

2016 Current Fiscal Year Report: Human Studies Review Board

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1. Department or Agency	2. Fiscal Year
Environmental Protection Agency	2016
3. Committee or Subcommittee	3b. GSA Committee No.
Human Studies Review Board	28234

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	03/28/2016	03/28/2018	

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

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

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Committee Type	14c. Presidential?
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 3

16b. Report Date	Report Title
01/12/2016	October 19-20, 2015 Human Studies Review Board Meeting Final Report
03/30/2016	January 12-13, 2016 EPA Human Studies Review Board Meeting Report
08/25/2016	July 12-13, 2016 EPA Human Studies Review Board Meeting Report

Number of Committee Reports Listed: 3

17a. 6 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 6
 Open

Meetings and Dates

Purpose	Start	End
The Human Studies Review Board (HSRB) is a federal advisory committee operating under the Federal Advisory Committee Act (FACA) that provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research.	10/19/2015	10/20/2015
The Human Studies Review Board (HSRB) is a federal advisory committee operating under the Federal Advisory Committee Act (FACA) that provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research.	12/07/2015	12/07/2015
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The Human Studies Review Board (HSRB) is a federal advisory committee operating under the Federal Advisory Committee Act (FACA) that provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research.	03/30/2016	03/30/2016
The Human Studies Review Board (HSRB) is a federal advisory committee operating under the Federal Advisory Committee Act (FACA) that provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research.	07/12/2016	07/13/2016
The Human Studies Review Board (HSRB) is a federal advisory committee operating under the Federal Advisory Committee Act (FACA) that provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research.	08/25/2016	08/25/2016

Number of Committee Meetings Listed: 6

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$21,541.00	\$25,324.00

18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$164,280.00	\$166,908.00
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. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	\$0.00	\$0.00
18d. Other (all other funds not captured by any other cost category)	\$19,254.00	\$25,672.00
18e. Total Costs	\$205,075.00	\$217,904.00
19. Federal Staff Support Years (FTE)	1.00	1.00

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 research with human subjects. While the Committee is charged to provide comments on the science and ethics of

human subjects research conducted, supported, or regulated by EPA, in FY 2016 and similar to previous years, it has mainly focused on proposed and completed third party research involving intentional exposure of non-pregnant, non-nursing human adults, such research intended for submission to the Agency under the pesticide laws.

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 2016. 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

Jim Downing Executive Director

Committee Members	Start	End	Occupation	Member Designation
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Chadwick, Gary	10/19/2014	08/31/2017	Tier 1, Senior Consultant, HRP Consulting Group, Inc., Fairport, NY	Special Government Employee (SGE) Member
Dawson, Liza	09/02/2013	08/31/2017	Tier 1, National Institutes of Allergy & Infectious Diseases, Bethesda, MD	Regular Government Employee (RGE) Member
Fernandez, George	05/01/2010	08/31/2017	Tier 1, Professor, SAS Institute, Statistical Training and Technical Services, Sparks, NV	Special Government Employee (SGE) Member
Galbraith, Kyle	09/02/2013	08/31/2018	Tier 1, Carle Foundation Hospital, Urbana, IL	Special Government Employee (SGE) Member
Gbur, Edward	09/02/2013	08/31/2019	Tier 1, Professor, Agricultural Statistics Laboratory, University of Arkansas, Fayetteville, AR	Special Government Employee (SGE) Member
Halanych, Jewell	11/14/2011	08/31/2017	Tier 1, Assistant Professor, Internal Medicine Residency Program, University of Alabama at Birmingham, Montgomery, AL	Special Government Employee (SGE) Member
Maddalena, Randy	09/02/2013	08/31/2017	Tier 1, Physical Reserch Scientist, Indoor Environment, Lawrence Berkeley National Laboratory, Berkeley, CA	Special Government Employee (SGE) Member
Ramos, Kenneth	09/02/2013	08/31/2016	Tier 1, Precision Health Sciences, Arizona Health Sciences Center, Tucson, AZ	Special Government Employee (SGE) Member
Rivera, Suzanne	10/19/2014	08/31/2017	Tier 1, Vice President for Research & Technology Management, Case Western Reserve University, Cleveland Heights, OH	Special Government Employee (SGE) Member

			Tier 1, Professor, Department of Health Sciences	Special Government Employee (SGE) Member
Suh, Helen	09/16/2015	08/31/2018		
			Tier 1, Professor of Statistics of Entomology, Dept. of Statistics, University of Wisconsin, Madison, WI	Special Government Employee (SGE) Member
Zhu, Jun	10/19/2014	08/31/2017		

Number of Committee Members Listed: 11

Narrative Description

The Human Studies Review Board addresses 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 2016, 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 2016 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
- Trust in government
- Major policy changes
- Advance in scientific research
- Effective grant making
- Improved service delivery
- Increased customer satisfaction

- Implementation of laws or regulatory requirements
- Other

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
- Unable to Determine
- Under \$100,000
- \$100,000 - \$500,000
- \$500,001 - \$1,000,000
- \$1,000,001 - \$5,000,000
- \$5,000,001 - \$10,000,000
- Over \$10,000,000
- Cost Savings Other

Cost Savings Comments

NA

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

269

Number of Recommendations Comments

During FY 2016, the EPA requested that the HSRB respond to twenty three (23) charge questions in various topic areas. The Board provided their responses to charge questions/recommendations to several topic areas, such as: a Completed Study from the U.S. Department of Agriculture Describing Laboratory Evaluation of Bite Protection from Repellent-Impregnated Clothing for the United States Military and Completed Studies and a Monograph Report for Agricultural Handler Exposure during Open Pour Mixing/Loading of Wettable Powders (Agricultural Handlers Exposure Task Force). The Committee submitted a final meeting report to EPA’s Science Advisor summarizing their advice and

recommendations to these and other interesting topics.

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

In FY 2016, the HSRB reviewed and responded to charge questions related to third party proposed and complete research evaluating pesticide human intentional exposure toxicity studies, and pesticide handler exposure research. 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
- Proposed legislation
- Approved grants or other payments

Other

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

Online Agency Web Site

Online Committee Web Site

Online GSA FACA Web Site

Publications

Other

Access Comments

N/A