked whether the risks to study participants of contracting the Zika virus would be different than the risks to residents in the same geographical location as the field testing. An HSRB consultant added that residents exploring the outdoors would be at a higher risk than study participants, whose exposure will be confined to a small area of exposed skin in the backdrop of full outer skin protection from the environment. The measured endpoint in these studies is landing with intent to bite. Human subjects do not receive bites.

EPA agreed that residents could be at a higher risk than study participants, but emphasized that the study sponsor has the responsibility of ensuring that risks are appropriately mitigated.

One HSRB member asked about the cost of performing Zika antibody titer testing and the information that could be conferred from the results. If feasible, performing these tests at the study end would offset the need for long-term monitoring. The HSRB Chair clarified that previous comments regarding antibody testing were not referring to continuous monitoring but for cause testing after evidence emerges of a Zika virus population near the field test site. The associated cost is not known, but can be

obtained from laboratories that provide this service. This practice is one EPA could consider requiring for any vector-borne disease outbreak, considering the constantly changing epidemiology. An HSRB member added that whether the HSRB has the expertise to make these types of decisions is something for EPA to evaluate. These decisions are best addressed by those engaged in the disease biology, clinical care and epidemiological aspects of vector-borne diseases.

Due to time restraints, Dr. Dawson suggested that the HSRB defer giving formal recommendations to EPA until the January 2017 meeting. Mr. Downing agreed and asked OPP staff for their comments. Dr. Bohnenblust suggested that the HSRB provide the best ideas on measures that could be implemented early on. The Agency does not anticipate reviewing any new studies before the next HSRB meeting.

Hearing no further comments, Dr. Dawson called for a vote to defer formal recommendations on mosquito repellency testing to the January 2017 meeting. The HSRB unanimously approved deferring formal recommendations to the January 2017 meeting. Dr. Dawson will circulate a draft working outline of the deliberations to members for comments before the next meeting.

Board Discussion and Decision on October 19-20, 2016 Final Report

Dr. Dawson called for final approval of the Report, pending minor editorial corrections and incorporation of clarifications on unrelated adverse events and whole-body dosimeter precautions. The Board approved the report (nine affirmed and one abstained).

Mr. Downing noted that the Report would be finalized by the next day and posted on the HSRB website. The Report also would be transmitted to the EPA Science Advisor and to OPP.

Adjournment

Dr. Dawson thanked the Board members for their efforts and turned the meeting over to Mr. Downing.

Mr. Downing announced that the next HSRB meeting is scheduled for January 25–26, 2017. Notification of the final schedule will be posted on the HSRB website[1] and published in the *Federal Register.*

Mr. Downing thanked the Board members once again for their contributions to the Final Report, and adjourned the meeting at 3:48 p.m. EST.

[1] The HSRB website is available at www.epa.gov/osa/human-studies-review-board.

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

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Professor of Statistics
Director, Agricultural Statistics Laboratory
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George C.J. Fernandez, Ph.D.
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Randy Maddalena, Ph.D.
Physical Research Scientist
Indoor Environment Group
Lawrence Berkeley National Laboratory
Berkeley, CA

Members (continued)

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

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

Consultant to the Board

Kendra L. Lawrence, Ph.D., BCE, PMP
Health Sciences Product Manager
U.S. Army Medical Materiel Development Activity
Fort Detrick, MD

Attachment B

***FEDERAL REGISTER* NOTICE ANNOUNCING MEETING**

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-9953-70-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, 2016, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time each day. A separate, subsequent teleconference meeting is planned for Tuesday, December 13, 2016, from 2:00 p.m. to approximately 3:30 p.m. for the HSRB to finalize its Final Report of the October 19-20, 2016 meeting.

ADDRESSES: Both of these meetings will be conducted entirely by telephone and on the Internet using Adobe Connect. For detailed access information visit the HSRB Web site: http://www2.epa.gov/osa/human-studies-review-board.

Comments: Submit your written comments, identified by Docket ID No. EPA–FRDOC–2016–0001, 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.

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?

The HSRB encourages the public's input. 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 FRL-9953-70-ORD 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 12, 2016, for the October 19-20, 2016 meeting and up to Noon Eastern Time on Thursday, December 8, 2016 for the December 13, 2016 conference call. To the extent that time permits, interested persons who have not pre-registered may be permitted by the HSRB Chair to present oral comments during either call at the designated time on the agenda. Oral comments before the HSRB are generally limited to five minutes per individual or organization. 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 12, 2016, for the October 19-20, 2016 conference call, and by noon Eastern Time on Thursday, December 8, 2016 for the December 13, 2016 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 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 Wednesday, October 19, 2016, EPA's Human Studies Review Board will consider a Protocol for Laboratory Evaluation of Mosquito Bite Protection from Permethrin-treated Clothing for the U.S. Army after 0, 20 and/or 50 washings. On Thursday, October 20, 2016 the HSRB will consider: A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of Two Solid Formulations Containing an Antimicrobial. Meeting materials for these two topics will be available in advance of the meeting at http://www2.epa.gov/osa/human-studies-review-board.

2. Then on Tuesday, December 13, 2016, the Human Studies Review Board will review and finalize their draft Final Report from the October 19-20, 2016 meeting. The draft report will be available prior to the conference call at http://www2.epa.gov/osa/human-studies-review-board.

3. *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: October 4, 2016.

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EPA Science Advisor.

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