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. App. 2. This Committee was established in February of 2006 under the authority of 40 CFR 26.1603. The HSRB is in the public interest and supports the U.S. Environmental Protection Agency (EPA) in performing its duties and responsibilities.

3. Objectives and Scope of Activities:

The HSRB will provide advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research.

The major objectives are to provide advice and recommendations 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.

4. Description of Committees Duties:

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

5. Official(s) to Whom the Committee Reports:

HSRB will report to the EPA Administrator through EPA's Science Advisor.

6. Agency Responsible for Providing the Necessary Support:

EPA will be responsible for financial and administrative support. Within EPA, this support will primarily be provided by the Office of the Science Advisor (OSA).

7. Estimated Annual Operating Costs and Person Years:

The estimated annual operating cost of HSRB is $424,000, which includes 1.2 person-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 a designee 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 approximately four (4) times a year. Meetings may occur approximately once every three (3) months or as needed and approved by the DFO. EPA may pay travel and per diem expenses when determined necessary and appropriate.

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 and 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.

11. Member Composition:

The HSRB will be composed of approximately fifteen (15) members who will serve as Special Government Employees (SGEs) or Regular Government Employees (RGEs). 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. The HSRB membership will include experts in relevant scientific or technical disciplines such as bioethics, biostatistics, human health risk assessment and human toxicology.

12. Subgroups:

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.

13. 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 26, Section 2 and EPA Records Schedule 181 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.

March 25, 2014
Agency Approval Date

MAR 2 8 2014
Date Filed with Congress