

December 12, 2006

**BYLAWS OF THE
U.S. ENVIRONMENTAL PROTECTION AGENCY
HUMAN STUDIES REVIEW BOARD**

ARTICLE I - NAME

The name of the organization is the Human Studies Review Board.

ARTICLE II - AUTHORITY

a) The Human Studies Review Board (hereinafter referred to as HSRB or the Board) is established by Agency authority, within the U.S. Environmental Protection Agency (EPA), under a charter approved by the Deputy Administrator, reviewed by the U. S. General Services Administration, and filed with the appropriate congressional committees.

b) HSRB advises the EPA Administrator consistent with its current approved charter and the requirements of the Federal Advisory Committee Act (FACA) (5 U.S.C.App.2).

ARTICLE III - MISSION AND SCOPE

The mission and scope of the HSRB is provided in the Board's charter.

ARTICLE IV - MEMBERSHIP

Section 1. Member Composition

a) Members of the Board are nationally recognized experts in relevant scientific or technical disciplines such as biostatistics; human toxicology, including pharmacokinetic and toxicokinetic studies, clinical trials, and toxicology of cholinesterase inhibitors and other classes of environmental substances; bioethics; and human health risk assessment.

b) In selecting Members of the Board, EPA considers experts 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.

Section 2: Participant Categories, Appointment Process, and Terms

a) Board Members

1) Members of the Board provide independent advice and serve either as Special Government Employees or Regular Government Employees.

2) Board members have full rights and decision-making in all Board actions. As a group, Board members provide recommendations to the Agency.

3) Board members are expected to attend and participate at all Board meetings and participate in preparing Board reports and recommendations.

4) Board members are appointed by the EPA Deputy Administrator, in consultation with the HSRB Designated Federal Officer (DFO). The Board Chair works with the DFO in developing member recommendations.

5) Board members may serve for a term of three years, utilizing a system of staggered terms of appointments. A Board member may be reappointed by the EPA Deputy Administrator.

6) A Board member may serve as a member of any HSRB Subcommittee formed under Board auspices.

b) HSRB Consultants

1) Consultants to the Board or its subcommittees serve either as Special Government Employees or Regular Government Employees.

2) Consultants provide specialized information or assistance to the Board or Subcommittee, as needed.

3) Consultants are selected by the EPA Science Advisor, in consultation with the Board Chair and DFO.

4) Consultants attend specific Board or Subcommittee meetings and provide input and advice as requested by the Board or Subcommittee. Consultants are not members of the Board and do not participate in the Board's decision-making process.

c) Subcommittee Members

1) As noted in the Board's charter, EPA or the HSRB with EPA's approval, may form HSRB subcommittees.

2) Subcommittee members serve as either Special Government Employees or Regular Government Employees and are appointed in the same way as Board members.

3) Subcommittee members need not be members of the Board.

4) Membership of subcommittees is expected to include at least one member (but fewer than one-half of the members) of the Board.

d) Working Groups Participants

- 1) The HSRB Chair (or Subcommittee Chair in consultation with the HSRB Chair and DFO), may form HSRB Working Groups.
- 2) Working Groups consist of two or more Board or Subcommittee members (but fewer than one-half of the Board or Subcommittee) or individuals who are not members of the Board.
- 3) Working Groups comprised of individuals who are not members of the Board or Subcommittee are expected to include at least one Board or Subcommittee member.

Section 3. Termination of Membership

- a) All Board and Subcommittee members serve at the pleasure of the Administrator.
- b) A Board or Subcommittee member may be removed for cause, as determined by the EPA Administrator, when:
 - 1) He/She is determined to have violated the Ethics in Government Act; or,
 - 2) For other reasons the Administrator deems appropriate, including missing two consecutive meetings.
- c) Replacement of a member who resigns or is removed results in a new membership term for the new member.

ARTICLE V – BOARD ORGANIZATION

Section 1. Officers

a) Board Chair

- 1) The Chair of the HSRB is appointed by the Administrator, in consultation with the DFO. The Board Chair is expected to serve a two-year term of office. The Chair may be reappointed if the Administrator deems it appropriate.
- 2) The Board Chair works with the DFO to establish priorities and identify issues to be addressed. In addition, the Board Chair is responsible for managing Board meetings and for certifying the accuracy of Board meeting minutes.

b) Board Vice Chair

- 1) The Board Vice Chair serves as chair of the Board in the absence of the Board Chair.
- 2) The Board Vice Chair is appointed by the Administrator, in consultation with the DFO.

c) Subcommittee Chairs

1) The Chair of each Subcommittee is to be a member of the Board. The Board Chair appoints the Subcommittee Chairs, in consultation with the DFO. Each Subcommittee Chair is expected to serve a one year term. Subcommittee Chairs may be reappointed.

2) The Subcommittee Chair works with the Board Chair, in consultation with the DFO, to establish priorities and identify issues that the subcommittee should address. In addition, the Subcommittee Chair is responsible for managing Subcommittee meetings and for certifying the accuracy of Subcommittee minutes.

3) The Board Chair, in consultation with the Subcommittee Chair and DFO can designate another Board member to serve in the absence of the Chair.

Section 2. Designated Federal Officers

a) As required by Section 10(e) of the Federal Advisory Committee Act, the Board must have a DFO or his/her designee present at all meetings. FACA authorizes the DFO to adjourn any meeting when it is determined to be in the public interest to do so. Under EPA policy, Subcommittees also have DFOs present for all meetings and the Subcommittee DFO also has the authority to adjourn meetings when it is in the public interest to do so.

b) EPA Office of the Science Advisor appoints the DFO.

Section 3. Board

a) The Board is comprised of the Board Chair and Board Members. Board members and the Board Chair are responsible for reviewing, determining whether to approve, and forwarding all approved reports and recommendations to the Agency.

Section 4. Subcommittee

a) The mission and scope of each Subcommittee is determined by the Board Chair, in consultation with the DFO. As required by FACA and GSA regulations, Subcommittees must report to the Board; they may not provide advice or recommendations directly to EPA.

Section 5. Working Groups

a) The mission and scope of each Working Group is determined by the Board Chair or Subcommittee Chair, in consultation with the DFO.

b) Working Groups report to the Board or Subcommittee where they were formed.

ARTICLE VI - MEETINGS

Section 1. Compliance with FACA

a) The Board is subject to FACA and will function in compliance with FACA. Under EPA policy, Subcommittees also follow the FACA openness procedures. Working Groups are not subject to FACA.

Section 2. Meeting Scheduling

a) Meeting frequency will occur as specified in the Board's charter.

b) The Board is expected to meet at times and places as designated by the DFO, in consultation with the Board Chair.

c) Subcommittees meet as needed at the call of the Board Chair, in consultation with the Subcommittee Chair and the DFO.

d) Working Groups meet as needed at the call of the Board Chair, in consultation with the DFO.

e) The DFO and Chair will strive to schedule meetings so that all areas of necessary expertise are adequately represented.

f) The DFO works with the Board Chair, Subcommittee Chair(s) and Working Group participants to schedule meetings taking into account member schedules.

Section 3. Quorum

a) The presence of 50 percent plus one of the Board (or Subcommittee) members constitutes a quorum for the transaction of Board (or Subcommittee) business in accordance with Article VI Section 2 e.

Section 4. Minutes

a) The DFO is responsible for the preparation and distribution of Board and Subcommittee meeting minutes.

b) Board meeting minutes are reviewed and certified by the Chair; Subcommittee meeting minutes are reviewed and certified by the Subcommittee Chair.

c) As required by FACA, the DFO will make certified copies of the meeting minutes available within 90 calendar days after the Board/Subcommittee meeting.

ARTICLE VII - REPORTS AND RECOMMENDATIONS

Section 1. Board Reports and Recommendations

- a) Board adoption of reports or recommendations will be approved by consensus. Consensus is defined as all Board members accepting the Board reports and/or recommendations. Through the consensus process every Board member's position is heard and each member is able to accept the decision. When a consensus is reached the report will reflect the decision as a "Board" decision. If a consensus cannot be reached, the report or recommendation of the majority should be forwarded to EPA noting that the conclusion is from a "majority of the Board." Minority views may be included in or appended to the majority report or recommendation at the request of dissenting member(s).
- b) The Board Chair transmits approved Board reports or recommendations to the EPA Administrator through the EPA Office of the Science Advisor.
- c) Each proposed report or recommendation is to be distributed to all Board Members for a minimum 7 calendar day review unless exceptional circumstances necessitate a more immediate response.
- d) The Board will strive to take its final action on a proposed report or recommendation within 45 calendar days from the date the initial proposed report or recommendation was submitted to the Board for review and approval, unless exceptional circumstances necessitate a more immediate response. Approval of a report or recommendation is to take place in an open Board meeting.

Section 2. Subcommittee Reports and Recommendations

- a) Subcommittees, with the Board Chair's approval, may bring a proposed report or recommendation forward to the Board for review and approval.
- b) Subcommittees operate under the same procedures as the Board.

ARTICLE VIII - AMENDMENTS TO BYLAWS

The HSRB's Bylaws can be amended or repealed (in whole or in part) by a vote of a minimum of two-thirds of the Board and with the approval of EPA. Such action may be taken at any regular meeting, by electronic mail, or by mail, provided that a notice of intent to do so has been given to each Member at least 30 days preceding the date for a final decision.