CHARTER

SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY

AUTHORITY

42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The Secretary's Advisory Committee on Genetics, Health, and Society (Committee) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

Scientific advances in genetics and genomics help provide a better understanding of health and disease and lead to new technologies and tools that are used in research, clinical care, public health, and nonmedical areas such as forensics. To maximize the contributions of genetic and genomic knowledge and technologies to personal and public health requires consideration of their appropriate integration into health promotion and disease prevention and management. In addition, ethical, legal, and social issues raised by genetic and genomic technologies must be considered to avoid the misapplication of emerging technologies or the creation of inequitable access to technologies with known clinical utility.

To consider these issues and concerns, the Secretary's Advisory Committee on Genetics, Health, and Society was established. This committee will: (1) provide a forum for expert discussion and deliberation and the formulation of advice and recommendations on the range of complex and sensitive issues raised by new scientific and technological developments in human genetics and genomics; (2) assist the Department of Health and Human Services (HHS) and other Federal agencies, at their request, in exploring issues raised by the development and application of genetic and genomic technologies; and (3) make recommendations to the HHS Secretary on how to address such issues.

DESCRIPTION OF DUTIES

The Committee will assess and consider policy questions associated with the development and use of genetic and genomic information and technologies and make recommendations to the HHS Secretary and other entities as appropriate. The Committee's charge includes exploring the following issues: Relative value of genetic and genomic technologies to improve health and reduce disparities; Development and use of methods to evaluate the clinical utility of existing and emerging genetic and genomic technologies; Regulatory needs for emerging and anticipated uses of genetic and genomic information and technologies in health, immigration, law, and forensics; Anticipated areas of genetic and genomic research; Patents and licensing practices associated with genetic and genomic technologies; Genetics and genomics education for clinicians, public health providers, and the public; Adequacy of federal protections against discrimination based on genetic information; Application of insights from genetic and genomic research to improve population health and personal health care; Appropriate integration of genetic information in electronic health records; and Ethical, legal, and social issues raised by the anticipated increase in large datasets of genomic information and their use in research and health care.

In addition, the HHS Secretary may assign particular issues for the Committee to study.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary).

SUPPORT

Management and support services will be provided by the Office of Biotechnology Activities (OBA), Office of Science Policy, Office of the Director, National Institutes of Health.

ESTIMATED ANNUAL OPERATING COST AND STAFF YEARS

The estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is $101,239. The estimated annual person-years of staff support required is 1.5 at an estimated annual cost of $76,084.

DESIGNATED FEDERAL OFFICER

The Director, Office of Science Policy will assign a full-time or permanent part-time OBA employee as the Designated Federal Officer (DFO) of the Committee. In the event that the DFO cannot fulfill the assigned duties of the Committee, one or more full time or permanent part time OBA or NIH employees will be assigned these duties on a temporary basis.

The DFO will approve or call all of the committee's and subcommittees' meetings, prepare and approve all meeting agendas, attend all committee and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Secretary.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Committee will be held not less than 2 times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

This committee is authorized until February 28, 2011.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for The Secretary's Advisory Committee on Genetics, Health, and Society will expire approximately six months from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee will consist of up to 17 members, including the Chair, appointed by the Secretary, or designee, from authorities knowledgeable about biomedical sciences, human genetics, health care delivery, evidence-based practice, public health, bioinformatics, behavioral sciences, social sciences, health services research, health policy, health disparities, ethics, economics, law, health care financing, consumer issues, and other relevant fields. Of the appointed members, at least two members will be specifically selected for their knowledge of consumer issues and concerns and the views and perspectives of the general public. All non-Federal members will serve as Special Government Employees. Members and the Chair will be invited to serve for overlapping terms of up to four-years. Members may serve after the expiration of their term until their successors have taken office. A quorum for the conduct of business by the full Committee shall consist of a majority of currently appointed members.

The following Federal officials, or their designees, will serve as nonvoting ex officio members of the Committee: Assistant Secretary for Children and Families; Assistant Secretary for Health; Administrator, Agency for Healthcare Research and Quality; Director, Indian Health Service; Director, Office of the National Coordinator for Health Information Technology; Director, Centers for Disease Control and Prevention; Administrator, Centers for Medicare & Medicaid Services; Commissioner, Food and Drug Administration; Administrator, Health Resources and Services Administration; Director, National Institutes of Health; Director, Office for Civil Rights; Director, Office for Human Research Protections; Attorney General of the United States; Secretary of Commerce; Secretary of Defense; Secretary of Education; Secretary of Energy; Secretary of Labor; Secretary of Veterans Affairs; Chair, Equal Employment Opportunity Commission; Chairman, Federal Trade Commission; and any other officers or employees of the United States Federal Government, as the Secretary determines are necessary for the Committee to effectively carry out its function.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Committee's jurisdiction. The advice/recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members' count towards the quorum for a subcommittee meeting. Ad hoc consultants do not count towards the quorum and may not vote. A quorum for a subcommittee will be three members. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records 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

September 23, 2010

APPROVED

AUG 26 2010

Date

Director, NIH