



CHARTER

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

AUTHORITY

Executive Order 13521, dated November 24, 2009. The Presidential Commission for the Study of Bioethical Issues (the “Commission”) is governed by provisions of Public Law 92-463, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Commission shall advise the President on bioethical issues that may emerge as a consequence of advances in biomedicine and related areas of science and technology. The Commission shall pursue its work with the goal of identifying and promoting policies and practices that ensure scientific research, healthcare delivery, and technological innovation are conducted in an ethically responsible manner. The Commission shall not be responsible for the review and approval of specific projects. The Commission may accept suggestions of issues for consideration from executive departments and agencies and the public as it deems appropriate in support of its mission.

DESCRIPTION OF DUTIES

To achieve this goal, the Commission shall:

- (1) identify and examine specific bioethical, legal, and social issues related to the potential impacts of advances in biomedical and behavioral research, healthcare delivery, or other areas of science and technology;
- (2) recommend any legal, regulatory, or policy actions it deems appropriate to address these issues; and
- (3) critically examine diverse perspectives and explore possibilities for useful international collaboration on these issues.

In support of its mission, the Commission may examine issues linked to specific technologies, including but not limited to the creation of stem cells by novel means; intellectual property issues involving genetic sequencing, biomarkers, and other screening tests used for risk assessment; and the application of neuro- and robotic sciences. The Commission also may examine broader issues not linked to specific technologies, including but not limited to the protection of human research participants; scientific integrity and conflicts of interest in research; and the intersection of science and human rights.

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In establishing priorities for its activities, the Commission shall consider, among other things, the significance of particular issues; the need for legal, regulatory, and policy guidance with respect to such issues; the connection of the issues to the goal of Federal advancement of science and technology; and the availability of other appropriate entities or fora for deliberating on the issues.

The Commission is authorized to conduct original empirical and conceptual research, commission papers and studies, hold hearings and establish committees and subcommittees, as necessary. The Commission is authorized to develop reports or other materials.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Commission shall provide advice and counsel to the President.

SUPPORT

The Department of Health and Human Services shall provide funding and administrative support for the Commission to the extent permitted by law within existing appropriations. Staff will be assigned to a program office established to support the activities of the Commission. Management and oversight for support services provided to the Commission will be the responsibility of the Office of Public Health and Science. The Office of Public Health and Science is a staff division within the Office of the Secretary.

All executive departments and agencies and all entities within the Executive Office of the President shall provide information and assistance to the Commission as the Chair may request for purposes of carrying out the Commission's functions, to the extent permitted by law.

ESTIMATED ANNUAL OPERATING COST AND STAFF YEARS

The estimated annual cost for operating the Commission, including reimbursement for travel expenses incurred by the members to conduct official business, but excluding staff support, is \$1,210,534. The estimated annual person-years of staff support required is 10.0 at an estimated annual cost of \$448,190.

DESIGNATED FEDERAL OFFICER

The program office established to support activities of the Commission shall be headed by an Executive Director, who will provide management and leadership for staff operations. The Executive Director also will serve as the designated Federal officer (DFO). The Executive Director shall be appointed by the Secretary of Health and Human Services, in consultation with the Chair and Vice Chair. The DFO will work under the broad guidance of the Assistant Secretary for Health, or other official to whom the authority has been delegated, within the general policy framework provided by legislation, policies of the Executive Branch, Departmental policies, as well as the policies and priorities of the Administration, the Secretary, and the ASH.

The DFO or designee will attend all meetings of the Commission and any respective subcommittees.

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Estimated Number and Frequency of Meetings

The Commission shall meet, at a minimum, four times a year. The Chair shall convene and preside at meetings of the Commission. Meeting agendas shall be developed by the Chair, who may consult with the Vice Chair and DFO to develop the agenda.

The Commission also is authorized to hold hearings. Commission meetings/hearings will be open to the public, except as determined otherwise by the Secretary, or other official to whom authority has been delegated, in keeping with the guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). Notice of all meetings/hearings will be given to the public. Meetings/hearings will be conducted and records of the proceedings will be kept, as required by applicable laws and Departmental policies. A majority of the appointed Commission membership is required for the Commission to meet to conduct business.

When it is determined by the Secretary, or other official to whom authority has been delegated, that a meeting will be closed or partially closed to the public, in accordance with stipulations of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report will be prepared that includes, at a minimum, a list of the members and their business addresses, the Commission's functions, date and place of the meeting, and a summary of the Commission's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department's Committee Management Officer.

Duration

The Commission has been established by a Presidential directive. Unless extended by the President, the Commission will be terminated two years after the date of the authorizing directive.

Termination

Unless renewed by appropriate action, the Presidential Commission for the Study of Bioethical Issues will be terminated two years from the date of the authorizing directive.

Membership and Designation

The Commission shall be an expert panel composed of not more than 13 members. The Commission members will be drawn from fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences. Commission members shall be appointed by the President. At least one, and not more than three members, may be bioethicists or scientists drawn from the executive branch, as designated by the President, and shall be classified as regular government employees. The Commission members, who are selected from the public and/or private sector, shall be classified as special government employees.

The President shall designate a Chair and Vice Chair from among the members of the Commission. The Chair shall convene and preside at meetings of the Commission, determine its agenda, and direct its work. The Vice Chair shall perform the duties of the Chair, in the absence or disability of the Chair, and shall perform such other functions as the Chair may from time to time assign.

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Members shall be appointed to serve terms of two years. Members are eligible to be reappointed and may continue to serve after the expiration of their terms until the appointment of a successor. A member who is appointed to fill a vacancy shall serve only for the remainder of the unexpired term unless reappointed by the President to serve an additional term.

Members shall receive no stipend from the Federal Government for the service they perform during their tenure on the Commission. Members, however, shall receive reimbursement for any applicable travel expenses incurred, including per diem, as authorized by law under 5 U.S.C. 5701-5707, for persons who are employed intermittently to perform services for the Federal Government, consistent with the availability of funds.

Committees/Subcommittees

In carrying out its function, the Commission is authorized to establish committees and subcommittees that are composed of Commission members and non-member special consultants. The DFO shall be present at all meetings of any such committees and subcommittees. Committees and subcommittees shall meet according to the committee/subcommittee plan, consider issues in accordance with the charge of the Commission, and shall make reports to the Commission for consideration, as appropriate. Committees and subcommittees may not report directly to the President or another Federal official unless there is specific statutory authority for such reporting.

The Department Committee Management Officer will be notified upon establishment of each committee and subcommittee, and will be provided information regarding the committee or subcommittee name, function, membership, and estimated frequency of meetings.

Recordkeeping

Records of the Commission and the respective subcommittees or subgroups will be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date: MAR 1 0 2010

Approved:

MAR 1 0 2010

Date



Secretary