

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY CHARTER

HUMAN STUDIES REVIEW BOARD

1. Committee's Official Designation (Title):

Human Studies Review Board

2. Authority:

This charter renews the Human Studies Review Board (HSRB) in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. 10. This Committee was established January 20, 2006 under the authority of the “Department of Interior, Environment, and Related Agencies Appropriations Act, 2006”, Public Law 109-54 and 40 CFR 26.1605.

3. Objectives and Scope of Activities:

The HSRB is a statutory FAC to provide advice, information, and recommendations on issues related to scientific and ethical aspects of proposed or completed human research submitted by EPA, including research involving intentional exposure of human subjects to any substance to be considered by EPA in connection with an action under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a), and research involving intentional exposure of human subjects to pesticides to be considered by EPA in connection with an action under any statute or regulation administered by EPA.

4. Description of Duties:

The duties of the HSRB are solely to provide scientific or policy advice to EPA on:

- a. Research Proposals and Protocols;
- b. Reports of completed research with human subjects; and
- c. How to strengthen EPA’s programs for protection of human subjects of research.

5. Agency or Official to Whom the Committee Reports:

The HSRB will report to the EPA Administrator through the Human Subjects Research Review Official (HSRRO).

6. Support:

EPA will be responsible for financial and administrative support. If it is determined necessary to have an in-person meeting, EPA may pay travel and per diem expenses as appropriate.

7. Estimated Annual Operating Costs and Staff Years:

The estimated annual operating cost of HSRB is \$182,900, which includes 0.3 staff-years of support.

8. Designated Federal Officer:

A full-time or permanent part-time employee of EPA will be appointed as the Designated Federal Officer (DFO). The DFO or an alternate will be present at all meetings of the advisory committee and subcommittees. Each meeting will be conducted in accordance with an agenda approved in advance by the DFO. The DFO is authorized to adjourn any meeting when he or she determines it is in the public interest to do so, and will chair meetings when directed to do so by the official to whom the committee reports.

9. Estimated Number and Frequency of Meetings:

The Committee expects to meet up to four (4) times a year. Meetings may occur approximately once every three (3) months or as needed and approved by the DFO and are expected to occur by teleconference.

As required by FACA, HSRB will hold open meetings unless the EPA Administrator determines that a meeting or a portion of a meeting may be closed to the public in accordance with 5 U.S.C. 552b(c). Interested persons may attend meetings, appear before the Board as time permits, and file comments with the HSRB.

10. Duration:

Continuing.

11. Termination:

This charter will be in effect for two years from the date it is filed with Congress. After this two-year period, the charter may be renewed as authorized in accordance with Section 14 of FACA.

12. Membership and Designation:

The HSRB will be composed of approximately fourteen (14) members who will serve as Special Government Employees (SGEs) or Regular Government Employees (RGEs), who are not EPA employees per 40 CFR 26.1605. In selecting members, the EPA will consider candidates from the environmental scientific/technical fields, human health care professionals, academia, industry, public and private research institutes or organizations, other governmental agencies,

and other relevant interest areas. In accordance with Executive Order 14035 (June 25, 2021), EPA values and welcomes opportunities to increase diversity, equity, inclusion and accessibility on its federal advisory committees. EPA's federal advisory committees have a workforce that reflects the diversity of the American people. The HSRB membership will include experts in relevant scientific or technical disciplines such as bioethics, biostatistics, human health risk assessment and human toxicology.

13. Subcommittees:

EPA, or the HSRB with EPA's approval, may form HSRB subcommittees or workgroups for any purpose consistent with this charter. Such subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the chartered HSRB for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee nor can they report directly to the Agency.

14. Recordkeeping:

The records of the Committee, formally and informally established subcommittees, or other subgroups of the Committee, will be handled in accordance with NARA General Records Schedule 6.2 and EPA Records Schedule 1024 or other approved agency records disposition schedule. Subject to the Freedom of Information Act, 5 U.S.C. 552, these records will be available for public inspection and copying, in accordance with the Federal Advisory Committee Act.

15. Filing Date:

March 6, 2024

Agency Approval Date

1-26-2024

GSA Consultation Completion Date

March 8, 2024

Date Filed with Congress