

2024 Current Fiscal Year Report: Human Studies Review Board

Report Run Date: 04/23/2024 09:23:50 PM

1. Department or Agency

Environmental Protection Agency

2. Fiscal Year

2024

3. Committee or Subcommittee

Human Studies Review Board

3b. GSA Committee No.

28234

4. Is this New During Fiscal Year?

5. Current Charter

6. Expected Renewal Date

7. Expected Term Date

No 03/28/2022 03/28/2024

8a. Was Terminated During Fiscal Year?

8b. Specific Termination Authority

No

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

No

10b. Legislation Pending?

Not Applicable

11. Establishment Authority

Statutory (Congress Created)

12. Specific

Establishment Authority

Public Law 109-54 and 40 CFR 26.1603

13. Effective Date

02/21/2006

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee

Scientific Technical Program Advisory Board

16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open

17b. Closed

17c. Partially Closed

Other Activities

17d. Total

Meetings and Dates

No Meetings

Current FY

Next FY

18a(1). Personnel Pmts to Non-Federal Members

\$0.00 \$0.00

| | | |
|---|--------|--------|
| 18a(2). Personnel Pmts to Federal Members | \$0.00 | \$0.00 |
| 18a(3). Personnel Pmts to Federal Staff | \$0.00 | \$0.00 |
| 18a(4). Personnel Pmts to Non-Member Consultants | \$0.00 | \$0.00 |
| 18b(1). Travel and Per Diem to Non-Federal Members | \$0.00 | \$0.00 |
| 18b(2). Travel and Per Diem to Federal Members | \$0.00 | \$0.00 |
| 18b(3). Travel and Per Diem to Federal Staff | \$0.00 | \$0.00 |
| 18b(4). Travel and Per Diem to Non-member Consultants | \$0.00 | \$0.00 |
| 18c. Other(rents,user charges, graphics, printing, mail, etc.) | \$0.00 | \$0.00 |
| 18d. Total | \$0.00 | \$0.00 |
| 19. Federal Staff Support Years (FTE) | 0.00 | 0.00 |

20a. How does the Committee accomplish its purpose?

The purpose of the Human Studies Review Board (HSRB) is to provide 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. In FY 2023, the committee met on seven occasions (all virtual meetings). The HSRB submitted three reports to EPA's Science Advisor summarizing their recommendations.

20b. How does the Committee balance its membership?

Balanced membership is driven by a number of considerations characterized by: inclusion of the necessary areas of technical expertise, different perspectives within each technical discipline, and

the collective breadth of experience needed to address the Agency's charge. HSRB members are selected on the basis of their qualifications addressing the scientific and ethical aspects of research with human subjects. The HSRB membership includes experts in relevant scientific or technical disciplines in bioethics, biostatistics, human health risk assessment and human toxicology.

20c. How frequent and relevant are the Committee Meetings?

The Committee meetings are scheduled approximately every quarter (4 times a year, typically January, April, July and October) with the committee providing comments on matters related to scientific and ethical aspects of research involving human subjects. Teleconference meetings typically occur after each face-to-face or virtual meeting when the HSRB has drafted their report. This meeting provides the HSRB the opportunity to finalize their draft report.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

EPA was directed by Congress to establish a Human Studies Review Board pursuant to the 2006 EPA Appropriations Act, and included the establishment of such a board in its final rule for the protection of subjects in human research. (See: "Department of Interior, Environment, and Related Agencies Appropriations Act, 2006", Pub. L. No. 109-54 and "Protections for Subjects in Human Research: Final Rule," 40 CFR 26). Additionally, in a report requested by the Agency, the National Academy of Sciences recommended that EPA establish such a board. (See: NRC 2004, Intentional Human Dosing Studies for EPA Regulatory Purposes. Washington, D.C.: National

Academy Press). There are no other existing EPA advisory committees that have the breadth of technical and ethical expertise that is needed for the scientific and ethical review of research with human subjects. Further, review of proposed and completed human studies for time-critical regulatory decisions requires procedures for focused, expert, and rapid review not presently available.

20e. Why is it necessary to close and/or partially closed committee meetings?

There were no closed or partially closed meetings in FY 2023. The Human Studies Review Board always meets in public.

21. Remarks

All members are Tier 1 (parent committee members). There are no Tier 2 (subcommittee) members serving.

Designated Federal Officer

Thomas Tracy DFO

| Committee Members | Start | End | Occupation | Member Designation |
|--------------------------|--------------|------------|--|--|
| Allen, Albert | 09/01/2018 | 08/31/2024 | Tier 1, Senior Medical Fellow, Eli Lilly and Company, Indianapolis, IN | Special Government Employee (SGE) Member |
| | | | Tier 1, Senior Toxicologist, Intertox, Inc., Seattle, WA | Special Government Employee (SGE) Member |
| Corey, Lisa | 09/01/2018 | 08/31/2024 | | |
| Cross, Chad | 10/01/2022 | 09/30/2025 | Associate Professor | Special Government Employee (SGE) Member |
| | | | Tier 1, Assistant Professor, Univ. of Texas, Southwestern, Dallas, TX | Special Government Employee (SGE) Member |
| Day, Philip | 09/01/2020 | 10/31/2023 | | |

| | | | | |
|----------------------|------------|------------|---|--|
| Deming, Nicole | 10/01/2022 | 09/30/2025 | Assistant Dean and Assistant Professor of Bioethics | Special Government Employee (SGE) Member |
| Jiang, Weiying | 10/01/2022 | 09/30/2025 | Toxicologist | Special Government Employee (SGE) Member |
| Lewandowski, Thomas | 12/02/2022 | 11/30/2025 | Principal | Special Government Employee (SGE) Member |
| McNair, Lindsay | 09/01/2018 | 08/31/2024 | Tier 1, Chief Medical Officer, WIRB-Copernicus Group, Princeton, NJ | Special Government Employee (SGE) Member |
| Melethil, Srikumaran | 10/01/2022 | 09/30/2025 | Professor Emeritus, Toxicology | Special Government Employee (SGE) Member |
| Milliken, George | 12/02/2022 | 11/30/2025 | Consultant | Special Government Employee (SGE) Member |
| Seicean, Sinziana | 10/01/2022 | 09/30/2025 | Senior Research and Environmental Scientist | Special Government Employee (SGE) Member |
| Sharp, Julia | 09/01/2022 | 08/31/2025 | Associate Professor | Special Government Employee (SGE) Member |
| Tuminello, Joseph | 10/01/2022 | 09/30/2025 | Assistant Professor of Bioethics | Special Government Employee (SGE) Member |
| Um, Eun | 09/01/2018 | 08/31/2024 | Tier 1, President and CEO, AMSTAT Consulting, Bethesda, MD | Special Government Employee (SGE) Member |
| Williams, David | 10/01/2022 | 09/30/2025 | Distinguished Professor of Toxicology | Special Government Employee (SGE) Member |

Number of Committee Members Listed: 15

Narrative Description

The Human Studies Review Board addresses the EPA's Goal of Assessing and reducing risks posed by chemicals and promote the use of safer chemicals in commerce. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of research with human subjects. In FY 2023, the Committee met on six occasions (all virtual meetings). The HSRB submitted three meeting reports to EPA's Science Advisor summarizing their recommendations. While the committee is charged to provide comment on the science and ethics of human subjects research conducted, supported, or regulated by EPA, similar to previous years, in FY 2023 the HSRB focused mainly on proposed and completed third party research involving non-pregnant, non-nursing human adults. This research was conducted for submission to the Agency under the pesticide laws and was used for making regulatory decisions.

What are the most significant program outcomes associated with this committee?

| | Checked if Applies |
|---|-------------------------------------|
| Improvements to health or safety | <input checked="" type="checkbox"/> |
| Trust in government | <input checked="" type="checkbox"/> |
| Major policy changes | <input type="checkbox"/> |
| Advance in scientific research | <input checked="" type="checkbox"/> |
| Effective grant making | <input type="checkbox"/> |
| Improved service delivery | <input checked="" type="checkbox"/> |
| Increased customer satisfaction | <input checked="" type="checkbox"/> |
| Implementation of laws or regulatory requirements | <input checked="" type="checkbox"/> |
| Other | <input checked="" type="checkbox"/> |

Outcome Comments

The HSRB's role as adviser to EPA on the ethical and scientific issues arising from studies using human subjects in research has strengthened the Agency's capabilities to support the ethical conduct and regulatory compliance of human subjects research

conducted, supported, or regulated by EPA.

What are the cost savings associated with this committee?

Checked if Applies

| | |
|----------------------------|-------------------------------------|
| None | <input type="checkbox"/> |
| Unable to Determine | <input checked="" type="checkbox"/> |
| Under \$100,000 | <input type="checkbox"/> |
| \$100,000 - \$500,000 | <input type="checkbox"/> |
| \$500,001 - \$1,000,000 | <input type="checkbox"/> |
| \$1,000,001 - \$5,000,000 | <input type="checkbox"/> |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/> |
| Over \$10,000,000 | <input type="checkbox"/> |
| Cost Savings Other | <input type="checkbox"/> |

Cost Savings Comments

NA

What is the approximate Number of recommendations produced by this committee for the life of the committee?

314

Number of Recommendations Comments

During FY 2023, the EPA requested that the HSRB respond to four (4) charge questions in various topic areas. The Board provided their responses to charge questions/recommendations to five topics: "Controlled Human Studies with Formaldehyde"; "Acute Odor and Irritation Response in Healthy Nonsmokers with Formaldehyde Exposure"; "Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-Based Repellent Spray with Ticks Under Laboratory Conditions."; "A Single Oral Dose Study with Acephate Technical in Humans"; "Efficacy Testing of SCJ Personal Repellents Products against Mosquitos in a Field Study". The Committee submitted final meeting reports to EPA's Science Advisor summarizing their advice and recommendations on these and other interesting topics. The Committee provided approximately 77 recommendations to EPA.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

0%

% of Recommendations Fully Implemented Comments

Partial versus full implementation of HSRB recommendations could not be assessed due to the nature of the charge questions/responses and the way the HSRB recommendations were presented. The following is an example of how HSRB recommendations were used by the Agency: EPA decided to rely on the results of a study to support a pesticide registration decision based on HSRB recommendations.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

0%

% of Recommendations Partially Implemented Comments

See previous response.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

The Agency sets aside time at each HSRB public meeting to provide an update on EPA follow-up to HSRB recommendations.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

| | |
|-----------------------------------|--------------------------|
| Reorganized Priorities | <input type="checkbox"/> |
| Reallocated resources | <input type="checkbox"/> |
| Issued new regulation | <input type="checkbox"/> |
| Proposed legislation | <input type="checkbox"/> |
| Approved grants or other payments | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Action Comments

NA

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

Checked if Applies

| | |
|---------------------------|-------------------------------------|
| Contact DFO | <input checked="" type="checkbox"/> |
| Online Agency Web Site | <input checked="" type="checkbox"/> |
| Online Committee Web Site | <input checked="" type="checkbox"/> |
| Online GSA FACA Web Site | <input checked="" type="checkbox"/> |
| Publications | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Access Comments

N/A