



CHARTER

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

PURPOSE

Extraordinary scientific advances are speeding the development of new genetic and genomic technologies to predict, prevent, diagnose, treat, and cure disease. To maximize their benefits and contribution to the realization of personalized health care, genetic and genomic information and technologies must be broadly integrated into health care and public health and considered comparable in value and sensitivity to other health information. At the same time, this translation must be done with great care because genetic and genomic information can be misapplied in ways that are harmful to individuals or society.

The Secretary's Advisory Committee on Genetics, Health, and Society (Committee) is established to: (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 and, at their request, other Federal agencies in exploring issues raised by the development and application of genetic and genomic technologies; and (3) make recommendations to the Secretary of Health and Human Services (Secretary) on how to address such issues.

AUTHORITY

42 U.S.C. 217a, section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Committee shall explore, analyze, and deliberate on the broad range of policy needs associated with issues raised by the development, use, and potential misuse of genetic and genomic information and technologies and make recommendations to the Secretary and other entities as appropriate. The Committee's charge includes assessing how genetic and genomic information and technologies are being integrated into health care and public health; studying the clinical, public health, ethical, economic, legal, and societal implications of genetic and genomic information and technologies and applications; identifying opportunities and gaps in research and data collection analysis efforts; examining the impact of patent policy and licensing practices

on access to genetic and genomic technologies; analyzing uses of genetic and genomic information in education, employment, insurance, and law; and serving as a public forum for discussion of issues raised by genetic and genomic information and technologies.

As necessary, and with the approval of the Executive Secretary, the Committee and subcommittees may call upon special consultants, assemble ad hoc working groups, and convene conferences and workshops.

STRUCTURE

The Committee shall 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 shall be specifically selected for their knowledge of consumer issues and concerns and the views and perspectives of the general public. None of these members serve as Representatives. A quorum for the conduct of business by the full Committee shall consist of a majority of currently appointed members. A quorum for each subcommittee shall be three members.

The following Federal officials, or their designees, shall 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, 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.

Members and the Chair shall be invited to serve for overlapping terms of up to four-years; terms of more than two years are contingent upon the renewal of the Committee's Charter by appropriate action prior to its expiration. Members may serve after the expiration of their term until their successors have taken office. A member who has been appointed for a term of four years may not be reappointed to this Committee before two years from the date of expiration of that term of office. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which that member's predecessor was appointed shall serve for the remainder of that term; persons appointed to complete an unexpired term of less than four years may be reappointed immediately for a full term following completion of the unexpired term.

As necessary, subcommittees may be established by the Executive Secretary or other designated Government official within the Committee's jurisdiction. The advice/recommendations of a

subcommittee 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. Subcommittee members who are not members of the parent committee may attend closed sessions of the parent committee meeting but they may not count towards the quorum of the parent committee and they cannot vote on committee actions. The Department Committee Management Officer shall be notified upon establishment of each standing subcommittee and shall be provided information on its name, membership, function, and estimated frequency of meetings.

The Director, Office of Science Policy will assign a full-time or permanent part-time Office of Biotechnology Activities employee to serve as the Executive Secretary (also known as a Designated Federal Official or Government official) of the committee. Management and support services shall be provided for the Committee by the Office of Biotechnology Activities, Office of Science Policy, Office of the Director, National Institutes of Health.

MEETINGS

Meetings of the full Committee shall be held not less than 2 times a year, at the call of the Executive Secretary or other designated Government official. A Government official shall give advance approval of the agenda and be present at all the meetings of the Committee and its subcommittees.

Meetings shall be open to the public except as determined otherwise by the Secretary of Health and Human Services in accordance with subsection (c) of section 552b of Title 5, U.S.C. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept, as required by applicable laws and Departmental policies.

COMPENSATION

Members shall be paid at the rate of \$200 per day, plus per diem and travel expenses, as authorized by section 5703, Title 5 U.S.C. as amended, for persons in the Government service employed intermittently. Members who are officers or employees of the United States Federal Government shall not receive compensation for service on the Committee.

ANNUAL COST ESTIMATE

The estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is \$646,549. The estimated annual person-years of staff support required is 1.0 at an estimated annual cost of \$130,706.

REPORTS

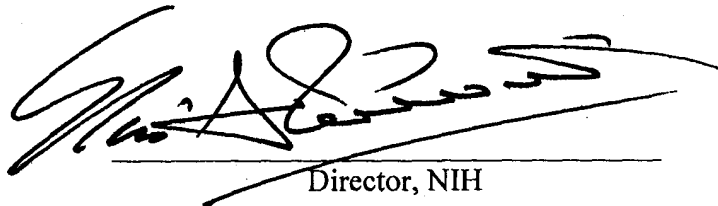
In the event a portion of a meeting is closed to the public, as determined by the Secretary of Health and Human Services, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report shall be prepared which shall contain, as a minimum, a list of members and their business addresses, the Committee's functions, dates and places of meetings, and a summary of Committee's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Charter for the Secretary's Advisory Committee on Genetics, Health, and Society will expire on September 23, 2010.

APPROVED:

6/30/08
Date



Director, NIH

Charter Filing Date: _____

CHARTER FILING DATE 9/23/08