EPA Human Studies Review Board (HSRB)

January 26, 2021 Meeting Minutes

Committee Members: (See EPA HSRB Members List – Attachment A)

Date and Time: Tuesday, January 26, 2021, 1:00 to 5:30 pm EST.

Locations: Via teleconference and webinar

Purpose: The HSRB provides advice, information and recommendations on issues related to scientific and ethical aspects of human subjects research.

Meeting was called to order at 1:00 p.m.by Tom O'Farrell, designated federal official (DFO) for the HSRB. Roll was taken and the following members and observers were present:

HSRB members	EPA staff members
Jennifer Cavallari, Sc.D. (Chair) Alesia Ferguson, Ph.D., (Vice-Chair) Philip Day, Ph.D. Thomas Lewandowski, Ph.D. Mark Aulisio, Ph.D. Janice Britt, Ph.D. AJ Allen, Ph.D., M.D. Ann Um, Ed.D. Lisa Corey, Ph.D. Lindsay McNair, M.D. George Milliken, Ph.D. Julia Sharp, Ph.D. Kendra Lawrence, Ph.D. (consultant)	Michelle Arling (EPA, OPP) Clara Fuentes, Ph.D. (EPA, OPP) Helen Hull-Sanders, Ph.D. (EPA, OPP) Virna Stillwaugh, Ph.D. (EPA, OPP) Shannon Borges (EPA, OPP) Ralph Narain (EPA, OPP) Tom O'Farrell (EPA, OSAPE)
Members of the public, representatives of research sponsor and research team Vanessa Chen-Hussey (ARCTEC) Robert Jones (ARTEC) Kristen Healy (Louisiana State Univ.)	

Dr. Tom O'Farrell provided an introduction to the meeting and outlined the Federal Advisory Committee Act (FACA) procedures and took role of the meeting participants. Dr. O'Farrell introduced new Board member Dr. Philip Day.

Ms. Michelle Arling gave an update on the wand spray study that the HSRB reviewed in the July 2020 meeting and said that the electrostatic spray portion of study has been completed. The HSRB will be reviewing this completed study, perhaps in the October 2021 meeting.

The Board reviewed one protocol during the session on January 26, 2021, "Protocol for field evaluation of two topically applied insect repellent products containing IR3535 against mosquitoes in Louisiana," sponsored by LivFul Incorporated.

The Agency's scientific review of this study was presented by Drs. Clara Fuentes and Helen Hull-Sanders of EPA's Office of Pesticide Programs (OPP). Dr. Hull-Sanders presented first. Louisiana State University, on behalf of LivFul Inc, submitted two versions of a mosquito repellent field testing protocol to determine the complete protection time (CPT) of two skin applied repellent products, Akiva 20 lotion and Akiva 20 wipes, containing a concentration of 20% of the active ingredient IR3535. The registrant previously submitted a similar protocol for field testing of IR3535 containing products in Florida. The HSRB reviewed the protocol in July 2017 and the completed study in October 2019. The first Florida site had adequate landing pressure and the CPT was calculated as 13 hours for the wipes and 14 hours for the lotion. The second Florida site had inconsistent landing pressure and the CPT from the second Florida site supported approximately three hours. The purpose of the proposed study is to replace the data from one Florida site, where the data were insufficient to support the protection time for more than three hours due to low landing pressure from predominantly *Culex* mosquito species. The testing design has subjects participate in a single day test for each product. The testing will be conducted in Louisiana with 13 treated subjects per product with two untreated control subjects per product with an approximate 50:50 ratio of males and females to be tested. CPT is estimated for each product at each site, and the guidance recommends selecting the most conservative CPT, at either site, rounded down to the nearest integer for product labeling.

Dr. Fuentes continued the presentation. The objective of this study is to evaluate the CPT of the proposed repellent in preventing mosquitoes from landing on humans and combine data from this study with data from a previous study conducted in Florida. Current acceptable Florida data support CPTs of 14 hours for lotion and 13 hours for the wipes formulation. The NOAEL for sub-chronic dermal toxicity is above 3000 mg/kg per day in rats from a 90 day dermal study. The NOAEL for sub-chronic oral toxicity is 2,600 mg/kg per day in rats from a four week oral study. The NOAEL for maternal developmental toxicity is 600 mg/kg, per day in rats. IR3535 is not mutagenic or genotoxic and the calculated margin of exposure or MOE is above 100. The products, both the wipe and the lotion, will be applied at a standard rate of one mg per 600 cm^2 of a skin surface area. The rate of application will be randomly applied to either the right or the left lower leg from ankle to knee by a technician using the single gloved finger. The product will be applied to the subject in the laboratory prior to transport to the field site and two hours in advance of the test initiation in the field. The test sites will be selected from locations in Louisiana. Selection will be based on the presence and activity of mosquitoes of public health importance within the genera *Aedes*, *Anopheles*, and *Culex*, and the absence of mosquito borne diseases. Untreated control subjects will monitor landing pressure throughout the test. Test subjects will expose treated skin at 30 minute intervals for five minutes; therefore, each interval will consist of a five minute exposure followed by a 25 minute rest period. The First Confirmed Landing is defined as a landing followed by another landing withing 30 minutes. CPT is defined as the time between application and the First Confirmed Landing. The sample size is 13 test

subjects. Having seven subjects experiencing the complete protection time is enough to end the test, so the test will end either by reaching 14 hours from the time of application of the test substance based on the Florida calculation of CPT, or when seven subjects have experienced complete protection time, whichever happens sooner. Subjects ending the test with no complete protection time at the end of the test will be right censored. Data will be analyzed to estimate the median complete protection time of all subjects using the Kaplan-Meier survival analysis. The following elements are adequately addressed in the protocol: experimental design, pre-training of subjects, risk minimization, and the stopping rules. Dr. Hull-Sanders continued the presentation. EPA gave the following recommendations for the study:

1) The protocol should refer to the OCSPP guidelines, 810.3700 specifically, to specify testing response against target mosquito species of human health importance to include in the objective of the study that data will replace the data from one site in Florida.

2) Removing all references to mosquito bites from the protocol and replace them with landings. To describe the procedure for randomly assigning subjects as test, control, or alternate subjects. To describe the procedure for randomly assigning pairs to collection stations in the field. To clarify who will collect mosquitoes from subjects that are paired with staff.

3) To indicate the number of traps per site to assess the mosquito diversity and density prior to testing. To indicate trap collection frequency to assess mosquito activity throughout the proposed testing period of 14 hours. To describe the proposed methods for species identification and pathogen screening.

4) To describe, in detail, the procedure employed to ensure no vector borne disease is present within 25 miles of the planned test site a week before each test day. To have the study director communicate, at least weekly, with the local public health service during the trapping period.

5) Individual applications should be converted to volume using specific gravity of the test substance. The protocol should specify how the amount of product will be dispensed onto the subject's leg, (i.e. by spatula or syringe or directly from the beaker) and specify whether one or multiple technicians will conduct the applications.

6) Raw data collection sheets should be revised to add pertinent information that needs to be recorded. Add explicit criteria for replacing withdrawn subjects and treatment of their data.

7) Data from subjects who withdraw before experiencing complete protection time will be treated as right censored data and subjects should not be replaced.

8) Revision of the protocol language to indicate that exposure periods will not be missed due to low landing pressure. Exposure periods should not be skipped or missed due to low landing pressure. Exposure periods may be skipped or missed due to bad weather.

9) First exposure is delayed for two hours. If a FCL occurs within the first three consecutive exposure periods, it should be considered as zero for statistical purposes. Subjects experiencing first confirmed landings within the first three consecutive exposure periods should not be replaced.

10) The total testing period, including the time of application, should not extend beyond 13 hours for wipes and 14 hours for lotion from the time of product application based on the acceptable data from the Florida testing site.

11) The protocol should include the assumption that the sample size of 13 per product is acceptable for achieving 90% power with a 95% confidence interval and it should include the ratio of LCL_{mCPT}/mCPT as greater than 0.6 for precision, given that the P5MR, which is the complete protection time fifth percentile over the median complete protection time, is greater than 0.5 for variation.

12) The protocol should indicate that the Kaplan-Meier survival curves will be presented in the study report.

13) The proposed standard operating procedures must meet good laboratory practice requirements. A statement of compliance or noncompliance with the 40 CFR part 160 should be included in the protocol, and the assigned representative of independent quality assurance unit must be an independent entity and not the study director.

If amended to address the EPA recommendations, the protocol is likely to yield scientifically reliable information satisfying the following scientific criteria from the framework recommended by the HSRB. It would produce important information that cannot be obtained except from research with human subjects. It has clear scientific objectives and the study design should produce adequate data to achieve those objectives.

The Board asked questions about the science presentation. Dr. Thomas Lewandowksi asked about monitoring a 25 miles radius for vector-borne disease and how that was decided and what diseases would be monitored. He also asked about the use of a finger to apply the product and whether that would be consistent and whether there was any concern from the agency about any residual product left over on the glove. Dr. Hull-Sanders replied that a 25 miles radius for monitoring vector-borne disease has been standard and they are mostly monitoring mosquito vector-borne diseases. She also said EPA is making an assumption that almost all the product is being applied, but can certainly address that question in EPA's comments to the company and the Louisiana State University. Dr. Fuentes added that the test substance will be evenly spread on the skin by one person applying the product with one gloved finger. EPA will want to know whether it is more than one technician applying the product or only one person. In relation to

amount of product lost the gloves during application, Dr. Fuentes said that in previous studies, EPA did not see a correlation between how much was on the glove and the length of CPT. Dr. Hull-Sanders said that EPA can recommend checking for other vector-borne diseases in the area like Lyme Disease. Dr. George Milliken recommended that the protocol be more specific regarding randomization controls for males and females. He was also concerned about having mixed races, ethnicities, and if there is one subject that is of one ethnicity and the others are not, and that one becomes a control, if that is a concern. He also suggested a randomization process for moving subjects to different test stations.

Ms. Arling of EPA OPP reviewed the ethical aspects of the study protocol. The protocol proposes recruiting subjects from the Baton Rouge Louisiana area using email, posters, bulletin boards, newspapers, digital advertising, email, and social media. No individuals under 18 years old or women who are nursing or pregnant will be eligible to enroll in the study. There are criteria to ensure subject safety, such as excluding people who are allergic or sensitive to, or phobic of mosquito bites, or have allergies to the repellent products, or skin disorders that can be exacerbated by exposure to the test substance. Based on their own self-evaluation, subjects will be invited to participate in a consent and screening meeting. When they arrive, their age will be verified and the study staff will provide information orally about the study, including the elements of the study participation, step-by-step. Before the consent form is signed, a member of the study staff will ask each candidate a series of questions to determine whether or not they have adequate comprehension of the materials so that their consent is really informed. The consent form will be reviewed and approved by the IRB prior to use in the study and the consent materials emphasize that participation is voluntary, and subjects are free to withdraw at any time. Subjects will receive $20 for participating in the consent meeting, $40 for participating in the attractiveness testing and aspirator training session, and $10 per hour for participating in the field test. Subjects will be trained to aspirate landing mosquitoes before they probe or bite, and will also wear work clothing, gloves, and head mat to protect untreated areas during the test periods. To minimize the risk of contracting any mosquito-borne diseases during the lab-based part of the test, the cages will be populated with mosquitoes from colony-reared in a lab, that are also screened for vector-borne illnesses. The eligibility criteria and mosquito attractiveness testing will eliminate the participation of people known to have severe reactions to mosquito bites. People who are sensitive to insect repellents and those with open cuts, scrapes, skin disease and skin problems will be excluded. The researchers provided the EPA with the protocol and consent materials that were sent to the IRB, and correspondence to the IRB - Louisiana State University. The IRB is registered with the Office of Human Research Protections, holds a federal-wide assurance, and is independent of the researchers. EPA reviewed the policies and procedures of the IRB and confirmed that they are in line with the requirements of EPA's human studies rule. EPA’s recommendations for the protocol regarding ethics were:

1) to limit the test period to the CBT established during the previous research. In this instance, it would be 14 hours for the wipe and 13 hours for the lotion. Extending beyond these limits would be unethical.
2) to acknowledge COVID-related risks and precautions that will be taken to protect both the subjects and the research staff. The study protocol should still indicate that the

conduct will comply with all federal, state, and local requirements and guidance related to COVID-19 that are in effect at the time of the study. Examples of precautions include conducting consent virtually by video conference, having all staff and subjects wear appropriate face covering, social distancing to the maximum extent possible, contacting subjects before the test day to assess their health and potential exposures to COVID and to determine whether with those criteria they're eligible to participate in a monitoring day, excluding subjects and staff who don't meet the CDC's screening criteria, and having a process in place to notify staff or subjects, if anyone they had contact with during the study becomes ill.

3) to make sure that there's a confirmation of adequate landing pressure at the test site for the duration of the test period before field testing is initiated. Make sure that the prescreening of the field site verifies that there is consistent adequate landing pressure, which increases the likelihood that a test day could be conducted to completion and minimize human exposure to both the test substance and the mosquitoes to the greatest extent possible.
4) include more information about the preparation for and timing of the study day in the protocol. For instance, details such as whether subjects will be reminded of the restrictions on substances used for washing for the 24 hours before the study, and if so, how and when. Or, how far in advance of the field testing, or at what time subjects should be instructed to arrive at the facility to receive their treatment. Subjects should know that a pregnancy test will be conducted for female subjects prior to any treatment. During the initial briefing for the test day, EPA also recommends that the research staff remind subjects that they're free to withdraw at any time and that they will be compensated for their participation up to the time of their withdrawal.
5) to make sure that the risk minimization measures are appropriate, it needs to be clarified what subjects will be wearing during the test day.
6) remove the upper age limit or providing a rationale for excluding subjects who are over 55 years old.
7) to address the discrepancy in compensation that is discussed in the protocol and consent form and more information should be provided about how alternates and subjects were dropped during the field study will be compensated.
8) If an hourly rate is chosen, EPA recommends increasing the rate to time and a half for any participation beyond eight hours. Additionally, EPA asks that the protocol confirm explicitly that subjects will be compensated for attending the consent meeting, regardless of whether they choose to enroll in the study, and for the attractiveness meeting, regardless of whether or not they continue their enrollment. Also, EPA recommends that for alternates, more information be provided about how long alternates are expected to remain at the test site and what compensation will be provided if they come to the test site and are not needed.
9) EPA recommends including more information about how subjects will be transported to the field site in both the protocol and the consent form. It should be indicated whether or not subjects can use their own transportation to get from the application site to the test site, how the integrity of the applications will be maintained during the transportation,

and how and when subjects will be able to leave the test site if they experienced their confirmed landing prior to the end of the test day.

10) EPA recommends that the study director have limited discretion to withdraw subjects from the study, and EPA would request either more information in the protocol about why the study director has unfettered discretion or more limitations around when a subject can be withdrawn from the study.
11) EPA recommends that the consent materials be revised to incorporate all of EPA comments, as well as to address all of the relevant elements of the consent form outlined in the human studies rule. The revision should include a simple summary of the study at the beginning of the form and should be written in a way that a subject has a really strong understanding of all of the tests, procedures, and all of the risks and benefits prior to consenting. For instance, the consent form should include more information about the risks of exposure to IRR3535, a more detailed discussion of the risks to subjects and how there'll be mitigated, the risks associated with mosquito-borne diseases and how we get more information, more updated information about the compensation, and deleting the listing of compensation as a benefit of participation, and then more information about the location of the test site relative to the facility where the test substance will be applied and how subjects will be transported.

With EPA's recommendations addressed, EPA believes that the requirements of the human studies rule will be met for this protocol.

The Board then asked questions about the ethics presentation. Dr. Cavallari asked if there was any information on how the landing pressure is confirmed and if it's done with or without human participants. Dr. Hull-Sanders said she believes that the trapping mechanisms can be used not only to monitor the species present but the density/abundance of mosquitoes present at the site over time. Dr. Lewandowski wanted to hear EPA's position on the possibility of the consumer using a product in a way that is different than is tested in the protocol and if the CPT determined will represent a realistic CPT. Dr. Fuentes replied that the protocol uses standard rate of application based on dosimetry data from previous studies where consumers applied the product to come up with a “typical dose”. Dr. Lewandowski asked if the formulations of the wipe and lotion are different enough to have two different trials and expose subjects twice. Dr. Hull-Sanders said the physical wipe is considered a separate formulation and standardizing the rate is what they are most concerned about. Dr. Hull-Sanders also said that the wipes actually have a one hour longer protection time. Dr. Alesia Ferguson asked if there was not enough landing pressure or missed periods in the previous study the HSRB reviewed. Dr. Hull-Sanders replied that there were missed periods and the landing pressure wasn't maintained in the previous study and because there were so many missed periods EPA could not accept the data.

The Chair asked if there were public comments and there were none.

The HSRB’s scientific review was presented by Board members Drs. Ferguson and Lewandowski and consultant Dr. Kendra Lawrence. Dr. Ferguson said it would be more consistent to have one person apply the dose of the product to all the subjects but that might be difficult to do logistically. Dr. Ferguson also said the consent form and the protocol and the

recruitment should all be consistent in mentioning spicy foods, restraining from spicy foods, not smoking, et cetera. Dr. Ferguson also did not recommend using Tyvek suits because they could be hot and difficult to take off. Dr. Ferguson also said the study sponsors should make sure the fans don't point to the people in the field where the mosquitoes need to be biting them. Dr. Ferguson also said the protocol should state that they will check for good weather before they choose a field day. Dr. Ferguson also suggested the study sponsors consider rapid testing for COVID if it is available. Dr. Ferguson recommended that the consent form state the social distancing and mask wearing requirements and that subjects will be asked to leave the study if those are not followed. Dr. Ferguson also said that the social distancing procedures should not interfere with the integrity of the science. Dr. Ferguson reiterated EPA's express clarifications on when to miss exposure periods and recommended that the data forms include where the subject is located each time in the field for randomization purposes. Dr. Lawrence recommended that the trap type be added to the description of the methods for site monitoring in addition to the number of traps and the frequency of trapping because not all traps are created equal. Dr. Lawrence recommended the data from the site surveillance be provided as part of the final submission package to the agency. Dr. Lawrence also recommended to add a question for the volunteers about their history of heat-related injury, whether that's heat exhaustion or heat stroke, and that the study sponsors should think about excluding folks from the volunteer pool that have a history of heat-related injury. Dr. Lewandowski said it is important to know what the residual impurities are in the applied substances and there should be a statement that says that subjects who are allergic to any ingredients of the test material will be excluded. Dr. Lewandowski said that there was some inconsistency in terms of the documentation of the pregnancy test. In some places it says it will not be recorded and in other places, it says that negative results will be recorded. Dr. Lewandowski also strongly also supported EPA's comment that the areas should be assessed for the activity of all three mosquito species of interest. Dr. Lewandowski also said in the recruitment script it says "If you have a known allergy to insect bites or have participated in an insect-repellent study in the last three months or insect-repellent study in the past 72 hours," where they are basically talking about the same thing, but giving two different time frames. Elsewhere in the protocol, they make a distinction between any study in the last three months and our study in the last 72 hours. That discrepancy in the recruitment script should be clarified. Dr. Lisa Corey said having a more explicit description of the start time would be useful because she could see how there could be a really varying degree.

The Board's statistical review was given by Dr. George Milliken. Dr. Milliken said that every time the researchers move the experimental unit or the subject from one place to another, there needs to be some form of randomization to prevent bias and that should be detailed. Dr. Milliken had concerns about how the protocol would maintain a 50-50 male to female ratio. Dr. Milliken recommended the protocol be specific on how they randomly assign the control to the person within a gender class and that the rule for stopping a test should say that at least 50% of the females and 50% of the males have experienced FCL (First Confirmed Landing). Dr. Milliken recommended that the QA person be available continuously through the study, not just at some type of interval, but to make sure everything's running all the time. Dr. Milliken questioned why subjects for the study could not begin mosquito exposures at 8.5 hours since it was previously shown the shortest CPT time was 10 hours. Dr. Hull-Sanders responded that the

problem with that is that if there is a first confirmed landing in the first exposure period that would have happened within that eight hours, well, essentially six and a half hours, they would not know when the product broke down, i.e., when the product stopped being efficacious. Two hours is sort of the minimum EPA knows that the product works. Dr. Milliken said the protocol should indicate 95% confidence interval of the estimated median CPT is calculated with a log-log transformation applied to survival function and Kaplan-Meier survival curves will be presented in a report. Dr. Julia Sharp had a further recommendation to define what right censored is in the protocol. Dr. Sharp also said the end of the field test period stopping rule for the sufficient number of subjects that experienced first confirmed landing should be clarified. This was clarified in the presentation today to be at least 50% of the subjects experiencing the first confirmed landing. The Board voted unanimously on the following answer to the science charge question: "the protocol field evaluation of two topically applied insect repellent products containing IR3535, against mosquitoes in Louisiana, is likely to generate scientifically reliable data useful for estimating the amount of time each of the products tested repels mosquitoes, provided that the comments and recommendations provided by the EPA and HSRB are adequately addressed".

Drs. Lindsay McNair and Philip Day presented the HSRB's ethics review of the study. They agreed that COVID-19 risks need to be addressed and assumed that those will be appropriately addressed in the protocol, and the IRB will review those to make sure that they are appropriate before the study goes forward. They agreed with the comments around the age range, neither justifying a cutoff at 55 or increasing it. They agree that there are other reasons to only enroll English speaking people, such as the information about the protocol will only be in English and the study team only speaks English. Drs. McNair and Day also wanted to make sure that the training for using the aspirator ensured that people were successful at the training before they were released into the field. They also had a question about whether it makes sense in this setting to ask participants for an additional person who can be contacted if the study team cannot contact them later, especially in case of COVID infections, and if any contract tracing may be necessary after the study is completed. The Board voted unanimously in the affirmative to the following response to the charge question: "the research proposed in the protocol field evaluation of two topically applied insect repellent products containing IR3535 against mosquitoes in Louisiana and related documents, is likely to meet the applicable requirements of 40 CFR, Part 26, Subparts K and L, if the recommendations made by the EPA and HSRB are adequately addressed".

This concluded the Board's session for January 26, 2021 and the meeting was adjourned.

Respectfully submitted:

4/22/2021

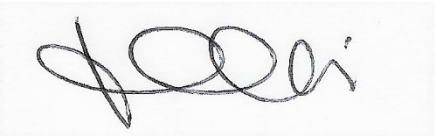
X Thomas O'Farrell

Thomas O'Farrell

Signed by: THOMAS O'FARRELL

Thomas O'Farrell, Ph.D.
Designated Federal Officer
Human Studies Review Board
United States Environmental Protection Agency

Certified to be true by:



Jennifer Cavallari, Sc.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

Jennifer Cavallari, Sc.D., CIH
Associate Professor
Department of Public Health Science
University of Connecticut School of Medicine
Farmington, CT

Vice Chair

Alesia Ferguson, Ph.D.
Associate Professor
Department of Built Environment
North Carolina A&T University
Greensboro, NC

Members

Janice Britt, Ph.D.
Managing Scientist
ToxStrategies, Inc.
Tallahassee, FL

Lisa Corey, Ph.D.
Toxicologist
Intertox, Inc.
Seattle, WA

George Milliken, Ph.D.
Consultant
Milliken Consultants
Manhatten, KS

Thomas Lewandowski, Ph.D.
Principal
Gradient
Seattle, WA

Mark Aulisio, Ph.D.
Professor
Case Western Reserve University
Cleveland, OH

Albert J. Allen, M.D., Ph.D.
Senior Medical Fellow
Eli Lilly
Indianapolis, IN

Eun Um, Ed.D.
President and CEO
AMSTAT Consulting
Bethesda, MD

Julia Sharp, Ph.D.
Associate Professor
Colorado State University
Fort Collins, CO

Lindsay McNair, M.D., Ph.D.
Chief Medical Officer
WIRB-Copernicus
Princeton, NJ

Philip Day, Ph.D.
Assistant Professor
University of Texas, Southwestern
Dallas, TX

Consultants 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 Registers Notice Announcing Meetings

ENVIRONMENTAL PROTECTION AGENCY

[FRL-10017-40-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development announces the 2021 public meetings dates of the Human Studies Review Board (HSRB) to advise the Agency on the ethical and scientific review of research involving human subjects.

DATES: Four three-day virtual public meetings will be held on:

1. January 26-28, 2021;
2. April 20-22, 2021;
3. July 20-22, 2021; and
4. October 19-21, 2021.

Meetings will be held each day from 1 p.m. to 5:30 p.m. Eastern Time. Separate, subsequent teleconference meetings are planned for the HSRB to finalize its Reports of the three-day meetings that proceed these dates on March 18, 2021; June 17, 2021; September 16, 2021; and December 14, 2021; all from 2 p.m. to approximately 3:30 p.m. Eastern Time.

ADDRESSES: These meetings are open to the public and will be conducted entirely virtually and by telephone. For detailed access information and meeting materials please visit the HSRB Website: https://www.epa.gov/osa/human-studies-review-board.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to receive further information should contact the HSRB Designated Federal Official (DFO), Thomas O'Farrell at the following telephone number: (202) 564-8451 or by email at: ofarrell.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

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 on issues related to scientific and ethical aspects of third-party human subjects research that are submitted to the Office of Pesticide Programs (OPP) to be used for regulatory purposes.

Meeting access: These meetings will be open to the public. The full agenda with access information and meeting materials will be available seven calendar days prior to the start of each meeting at the HSRB Website: https://www.epa.gov/osa/human-studies-review-board.

For questions on document availability, or if you do not have access to the Internet, consult with the DFO, Thomas O'Farrell, listed under **FOR FURTHER INFORMATION CONTACT.**

Special Accommodations. For information on access or services for individuals with disabilities, or to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to each meeting to give EPA as much time as possible to process your request.

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.

1. Oral comments. To pre-register to make oral comments, please contact the DFO, Thomas O'Farrell, listed under **FOR FURTHER INFORMATION CONTACT**. Requests to present oral comments during the meetings will be accepted up to Noon Eastern Time, seven calendar days prior to each meeting date. 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 the meetings 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. For the Board to have the best opportunity to review and consider your comments as it deliberates, you should submit your comments prior to the meetings via email by Noon Eastern Time, seven calendar days prior to each meeting date. 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 the DFO, Thomas O'Farrell listed under **FOR FURTHER INFORMATION CONTACT**. There is no limit on the length of written comments for consideration by the HSRB.

Topics for discussion. The agenda and meeting materials will be available seven calendar days in advance of each meeting at https://www.epa.gov/osa/human-studies-review-board.

Meeting minutes and final reports. Minutes of these meetings, summarizing the topics discussed and recommendations made by the HSRB, will be released within 90 calendar days of

each meeting. These minutes will be available at https://www.epa.gov/osa/human-studies-review-board. In addition, information regarding the HSRB's Final Reports, will be found at https://www.epa.gov/osa/human-studies-review-board or can be requested from Thomas O'Farrell listed under **FOR FURTHER INFORMATION CONTACT**.

Dated:

Jennifer Orme-Zavaleta,
EPA Science Advisor.