

CHARTER

NATIONAL ADVISORY COUNCIL FOR HUMAN GENOME RESEARCH

PURPOSE

The Secretary of Health and Human Services (Secretary) is mandated under Section 301 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 241), to support, conduct, and encourage research studies, and related activities in the health fields. This mandate is fulfilled in part by the mechanism of research grants-in-aid awarded by the research institutes, centers, and other authorized components of the National Institutes of Health (NIH). In addition, the Secretary is authorized under section 487 of the PHS Act, as amended (42 U.S.C. 288), to support research training through National Research Service Awards. The National Advisory Council for Human Genome Research (Council) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the National Human Genome Research Institute (NHGRI also referred to as "Institute") on matters related to activities carried out by and through the Institute and the policies respecting these activities.

AUTHORITY

42 U.S.C. 284a, Section 406 of the PHS Act, as amended. The Council 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 Council shall advise the Secretary; the Assistant Secretary for Health; the Director, NIH; and the Director, NHGRI, on matters relating to the conduct and support of research, training, and health information dissemination, with respect to human genome research, training, and other programs related to human genome research.

The Council may recommend to the Secretary, in accordance with Section 231 of the PHS Act, as amended, acceptance of conditional gifts for study, investigation, or research aimed at the development of knowledge basic to understanding genomic research, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

In addition, the Council may, on the basis of material provided, make recommendations respecting research conducted at the Institute, may review applications for grants and cooperative agreements for research or training and recommend applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute; may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to genome research and, with the

approval of the Director, NHGRI, make available this information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public; and with the approval of the Executive Secretary, may seek advice from special consultants, appoint subcommittees, assemble ad hoc working groups, and convene conferences and workshops.

The Council may implement procedures for expediting en bloc Council concurrence of Scientific Review Group recommendations. A member or members may be selected by the Executive Secretary or Chair to provide en bloc concurrence on behalf of the Council. Only those applications that do not require individual consideration shall be included in this expedited process. A report of the en bloc recommendations will be presented at each Council.

STRUCTURE

The Council shall consist of 18 members appointed by the Secretary and 5 non-voting ex officio members: the Secretary; the Director, NIH; the Director, NHGRI; the Chief Medical Director of the Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its function. Of the 18 appointed members, 12 shall be selected from the leading representatives of the health and scientific disciplines relevant to the activities of the Institute, such as representatives of the health and scientific disciplines in the areas of genomics and other large-scale approaches to biology, molecular genetics and molecular biology, human and medical genetics, medicine, information science, chemistry, mathematics, engineering, bioethics, social science, and behavioral science. Six of the members shall be appointed by the Secretary from the general public and shall include leaders in such fields as public health, public policy, health policy, management, law, and economics. None of these members serve as Representatives. A quorum for the conduct of business shall consist of a majority of currently appointed members. A quorum for a subcommittee shall be three members.

Members shall be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member may serve up to 180 days after the expiration of the member's term if a successor has not taken office.

Terms of more than two years are contingent upon the renewal of the Council's Charter by appropriate action prior to its expiration. A member who has been appointed for a term of four years may not be reappointed to this Council before two years from the date of expiration of that member's term of office. If a vacancy occurs among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

The Chair of the Council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, NHGRI, to be the Chair. The term of office of the Chair shall be two years.

As necessary, subcommittees may be established by the Executive Secretary or other designated Government official to perform functions within the Council'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, NHGRI, will assign a full-time or permanent part-time NHGRI employee to serve as the Executive Secretary (also known as the Designated Federal Official) of the committee. Management and support services shall be provided by the Division of Extramural Research, NHGRI.

MEETINGS

Meetings of the full Council shall be held not less than three 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 meetings of the Council 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 proceeding 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 shall not receive compensation for service on the Council.

ANNUAL COST ESTIMATE

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is \$53,637. The estimate of annual person-years of staff support required is 0.4, at an estimated annual cost of \$48,110.

REPORTS

The Council may prepare for inclusion in the biennial report prepared by the Director, NIH, under Section 403 of the PHS Act, as amended, (1) comments respecting the activities of the Council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. The Council may prepare any additional reports as it may determine appropriate.

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 Council's functions, dates, and places of meetings, and a summary of Council 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 National Advisory Council for Human Genome Research will expire May 8, 2010.

APPROVED:

Date

Director of NIH