

## 2025 Current Fiscal Year Report: Human Studies Review Board

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<b>1. Department or Agency</b>	<b>2. Fiscal Year</b>
Environmental Protection Agency	2025
<b>3. Committee or Subcommittee</b>	<b>3b. GSA Committee No.</b>
Human Studies Review Board	28234

<b>4. Is this New During Fiscal Year?</b>	<b>5. Current Charter</b>	<b>6. Expected Renewal Date</b>	<b>7. Expected Term Date</b>
No	03/08/2024	03/08/2026	

<b>8a. Was Terminated During Fiscal Year?</b>	<b>8b. Specific Termination Authority</b>	<b>8c. Actual Term Date</b>
No		

<b>9. Agency Recommendation for Next Fiscal Year</b>	<b>10a. Legislation Req to Terminate?</b>	<b>10b. Legislation Pending?</b>
Continue	No	Not Applicable

**11. Establishment Authority** Statutory (Congress Created)

<b>12. Specific Establishment Authority</b>	<b>13. Effective Date</b>	<b>14. Committee Type</b>	<b>14c. Presidential?</b>
Public Law 109-54 and 40 CFR 26.1603	02/21/2006	Continuing	No

**15. Description of Committee** Scientific Technical Program  
Advisory Board

**16a. Total Number of Reports** 2

<b>16b. Report Date</b>	<b>Report Title</b>
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11/22/2024	Report of the U.S. Environmental Protection Agency Human Studies Review Board
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05/09/2025	Report of the U.S. Environmental Protection Agency Human Studies Review Board - April 3, 2025
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**Number of Committee Reports Listed:** 2

<b>17a. Open</b>	<b>17b. Closed</b>	<b>17c. Partially Closed</b>	<b>Other Activities</b>	<b>17d. Total</b>
3	0	0	0	3

## Meetings and Dates

Purpose	Start	End
Quarterly HSRB meeting	10/10/2024	10/11/2024
Follow-up to October HSRB Meeting	11/06/2024	11/06/2024
HSRB Science and Ethics review of "Evaluation of Topically Applied Insect Repellent Products Containing Oil of Lemon Eucalyptus (Citriodiol) Against Mosquitoes in the Field."	04/03/2025	04/03/2025

## Number of Committee Meetings Listed: 3

	Current FY	Next FY
<b>18a(1). Personnel Pmts to Non-Federal Members</b>	\$0.00	\$0.00
<b>18a(2). Personnel Pmts to Federal Members</b>	\$0.00	\$0.00
<b>18a(3). Personnel Pmts to Federal Staff</b>	\$0.00	\$0.00
<b>18a(4). Personnel Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$0.00	\$0.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)</b>	\$0.00	\$0.00
<b>18d. Other (all other funds not captured by any other cost category)</b>	\$0.00	\$0.00
<b>18e. Total Costs</b>	\$0.00	\$0.00
<b>19. Federal Staff Support Years (FTE)</b>	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. So far in FY 2025, the committee has met on two occasions (all virtual meetings) - October 10-11, 2024, and November 6, 2024. The HSRB submitted one report to EPA's Human Subjects Research Review Official 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 (four 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 in-person or virtual meeting when the HSRB has drafted their

report. This meeting provides the HSRB the opportunity to finalize their draft report. Though meetings are scheduled for every quarter, if no topics or charge questions are presented to the Board at the time, a meeting may be cancelled.

**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 have not been any closed or partially closed meetings in FY 2025. 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

Emily Sokol DFO

Committee Members	Start	End	Occupation	Member Designation
Allen, Albert	09/01/2018	08/31/2025	Tier 1, Senior Medical Fellow, Eli Lilly and Company, Indianapolis, IN	Special Government Employee (SGE) Member
Bruce, Gretchen	09/01/2024	08/31/2027	Director of Toxicology	Special Government Employee (SGE) Member
Cross, Chad	09/30/2022	09/29/2025	Associate Professor	Special Government Employee (SGE) Member
Day, Philip	09/01/2023	09/30/2026	Tier 1, Assistant Professor, Univ. of Texas, Southwestern, Dallas, TX	Special Government Employee (SGE) Member
Deming, Nicole	09/30/2022	09/29/2025	Assistant Dean and Assistant Professor of Bioethics	Special Government Employee (SGE) Member
Feinn, Richard	09/01/2024	08/31/2027	Professor	Special Government Employee (SGE) Member
Gillam-Shaffer, Thomas	09/01/2024	08/31/2027	Environmental Health Navigator	Special Government Employee (SGE) Member
Jiang, Weiying	09/30/2022	09/29/2025	Toxicologist	Special Government Employee (SGE) Member
Lewandowski, Thomas	12/01/2022	11/30/2025	Principal	Special Government Employee (SGE) Member

Melethil, Srikumaran	09/30/2022	09/29/2025	Professor Emeritus, Toxicology	Special Government Employee (SGE) Member
Milliken, George	09/30/2022	09/30/2025	Consultant	Special Government Employee (SGE) Member
Seicean, Sinziana	09/30/2022	09/29/2025	Senior Research and Environmental Scientist	Special Government Employee (SGE) Member
Sharp, Julia	10/01/2022	09/30/2025	Associate Professor	Special Government Employee (SGE) Member
Tuminello, Joseph	09/30/2022	09/29/2025	Assistant Professor of Bioethics	Special Government Employee (SGE) Member
Williams, David	09/30/2022	09/29/2025	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. So far in FY 2025, the committee has met on two occasions (all virtual meetings). The HSRB submitted one meeting report to EPA's Human Subjects Research Review Official summarizing their recommendations.

**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?

347

### Number of Recommendations Comments

So far in FY 2025, the EPA has requested that the HSRB respond to three (3) charge

questions in various topic areas. The board has provided their responses to charge questions/recommendations to on topic: "Operator dermal exposure and individual protection provided by personal protective equipment during application using a backpack sprayer in vineyards". The committee submitted final meeting report to EPA's Human Subjects Research Review Official summarizing their advice and recommendations on these and other interesting topics. The committee has provided approximately 2 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 ☐

Reallocated resources ☐



- |                                   |                          |
|-----------------------------------|--------------------------|
| 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