

US EPA ARCHIVE DOCUMENT

Dated: October 6, 2008.

Sara Hisel-McCoy,

Director, Collection Strategies Division.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2008-0720; FRL-8728-2]

Request for Nominations to the EPA Human Studies Review Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) Office of the Science Advisor (OSA) is soliciting nominations of people qualified in the areas of bioethics, biostatistics, human health risk assessment and human toxicology to serve on the Human Studies Review Board (HSRB). The HSRB is a Federal advisory committee, operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. App. 2 § 9, providing advice and recommendations to EPA on scientific and ethical aspects of research with human subjects.

DATES: Nominations ("comments") should be submitted to EPA no later than November 10, 2008.

ADDRESSES: Submit your nominations, identified by Docket ID No. EPA-HQ-ORD-2008-0720, by any of the following methods:

Internet: <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

E-mail: ORD.Docket@epa.gov.

USPS Mail: ORD Docket, Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

Hand or Courier Delivery: EPA Docket Center (EPA/DC), Room 3304, EPA West Building, 1301 Constitution Avenue NW., Washington, DC 20460, Attention Docket ID No. EPA-HQ-ORD-2008-0720. Deliveries are accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your nominations to Docket ID No. EPA-HQ-ORD-2008-0720. EPA's policy is that all nominations received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the nomination includes

information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through <http://www.regulations.gov> or e-mail that you consider to be CBI or otherwise protected from disclosure.

The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your nomination. By contrast, if you send an e-mail nomination directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the nomination that is placed in the public docket and made available on the Internet. If you submit a nomination electronically, EPA recommends that you include your name and other contact information in the body of your nomination and with any disk or CD-ROM you submit. If EPA cannot read your nomination due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider it. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index under the docket number. Even though it will be listed by title in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Copyright material will be publicly available only in hard copy. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the ORD Docket, EPA/DC, Room 3334, EPA West, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

FOR FURTHER INFORMATION CONTACT: Paul I. Lewis, Office of the Science Advisor, Mail Code 8105R, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564-8381, fax number: (202) 564-2070, e-mail: lewis.paul@epa.gov.

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be

of particular interest to persons who conduct or assess human studies, especially studies on substances regulated by EPA, and to persons who may sponsor or conduct research with human subjects with the intention to submit it to EPA for consideration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

You may access this **Federal Register** document electronically either through <http://www.regulations.gov> or through the EPA Web site under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

C. What Should I Consider as I Prepare My Nomination for EPA?

You may find the following suggestions helpful for preparing your nomination:

1. Provide as much supporting information as possible about the nominee, including contact information.
2. Make sure to submit your nomination by the deadline in this document.
3. To ensure proper receipt by EPA, be sure to include the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date and **Federal Register** citation.

SUPPLEMENTARY INFORMATION

Background

On February 6, 2006 the Agency published a final rule for protection of human subjects of research (71 FR 24 6138) that called for creating a new, independent human studies review board (i.e. HSRB). The HSRB is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. App. 2 § 9. The HSRB provides advice, information, and recommendations to EPA on issues related to scientific and ethical aspects of human subjects research. The major objectives of the HSRB are to provide advice and recommendations on: (1) Research proposals and protocols; (2) reports of completed research with human subjects; and (3) how to strengthen

EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through EPA's Science Advisor.

This notice solicits nominations of individuals with expertise in bioethics, biostatistics, human health risk assessment and/or human toxicology to fill anticipated vacancies on the Board. General information concerning the HSRB, including its charter, current membership, and activities can be found on the EPA Web site at <http://www.epa.gov/osa/hsrb/>.

Process and Deadline for Submitting Nominations

Any interested person or organization may nominate someone to be considered as prospective nominees for the HSRB. Additional avenues and resources may be utilized in the solicitation of nominees to encourage a broad pool of expertise. Nominees should be experts who have sufficient professional qualifications, by training and experience, to provide expert comment on the ethical and scientific issues that may come before the HSRB. Responsibilities of HSRB members include reviewing extensive background materials between meetings of the Board, preparing draft responses to Agency charge questions, attending Board meetings, participating in the discussion and deliberations at these meetings, drafting assigned sections of meeting reports, and reviewing and helping to finalize Board reports.

EPA seeks nominees who are nationally recognized experts in one or more of the following areas:

- Bioethics: Expertise in the ethics of research with human subjects.
- Biostatistics: Expertise in statistical design and analysis of research with human subjects, especially research with small sample sizes.
- Human health risk assessment: Expertise in epidemiology, exposure analysis, public health or human research regulations.
- Human toxicology: Expertise in toxicity of environmental substances, mechanisms of toxicity and/or clinical studies.

All nominations should include: (1) A current curriculum vitae (C.V.) providing the nominee's educational background, qualifications, leadership positions in national associations or professional societies, relevant research experience and publications; and (2) a summary of the above in a one-page biographical sketch.

The qualifications of nominees for membership on the HSRB will be assessed in terms of the specific expertise sought for the HSRB. Qualified

nominees who agree to be considered further will be included in a smaller "Short List". The Short List of nominees' names and biographical sketches will be posted for 14 calendar days for public comment on the EPA Web site at <http://www.epa.gov/osa/index.htm>. The public will be encouraged to provide additional information about the nominees that EPA should consider. At the completion of this comment period, EPA will select new Board members from the Short List. Candidates not selected for HSRB membership at this time may be considered for HSRB membership as vacancies arise in the future, or for service as consultants to the HSRB. The Agency estimates that the names of Short List candidates will be posted in February, 2009. However, please be advised that this is an approximate time frame and the date could change. Thus, if you have any questions concerning posting of Short List candidates on the OSA Web site, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Interested candidates who are employees of a federal department or agency (other than EPA) or are members of another federal advisory committee are eligible to serve on the HSRB, and their nominations are welcome. Other factors that will be considered include: Availability to participate in the Board's scheduled meetings, absence of any conflicts of interest and absence of an appearance of a lack of impartiality, and independence with respect to the matters likely to come under HSRB review. Though financial conflicts of interest or the appearance of a lack of impartiality, lack of independence, or bias may lead to nonselection, the absence of such concerns does not ensure that a candidate will be selected to serve on the HSRB. Numerous qualified candidates are likely to be identified. Selection decisions will involve careful weighing of many factors, including, but not limited to, the candidates' areas of expertise and professional qualifications, and responses to the Short List in achieving the overall balance of different perspectives and areas of expertise on the Board.

Members of the HSRB are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, each nominee will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of

research support. The information provided is confidential and will not be disclosed to the public. Before a candidate is considered further for service on the HSRB, EPA will evaluate each candidate to assess whether there is any conflict of financial interest, appearance of a lack of impartiality, or prior involvement with matters likely to be reviewed by the Board.

Nominations should be submitted by one of the methods listed under **ADDRESSEES**. The Agency will consider all nominations received on or before November 10, 2008. Final selection of members is a discretionary function of the Agency and will be announced on the EPA Web site at <http://www.epa.gov/osa/hsrb> as soon as they are made.

Dated: September 26, 2008.

George M. Gray,
Science Advisor.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-8726-7]

National and Governmental Advisory Committees to the U.S. Representative to the Commission for Environmental Cooperation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Under the Federal Advisory Committee Act, Pub. L. 92-463, EPA gives notice of a meeting of the National Advisory Committee (NAC) and Governmental Advisory Committee (GAC) to the U.S. Representative to the North American Commission for Environmental Cooperation (CEC). The National and Governmental Advisory Committees advise the EPA Administrator in his capacity as the U.S. Representative to the CEC Council. The Committees are authorized under Articles 17 and 18 of the North American Agreement on Environmental Cooperation (NAAEC), North American Free Trade Agreement Implementation Act, Pub. L. 103-182, and as directed by Executive Order 12915, entitled "Federal Implementation of the North American Agreement on Environmental Cooperation." The NAC is composed of 12 members representing academia, environmental non-governmental organizations, and private industry. The GAC consists of 12 members representing state, local, and Tribal governments. The Committees are