

[FR Doc. 94-19568 Filed 8-11-94; 8:45 am]
BILLING CODE 4710-20-M

OFFICE OF SCIENCE AND TECHNOLOGY

National Bioethics Advisory Commission Proposed Charter

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Request for Comments.

SUMMARY: This notice describes a proposal to establish a National Bioethics Advisory Commission within the Executive Branch. The Commission would be charged to consider issues of bioethics arising from research on human biology and behavior, and the applications of that research.

DATES: Comments must be received on or before October 11, 1994.

ADDRESSES: Submit written comments by mail to: Bioethics Docket, Office of Science and Technology Policy, Room 436, OEOB, Washington, D.C. 20500, or by FAX to: 202-456-64027.

FOR FURTHER INFORMATION CONTACT: By mail: Rachel E. Levinson, Assistant Director for Life Sciences, Office of Science and Technology Policy, Room 436, OEOB, Washington, D.C. 20500. Office telephone number: 202-456-6137.

SUPPLEMENTARY INFORMATION: OSTP proposes that a standing advisory body be established within the Executive Branch to consider issues of bioethics arising from research on human biology and behavior, and the applications of that research. This action would fulfill a need recognized by all branches of the Federal government. For example, a report by the House of Representatives committee on Government Operations recommended establishment of an advisory committee to examine the ethical, legal and social implications of the Human Genome Project. The proposed advisory body would expand the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Department of Health, Education and Welfare's Ethics Advisory Board; and the President's Commission for the Study of Ethics Problems in Medicine and Biomedical and Behavioral Research.

OSTP seeks comments on a draft charter for a proposed National Bioethics Advisory Commission (NBAC). The NBAC would report to the President's National Science and Technology Council (NSTC). This arrangement will facilitate access to the

deliberations and recommendations of the NBAC for the Executive Branch agencies most heavily invested in biological and behavioral research.

The Commission would be asked to identify and develop broad overarching principles to govern the ethical conduct of biological and behavioral research, and the applications of that research. The proposed NBAC would not have responsibility for the review and approval of individual projects.

The draft charter seeks to strike a balance between defining the NBAC's agenda so as to fulfill governmental needs, and allowing the Commission sufficient flexibility to advise the government on issues this group of experts and stakeholders believe should be addressed.

The charter specifies two prospective areas of inquiry, issues in the management and use of genetic information and protection of the rights and welfare of research subjects. Discrete issues that fall under these two broad topics include: issues of genetic privacy, screening for genetic disorders, intellectual property rights, access to research data or materials developed with public funding, current views on informed consent, adequacy and implementation of Federal human subject research guidelines, and the concept of "minimal risk."

In addition, several other potential issues for consideration by the Commission have been raised in discussions to date including: adequacy and implementation of Federal human subject research guidelines, recommendations on requirements to maintain research data, and the ethical aspects of access to costly health care technology. The question is, how best might the scope of the Commission's charge be defined so as to meet public needs for deliberation of pressing issues in bioethics, without being so broad as to limit its effectiveness? An alternative option for addressing the last issue, for example, might be referral to a body more directly involved with decisions related to the provisions of health care and relevant cost/benefit analysis.

The Commission would be established in accordance with the Federal Advisory Committee Act (FACA). As such, its meetings would be open to the public and announced in advance to facilitate public participation. In addition, reports produced by the NBAC would be made available to public either *in toto*, or in summary. The purpose of these efforts would be to involve the public in the deliberation of the NBAC to the greatest extent possible.

As a FACA committee, the NBAC will be required to have a balanced membership. Naturally, selection of Commission members is going to be a delicate process that should take into account the social and cultural mores of the times in order to establish a body that is sensitive to the potential impacts of its deliberations and recommendations. The draft charter proposes that members be appointed by the President. Suggestions for potential members or membership posts are sought through this Notice.

Draft Charter

Proposed National Bioethics Advisory Commission

Purpose

The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, other appropriate entities and the public, on bioethical issues arising from research on human biology and behavior, and the applications of that research.

Authority

42 U.S.C. 6617(a)(2). This Commission is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation of advisory committees, and implementing regulations (41 CFR 101-6.10).

Functions

The National Bioethics Advisory Commission shall advise, consult with, and make recommendations to the National Science and Technology Council and other appropriate entities, and also make their advice and recommendations available to the public. The Commission's purview includes the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior, and applications of that research. The Commission shall identify broad, overarching principles to govern the ethical conduct of research, citing individual projects only as illustrations for such principles. The Commission shall not be responsible for the review and approval of individual projects.

As a first priority, the Commission will direct its attention to consideration of:

- A. Issues in the management and use of genetic information; and

B. Protection of the rights and welfare of research subjects.

In receiving and responding to requests for advice and recommendations from the National Science and Technology Council, the Commission shall consider four criteria in establishing priority for its activities:

- A. The public health or public policy urgency of the bioethical issue.
- B. The relation of the bioethical issue to the goals for Federal investment in science and technology,
- C. The absence of another body able to fruitfully deliberate on the bioethical issue.
- D. The extent of interest in the issue across the government. (The Commission ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)

The Commission also shall have the authority to identify bioethical issues, on its own behalf, for deliberation. The Commission will accept suggestions of issues for consideration from Federal agencies, Congress and the public. The Commission's decision to deliberate on a specific topic shall be made in consultation with the National Science and Technology Council. In all such instances, the four stated criteria for establishing priority shall pertain.

Structure

The National Bioethics Advisory Commission shall consist of not more than 15 members, including the Chairperson. Appointments shall be made by the President, who shall select from knowledgeable non-Government experts and community representatives with special qualifications and competition to deal effectively with bioethical issues of concern to the participating departments and agencies. At least one member shall be selected from each of the following categories of primary expertise: (i) bioethics/theology; (ii) social/behavioral science; (iii) law; (iv) medicine/allied health professions; and (v) biological research. At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and non-scientists.

Members shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by appropriate action prior to its termination. The Chairperson shall be appointed by the

President. The term of office for the Chairperson shall be two years, renewable by appropriate action of the President.

If a vacancy occurs on the Commission, the President shall make an appointment to fulfill the term. Any member appointed to fill a vacancy occurring prior to expiration of the term for which his or her predecessor was appointed shall serve for the remainder of such term. Members may serve after the expiration of their terms until their successors have taken office.

The Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary.

The Commission is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on the Commission, the Commissioner is also authorized to contract for the services of non-governmental consultants who may conduct analyses, prepare reports and background papers or prepare other materials for consideration by the Commission, as appropriate.

In order to avoid duplication of effort, the Commission may, in lieu of, or as part of any of its authorized activities, incorporate the results of the deliberations of another entity as long as the Commission sets forth its reasons for doing so.

The Assistant to the President for Science and Technology shall be notified upon establishment of each subcommittee, and shall be provided information on the name, membership (including chair), function, estimated duration of the subcommittee, and estimated frequency of meetings.

Management and support services shall be provided by the Office for Protection from Research Risks, Department of Health and Human Services. Additional resources including, but not limited to personnel, office support and printing will be provided by other NTSC member agencies.

Meetings

Meetings of the Commission shall be held up to 10 times a year at the call of the Chairperson with the advance approval of a Federal Government official who shall also approve the agenda. Meetings of the subcommittee(s) shall be convened as necessary. A Federal Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Assistant to the President for Science and Technology. Advance notice of all meetings shall be given to the public

Meetings shall be conducted, and records of proceedings kept, as required by applicable laws and Federal regulations.

Compensation

Members may be compensated at a rate not to exceed the maximum pay authorized by 5 U.S.C. 3109, plus per diem and travel expenses as in accordance with standard government travel regulations.

Annual Cost Estimate

The estimated annual cost for operating the National Bioethics Advisory Commission, including compensation and travel expenses for members and contracting and publication services costs, but excluding that for staff support, \$1,500,000. The estimated annual person years of staff support is six, at an estimated annual cost of \$500,000.

Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, the appropriate committees of Congress, and other appropriate entities. The Commission may specifically identify the Federal department, agency or other entity to which particular recommendations are directed and request a response from the Federal department, agency or other entity within 180 days of publication of such recommendations.

Executive summaries of each report of the Commission shall be promulgated in the **Federal Register**. Such summaries shall specifically list the department, agency, or other entity to which any recommendations are directed and the date by which such responses are expected.

An annual report shall be submitted to the National Science and Technology Council and the appropriate committees of Congress. It shall contain, at a minimum, (i) the Commission's function; (ii) a list of members and their business addresses; (iii) the dates and places of meetings; (iv) a summary of the Commission's activities during the year, (v) a summary of the Commission's recommendations made during the year, and (vi) a summary of responses made by departments, agencies, or other entities to the Commission's recommendations during the year.

Termination Date

Unless renewed by appropriate action prior to its expiration, this National Bioethics Advisory Commission will

terminate two years from the date this charter is approved.

Barbara Ann Ferguson,

Administrative Officer, Office of Science and Technology Policy.

[FR Doc. 94-19688 Filed 8-11-94]

BILLING CODE 3170-01 OSTP-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Criteria and Application Process for the Secretarial Award for Excellence in Transportation Technology Research and Development

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Notice of Request for Nominations.

SUMMARY: the Department of Transportation (DOT) announces procedures for nominating individuals and organizations for the Secretarial Award for Excellence in Transportation Technology Research and Development. Awards are made annually by the Secretary of Transportation to recognize research and development contributions advancing the ability of the U.S. transportation industry to compete globally.

DATES: Nominations must be postmarked no later than October 30, 1994.

ADDRESSES: An original and three copies of the nomination should be sent to: Noah Rifkin, Director of Technology Deployment, Office of the Secretary, U.S. Department of Transportation, 400 7th Street, SW, Washington, DC 20590, Room 10200.

FOR FURTHER INFORMATION CONTACT: John E. Hohl, Technology Sharing Officer, Research and Special Programs Administration, U.S. DOT 400 7th Street, SW, Washington D.C. 20590 Telephone: (202) 366-4978.

SUPPLEMENTARY INFORMATION:

Background

This notice solicits nominations for the Secretarial Award for Excellence in Transportation Technology Research and Development and provides relevant information on the nomination and selection process. The award is honorary recognition in the form of a certificate from the Secretary of Transportation. Awards will be presented annually.

Purpose

DOT is committed to providing the nation with a safe, efficient, environmentally sound and

technologically advanced transportation system that promotes economic growth, enhances international economic competitiveness, and contributes to a secure and healthy environment. In fulfilling this mission, the Department intends to accelerate technological advances that promote the development and export of transportation technology and manufactured products. To further these goals, the Secretary of Transportation has established the Secretarial Award for Excellence in Transportation Technology Research and Development to recognize significant contributions to expanding the technology knowledge base and the ability of the transportation industry to compete internationally.

Organization Defined

• For purposes of this award, organizations include but are not limited to:

- Domestic or U.S. Corporations, including nonprofit corporations;
- Partnerships;
- Professional associations;
- Institutions of higher education;
- Federal, State, or local government; and
- Professional teams assembled for the special projects.

Evaluation Criteria

Nominations will be evaluated based on the following criteria:

- Quality and innovative nature of the technology developed;
- How the technology has enhanced industry competitiveness, both domestically and internationally;
- Significance of individual or organization nominated to the success of the development effort;
- Entrepreneurial nature of research effort (nature of collaboration);
- Potential for positive economic benefits to the U.S. or specific region; and
- Applicability to more than one mode of transportation.

The qualifying work may be a singular accomplishment or a series of accomplishments that have had a substantial effect over time. Generally, technologies applicable to more than one transportation mode will be more favorably considered.

Examples of achievements that may be recognized include but are not limited to:

- Safety Improvements—Technology that reduces the likelihood of vehicle accidents or the likelihood of serious injury when a vehicle accident does occur or otherwise improves the chances of post-accident survival/recovery of accident victims. This could

include research and development of instrumentation equipment, human factors, or biomechanics.

- Energy Savings—Technology that saves energy in the production, operation, or disposition of vehicles through research in materials development, alternative fuels, engine and propulsion modifications, aerodynamic modeling and drag reduction, and combustion research.

- Environmental Quality—Technology applicable to transportation that reduces emissions; hazardous, solid or toxic waste; noise. This could include research and development of products, processes, or measurement instrumentation.

- International Industrial Competitiveness—Technology that allows the U.S. transportation industry to achieve sustainable world-class capabilities to compete in the global marketplace through the sale of transportation vehicles and equipment in overseas markets or the provision of freight and passenger transportation services to support international trade and travel.

- Job Creation—Transportation technology that creates jobs and makes a positive contribution to the U.S. economy.

Evaluation Process

The DOT Research and Technology Coordinating Council, chaired by the Director of Technology will appoint an Evaluation Committee to evaluate nominations under the prescribed criteria and to recommend awardees.

Recommendations of the Evaluation Committee will be reviewed by a Selection Committee made up of members of the Research and Technology Steering Committee. Final selections will be made by the Secretary of Transportation.

Nominating Procedures

Any person may nominate individuals or organizations from industry, academia, or government. Nomination should be in the form of a letter and must demonstrate that the nominee has provided significant contributions, through technology research and development, to advancing the ability of the U.S. transportation industry to compete globally in an area of transportation systems development, vehicle or facility design, construction, operation, or maintenance. Nominations must include the following:

- Name and address of the individual or organization being nominated;
- Name, address, and telephone number of the nominator. If the