EPA Human Studies Review Board (HSRB)
February 15, 2023 Meeting Minutes

Committee Members: (See EPA HSRB Members List – Attachment A)
Date and Time: Wednesday, February 15, 2023, 1:00 to 2:00 pm EDT.
Location: Via Zoom
Purpose: The HSRB provides advice, information and recommendations on issues related to scientific and ethical aspects of human subjects research.
HSRB Website: https://www.epa.gov/osa/human-studies-review-board

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EPA Human Studies Review Board (HSRB)
February 15, 2023 Meeting Minutes

Wednesday, February 15, 2023:

A. Meeting Topic and Charge Questions

Topic: Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-Based Repellent Spray with Ticks Under Laboratory Conditions. Sponsored by MIMIKAI and conducted by Carroll-Loye Biological Research. Study Completed January 5, 2022.

Charge to the Board – Science: Did the research summarized in "Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-Based Repellent Spray with Ticks Under Laboratory Conditions" generate scientifically reliable data, useful for estimating the amount of time the product tested repels ticks?

Charge to the Board – Ethics: Does the available information support a determination that the research was conducted in substantial compliance with the applicable requirements of 40 CFR part 26, subparts K and L?

B. Convene Public Meeting and Identification of Board Members

Tom Tracy, Designated Federal Officer, EPA Human Studies Review Board (HSRB), Office of the Science Advisor, Policy and Engagement (OSAPE)

Mr. Tom Tracy, Designated Federal Official (DFO) for the HSRB, called the meeting to order at 1:00 p.m., EDT. He introduced the meeting, outlined the Federal Advisory Committee Act procedures, and performed a roll call of the meeting participants. The following members and observers were present:

HSRB members	Lisa Corey, Ph.D., Co-Chair (Intertox, Inc.) Julia Sharp, Ph.D., Co-Chair (National Institute of Standards and Technology) Albert J. Allen, M.D., Ph.D. (Consulting Specialist) Chad Cross, Ph.D. (University of Nevada - Las Vegas) Philip Day, Ph.D. (University of Massachusetts, Chan Medical School) Nicole Deming, J.D., M.A. (Case Western Reserve University, School of Medicine) Weiying Jiang, Ph.D. (California Environmental Protection Agency) Thomas Lewandowski, Ph.D. (Gradient) Srikumaran Melethil, Ph.D., J.D. (University of Missouri - Kansas City) George Milliken, Ph.D. (Milliken Consultants) Sinziana Seicean-Boose, M.D., Ph.D., M.P.H. (Case Western Reserve University) Joseph Tuminello, Ph.D. (McNeese State University) Eun Um, Ed.D. (AMSTAT Consulting) David Williams, Ph.D. (Oregon State University)

EPA staff members	Michelle Arling (EPA, Office of Pesticide Programs (OPP)) Tom Tracy (EPA, Office of Science Advisor, Policy and Engagement (OSAPE)) Monique Tadeo (EPA, Program in Human Research Ethics and Oversight (PHREO)) Angela Meyer (EPA, OPP) Clara Fuentes (EPA, OPP) Stephanie Watson (Office of Transportation and Air Quality)
Members of the public, representatives of research sponsor and research team:	Scott Carroll, Ph.D. (Carroll-Loye Biological Research) Shawn King, M.S. (Caroll-Loye Biological Research) Afroditi Katsigiannakis (ICF, Contractor Support) Angelina Guiducci (ICF, Contractor Support)

C. Meeting Administrative Procedures

Tom Tracy, Designated Federal Officer, HSRB, OSAPE

Mr. Tom Tracy reviewed Zoom Meeting platform tools and features and stated the purpose of the meeting was to review the paper by Carroll-Loye Biological Research, "Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-Based Repellent Spray with Ticks Under Laboratory Conditions." He noted minutes of the meeting and a report will be prepared, certified, and posted on the website within 90 days of February 15, 2023.

D. Updates on Human Subject Research Program

Monique Tadeo, M.S., CIP, HSRB Official and Director

There were no updates to report.

E. Meeting Process

Lisa Corey, Ph.D., HSRB Co-Chair
Julia Sharp, Ph.D., HSRB Co-Chair

Dr. Lisa Corey welcomed everyone to the EPA HSRB meeting, thanked the leads for providing comments, and stated the purpose of the meeting was to review the final draft of the December report. She then outlined the process for the meeting and asked Dr. Michelle Arling for updates from OPP.

F. Updates from OPP

Michelle Arling, J.D., OPP

Dr. Michelle Arling stated she would provide updates from the previous meeting and then answer questions from the Board.

- **Michelle Arling**: Aa a follow-up to the December meeting, EPA conducted two statistical analyses recommended by the Board and emailed them this morning for the Board to review. There is nothing else new to report.
    - **Julia Sharp**: Were the analyses sent to the entire Board?

- **Tom Tracy**: No.
- **Julia Sharp**: How should we proceed then, Lisa?
- **Lisa Corey**: Can you provide more details so the statisticians on the call can decide whether they need more time to review the results before finalizing the document?
- **Michelle Arling**: Sure. Discussion at the December meeting recommended we conduct follow-up sensitivity analyses. EPA statisticians conducted an analysis to evaluate gender effect on cpt estimates. The analysis indicated gender was not significantly associated with cpt data. In response to another recommendation to address potential variability related to tick rearing and maintenance conditions, we conducted a sensitivity analysis regarding the missing tick attractiveness assay for subject 73. There was no effect on the data when subject 73's data were excluded. Does that help?
- **Julia Sharp**: Yes, that is a great summary, thank you. Please send this out. I do not see any changes in the statistical analysis results or interpretation resulting from these additional analyses that are problematic. When these additional analyses are conducted, where are they included in the report?
- **Michelle Arling**: I am not sure we will edit the report. Are you talking about HSRB's report?
- **Julia Sharp**: Either. What do we do with this great information?
- **Michelle Arling**: You can recommend it be included in EPA's overall science assessment report. That is the plan we will probably follow going forward, because we conducted these analyses on the HSRB's recommendation to further refine our assessment and strengthen our science review to address some uncertainties. The HSRB report could include it, or we could post it on the HSRB website as another source of information for the public.
- **Julia Sharp**: Great, thank you.
- **Sinziana Seicean-Boose**: Thank you for conducting the sensitivity analysis. I was the reviewer who suggested those, and I am very excited to read it. I would appreciate the chance to review the work and think you should do everything the previous speaker suggested. It is very important and will solve a lot of additional questions, not just for the statistical part but also for the science part. Great work! Thank you.
- **Srikumaran Melethil**: EPA states it is reliable data. The Board is asked to comment on scientific reliability of the data. I am wondering, is that assumed to be the same? Reliable versus scientific reliability? I am reading on page six.
- **Lisa Corey**: Let's come back to that when we discuss the document. Unless you mean the statistical analysis we are currently discussing?
- **Srikumaran Melethil**: No.
- **Lisa Corey**: Okay, let's come back to your question. It sounds like we can make a recommendation for EPA to include this information and make it available in some way, but it doesn't appear to change the recommendations we reached at end of the last meeting, and it does not change EPA's assessment. Unless I hear otherwise, we can proceed with a recommendation.
- **Thomas Lewandowski**: It sounds like EPA conducted all of the analyses asked for by the HSRB, and the results did not change the conclusions. Is that a fair synopsis? If that is true, then that is fine.
- **Michelle Arling**: We conducted the analyses requested at the December meeting. If there

were additional recommendations for statistical analyses that were not in those three I talked about, we have not done them yet, because we learned about them last week.
    - **Thomas Lewandowski**: Is there a plan to conduct those? It seems we are trying to move towards finalizing the report while there are missing pieces.
    - **Michelle Arling**: I think we would look at the recommendations and then conduct the analysis and share the results with the HSRB. If that is not possible, we will explain.
    - **Thomas Lewandowski:** Okay.
    - **Lisa Corey**: This is a little bit unusual because we already voted to approve our response to the charge question, and conducting these tests were a direct result of the recommendations. We don't often receive the analyses before finalizing the report. Ordinarily, we move forward with only the stated recommendations. Our report will still include recommendations relevant to what we discussed and concluded.

Dr. Corey then asked whether the Board was ready to conclude this part of the discussion before opening the meeting to public comments.

G. Public Comment

Dr. Corey requested public comments to be kept to less than five minutes.

- **Scott Carrol**: We do not have any public comments today. Thank you.

H. Review and Finalize HSRB Report on Caroll-Loye Research

Lisa Corey, Ph.D., HSRB Co-Chair

Dr. Corey shared the December 2022 HSRB draft document and provided an overview of past events leading to the current draft. She stated the goal for the day was to approve or not approve this final draft by the end of the meeting. Dr. Corey then invited Dr. Melethil to share his question.

- **Srikumaran Melethil**: I have a question about wording in the report. On page six the Board is asked to determine whether the study is scientifically reliable. This is the page after the charge questions and contents. Does EPA's response adequately address the issue?
    - **Lisa Corey**: Are you talking about the charge question?
    - **Srikumaran Melethil**: The charge question is okay. The heading begins with Science Review. The sentence reads, "In general, the HSRB concluded the results generated form this study are scientifically reliable."
    - **Lisa Corey**: Do you have a proposed edit?
    - **Srikumaran Melethil**: I don't know whether I should edit EPA.
    - **Lisa Corey**: This is our document.
    - **Srikumaran Melethil**: We significantly rely on EPA's information, so I am not sure how to modify that.
    - **Julia Sharp**: Would an appropriate edit be, "...from the study are scientifically reliable and agree with the U.S. EPA that the data can be used for estimating the amount of time"?
    - **Lisa Corey**: We could remove this sentence. We already have a response to the charge question, and this is concluding information. Would it work to remove that sentence entirely?
    - **Srikumaran Melethil**: Yes.

- **Lisa Corey**: Any objections?

No objections were made.

- **Srikumaran Melethil**: I have one more comment. When reviewing page nine, just above Study Report 2, I thought I should provide more direction to the sponsor and EPA. I wonder whether it would be preferable to write, "The sponsor should address the issue" instead of "The sponsor was silent on the issue."
  - **Lisa Corey**: Are there any objections?

No objections were made.

- **Thomas Lewandowski**: What typically happens might be a question for EPA. In the report we are listed with our affiliations, which provides an impression we are representing our companies or institutions, and I think that is not the case. I believe we represent ourselves, so maybe the report should include a statement to that effect? Is that typical in our reports?
  - **Tom Tracy**: It is customary to have members' names listed with their affiliation, but you are right, this is a non-representative Board. We can add a generic disclaimer underneath.
  - **Thomas Lewandowski**: Yes, I think that would be good. Another minor correction is that Gradient is not a corporation, despite our email address suggesting otherwise.
  - **Tom Tracy**: Yes, we will fix that before submitting the report.

Dr. Corey then prompted Dr. Weiying Jiang to ask his question.

- **Weiying Jiang:** My first question is regarding the comment Sri mentioned on page seven. Instead of removing the sentence entirely, I think it would be preferable to move the sentence elsewhere and replace it with our current response to EPA. The current sentence is long and hard to follow and understand.
  - **Lisa Corey**: Do you mean the response to the charge question?
  - **Weiying Jiang:** Yes.
  - **Lisa Corey:** We already voted at the last meeting to approve the charge question response.
  - **Weiying Jiang**: Oh, okay.
  - **Julia Sharp**: I agree we should not replace that sentence since we already approved it. I think the time for editing might have passed.
  - **Weiying Jiang**: Okay. My second question relates to the last bullet point on page eight, which states, "The third and fourth tables on page 49...." I think the margin of error calculation in the fourth table should be recalculated due to an error there.

Dr. Corey then prompted Dr. Sinziana Seicean-Boose to ask her question.

- **Sinziana Seicean-Boose**: My last name is misspelled by one letter.
  - **Lisa Corey**: Tom Tracey, are you able to take care of this edit?
  - **Tom Tracy**: Yes, sorry.

Dr. Corey then prompted Dr. Julia Sharp to ask her question.

- **Julia Sharp**: I like the idea of including a disclaimer and was also wondering whether we could add our expertise to the subject line. For example, I would be listed as a statistician on the HSRB. This would better define our roles.
  - **Tom Tracy**: Sure, I can do that.

Dr, Corey next thanked EPA and the contractor firm providing support for the new report format. She then asked for further comments on the document.

- **Srikumaran Melethil**: For our expertise area, would it be helpful if we provided information to Tom Tracy?
    - **Tom Tracy:** I was going to list your roles on the HSRB. For example, Ethics, Science, or Statistical Reviewer. Do you prefer something different?
    - **Srikumaran Melethil**: That is up to Julia, but I agree with either.
    - **Julia Sharp**: Tom's examples are what I had in mind.

Dr. Sharp then noted there were comments Dr. Arling highlighted in her review document and asked her to discuss them.

- **Michelle Arling**: They are mainly editorial comments about typos.
    - **Tom Tracy**: There were a few typos. I can correct those, and with Lisa's and Julia's approval I can modify the report template to make the recommendations boldface or list them in a box.
- **Michellee Arling:** The report highlighted recommendations in a few places, which is helpful for distintuishing between general comments and specific recommendations for consideration.
- **Julia Sharp**: One of the comments noted the study used a nominal application rate at 0.5 grams per 600 cm squared. It was unclear how this rate was selected and whether this value relates to the application rate of future end use products. There was a comment advising the Board to consider EPA's protocol review for this study noted the rate is based on dosimetry studies on file with the Agency and represents what we call a typical consumer dose. The study report did not clearly cite where that information comes from, but EPA can provide that document as a reference document for the Board when reviewing skin applied repellant studies.
    - **Lisa Corey**: Yes, that would be useful.
    - **Michelle Arling**: I think one of our comments requested the protocol include that information. It should have carried over to study report, but EPA can provide standard information about dosage for this kind of study.
    - **Julia Sharp**: Do you need us to add a recommendation in the report regarding that?
    - **Michelle Arling**: No. Thank you, though.

Dr. Corey then asked for other comments about the document.

- **Albert J. Allen:** At the end of the last meeting, I brought up a few things unrelated to our vote. They are things worth discussing. I wonder whether we should talk more about those.
    - **Lisa Corey**: Sure, those are in the document at very end of the ethics review.
    - **Albert J. Allen**: They are right after recommendations regarding the ethics charge.
    - **Lisa Corey**: AJ, do you want to provide a quick review?
    - **Albert J. Allen**: Yes. The first recommendation related to study report formatting. In response, EPA included some comments and provided direction to the sponsor for better report organization. It was encouraging to see EPA implement recommendations with this sponsor. The recommendation further states EPA expanded this guidance because the sponsor was struggling with report organization, so providing more guidance to others likely would be helpful. It could resemble a clinical studies report or be a simplified template. Such guidance would have saved both the sponsor and EPA a significant amount of time. The second recommendation related to a deviation for an undisclosed

protocol regarding screening of ticks for illnesses. This deviation was not reported through the IRB and potentially could have resulted in harm to individuals. I do not think it would have been something difficult to address with the IRB, but they did not report it. This is the responsibility and failure of sponsor. The recommendation encourages EPA to consider appropriate consequences if deemed warranted. The third recommendation is regarding study design. The original protocol ended after the final testing visit, but it is possible to have adverse events associated with tick bites or chemical exposure after a study visit date, perhaps as far out as a few weeks. Thus, it is recommended to closely review protocols in the future and make unsolicited follow-up calls for up to thirty days to ask subjects about any adverse events. Good Laboratory Practices (GLPs) don't mention Institutional Review Boards (IRBs) because they are largely concerned about laboratory studies. Having conducted a lot of FDA-regulated research, I know there is a separate guideline describing Good Clinical Practices (GCPs) that addresses the responsibilities of investigators, the sponsor, and the IRB. One can argue this is not a clinical study, but it has a lot more similarities to a clinical study than an animal study with respect to ethics and safety concerns. The recommendation is that EPA explore a collaboration with stakeholders about using both GLPs and GCPs, as appropriate. There is also a suggestion for EPA to consider hosting a small workgroup with a select members representing the HSRB, EPA, sponsors, and investigators to review this guidance and make recommendations for review by the HSRB.

- **Lisa Corey**: We do not need to vote on this, but if there are comments or edits that would change finalization of the document, we should address those.
- **David Williams**: There are a couple descriptors about using Vertex ticks. On page 16 towards the bottom, we say it is "inexcusable," but I think we should say it is "indefensible." Same situation for the descriptor on the bottom of page 17; it says we "condemn" things, but we can't really condemn things. Maybe we should say "refutes" instead.
- **Albert J. Allen**: I like replacing "inexcusable" with "indefensible". Regarding "condemns," I wonder whether "reprimands" would work as well.
- **David Williams**: I would be okay with "reprimands."
- **Albert J. Allen**: I am also happy with that substitution. We need to note the sponsor's actions were generally appropriate, but this is a fundamental concern with the safety of study participants. We should send a strong message.
- **David Williams**: I agree, we should send a strong message.
- **Lisa Corey**: Any objections to those two word changes?
- **Thomas Lewandowski**: I think "reprimands" seems fine. As for "indefensible," we are not a court, and I think it is up to EPA to take whatever action they deem appropriate. I tend to think we want to avoid legalistic wording.
- **Julia Sharp**: We could use "unjustified," "unjustifiable," or "unforgivable." Would any of those work?
- **Thomas Lewandowski**: Is that any less legalistic? Its common usage is consistent for the fact they didn't provide a rationale.
- **Albert J. Allen**: Let me provide an ethics regulations perspective. One is supposed to report every deviation because they can result in adverse events to research subjects. Technically, this is a deviation from an approved protocol that potentially puts research

subjects at risk, which is a violation of the regulations. There are mitigating circumstances, but it is a violation of the regulations.

- **Thomas Lewandowski:** Would it be more appropriate to say it is contrary to the regulations?
- **Sinziana Seicean-Boose**:: How about "questionable"?
- **Albert J. Allen**: My problem with "questionable" is that it should have occurred, and there was no question. I think some of that relates to concerns about some other regulations, so there is a need to provide proper advice and guidance to persons conducting these studies. When you work with an IRB, they say you need to report all protocol deviations.
- **Srikumaran Melethil**: How does this impact our final reliable data? Does it apply in any way to the existing charge? It should be made clear this is for the future. I'm concerned with us saying, don't do this, but then saying, this is okay.
- **Albert J. Allen**: There was an extensive discussion of protocol deviations that is described in the report just prior to the recommendations. We held several discussions about the ethical and safety concerns related to the protocol deviation. Another ethics concern is we told participants one thing and they were in fact subjected to something else.
- **Srikumaran Melethil**: Is an unethical study still scientifically reliable?
- **Albert J. Allen**: There are all sorts of discussions about that. When you say a study is unethical, the question is what was the context of the violation. I do think the study met the requirements. The deviation raises a concern but doesn't make the study results questionable. They did not follow the applicable regulations, and it is possible they overlooked this.
- **Srikumaran Melethil**: There are some required actions, but lack thereof shouldn't affect scientific reliability of the data. Is that correct?
- **Albert J. Allen**: Yes.
- **Thomas Lewandowski**: One of challenges is the comments we are talking about lead any reasonable person to wonder whether they can accept the study. We say the study meets compliance overall, then we explain a serious problem. It would be clearer if we finished with our conclusion.
- **Lisa Corey**: Any there any issues with this change?
- **Albert J. Allen**: I can live with that.
- **Lisa Corey**: Did we decide on "inexcusable" versus "indefensible?"
- **Albert J. Allen**: Julia suggested "concerning," but we already used that. Would "unacceptable" work?
- **Thomas Lewandowski**: Yes, that sounds good to me.
- **Lisa Corey**: Any objections?

No objections were made. Dr. Corey asked whether there were other concerns regarding the document. There were no responses. She then asked the Board to vote for approval of the document, and everyone voted "yes."

I. Plans for March & April Meetings

Michelle Arling, J.D., OPP

Dr. Arling noted the HSRB is planning to reconvene in April. Potential discussion topics might relate to two more formaldehyde studies, one unpublished intentional dosing study, and one insect repellant protocol for which proposed testing has not yet occurred. Mr. Tom Tracy asked whether the Board should cancel the March meeting. The group decided to leave it on the schedule as a placeholder unless a decision to cancel is reached closer to March.

J. Adjournment

The meeting adjourned at 2:21 p.m., EDT.

Attachment A: HSRB Current Committee Membership

Name	Title	Affiliation
Lisa Corey, Ph.D.	Senior Toxicologist	Intertox, Inc. Seattle, WA
Julia Sharp, Ph.D.	Mathematical Statistician	National Institute of Standards and Technology Fort Collins, CO
Albert J. Allen, M.D., Ph.D.	Consulting Specialist	Self-Employed
Chad Cross, Ph.D.	Associate Professor In-Residence	University of Nevada Las Vegas, NV
Philip Day, Ph.D.	Assistant Professor	University of Massachusetts, Chan Medical School Worcester, MA
Nicole Deming, J.D., M.A.	Assistant Dean Faculty Affairs and Human Resources	Case Western Reserve University, School of Medicine Cleveland, OH
Weiying Jiang, Ph.D.	Staff Toxicologist	California Environmental Protection Agency, Department of Pesticide Regulation Sacramento, CA
Thomas Lewandowski	Principal	Gradient Seattle, WA
Srikumaran Melethil, Ph.D., J.D.	Professor Emeritus	University of Missouri-Kansas City Kansas City, MO
George Milliken, Ph.D.	President	Milliken Consultants Manhattan, KS
Sinziana Seicean-Boose, M.D., Ph.D., M.P.H.	Assistant Professor	Case Western Reserve University Cleveland, OH
Joseph Tuminello, Ph.D.	Assistant Professor	McNeese State University Lake Charles, LA
Eun Um, Ed.D.	President and CEO	AMSTAT Consulting San Jose, CA
David Williams, Ph.D.	Distinguished Professor	Oregon State University Corvallis, OR

Attachment B: Federal Register Notice Announcing Meetings

ENVIRONMENTAL PROTECTION AGENCY

[FRL-10408-01-ORD]

Human Studies Review Board; Notification of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of 2023 public meetings of the Human Studies Review Board (HSRB). 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.

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

1. February 15–17, 2023;
2. April 18–20, 2023;
3. July 25–27, 2023; and
4. October 11–13, 2022.

Meetings will be held each day from 1 p.m. to 4 p.m. Eastern Time. For each meeting, separate subsequent follow-up meetings are planned for the HSRB to finalize reports from the three-day meetings. These meetings will be held from 1 p.m. to 4 p.m. Eastern Time on the following dates: March 23, 2023; May 18, 2023; August 23, 2023; and November 16, 2023.

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), Tom Tracy, via phone/voicemail at: 919-541-4334; or via email at: *tracy.tom@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, Tom Tracy, 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, Tom Tracy, 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, Tom Tracy 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 Tom Tracy listed under **FOR FURTHER INFORMATION CONTACT** .

Dated:

Mary Ross, Director, Office of Science Advisor, Policy and Engagement.