



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

AUTHORITY

Establishment of the Presidential Commission for the Study of Bioethical Issues (the “Commission”) was required by Executive Order 13521, dated November 24, 2009. Authority to continue the Commission must be given by the President. The Commission is currently operating by the authority given under Executive Order 13708, dated September 30, 2015. 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.

Presidential Commission for the Study of Bioethical Issues

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, with approval of the Secretary or designee. The Commission is authorized to develop reports or other materials.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Commission shall provide advice to the President.

Presidential Advisory Committee Follow-up Report: HHS is responsible for ensuring the reporting requirements of Section 6(b) of FACA are fulfilled.

SUPPORT

The Department of Health and Human Services (HHS) 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. This program office shall be organizationally located within Office of the Assistant Secretary for Health (OASH). OASH, a staff division within Office of the Secretary, shall have responsibility for providing management and oversight to support the activities and operation of the Commission.

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 \$1,353,804. The estimated annual person-years of staff support required are 12.0 at an estimated annual cost of \$1,399,196.

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 (ASH), or other official to whom the authority has been delegated, within the general policy framework provided by legislation, the Executive Branch, and HHS, as well as the policies and priorities of the Administration, the Secretary, and the ASH.

Presidential Commission for the Study of Bioethical Issues

The DFO or designee will approve and attend all meetings and subcommittee meetings of the Commission, prepare all meeting agendas, as determined by the Chair or Vice Chair, and adjourn any meeting when determined to be in the public interest.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

The Commission shall meet, at a minimum, four times a year. 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. 552(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. The need for the Commission is continuing; however, it is subject to terminate pursuant to the Termination section below.

TERMINATION

Unless extended by the President, the Commission will terminate on September 30, 2017.

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.

Presidential Commission for the Study of Bioethical Issues

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.

SUBCOMMITTEES

In carrying out its function, the Commission is authorized to establish subcommittees, with the approval of the Secretary or designee, that are composed of Commission members and non-member special consultants. The Commission Chair, Vice Chair, and/or DFO, in consultation with the Commission leadership shall select non-member special consultants to serve on the subcommittees. The DFO shall be present at all meetings of any such subcommittees. The established subcommittees shall meet according to the guidance given in the FACA about the use of subcommittees. The subcommittees will consider issues in accordance with the charge of the Commission, and shall make reports to the Commission for consideration, as appropriate. Such reports must be discussed at an open meeting of the Commission. Subcommittees may not report directly to the President or another Federal official outside the context of an open meeting of the full Commission.

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

RECORDKEEPING

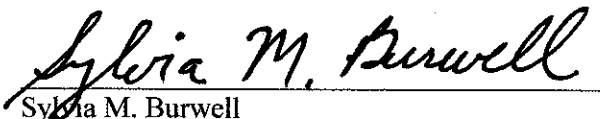
Records of the Committee and any established subcommittee will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. Applicable records will be made available to the public for inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE: March 10, 2016

APPROVED:

MAR 10 2016

Date


Sylvia M. Burwell