



CHARTER MUSCULAR DYSTROPHY COORDINATING COMMITTEE

AUTHORITY

42 U.S.C. 283g, Section 404E of the Public Health Service Act, as amended. The Muscular Dystrophy Coordinating Committee (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

The Committee will coordinate research activities across the National Institutes of Health (NIH) and with other Federal health programs and activities relating to the various forms of muscular dystrophy, including Duchenne, myotonic, facioscapulohumeral muscular dystrophy and other forms of muscular dystrophy.

DESCRIPTION OF DUTIES

The Committee will develop a plan for conducting and supporting research and education on muscular dystrophy through the national research institutes, and will periodically review and revise the plan. The plan will (a) provide for a broad range of research and education activities relating to biomedical, epidemiological, psychosocial, and rehabilitative issues, including studies of the impact of these diseases in rural and underserved communities; (b) identify priorities among the programs and activities of the NIH regarding these diseases; and (c) reflect input from a broad range of scientists, patients, and advocacy groups. In developing this plan, the Committee may evaluate the potential need to enhance the clinical research infrastructure required to test emerging therapies for the various forms of muscular dystrophy by prioritizing achievement of goals related to this topic.

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), to the Director, NIH, and the Director, National Institute of Neurological Disorders and Stroke (NINDS).

SUPPORT

Management and support services will be provided by the Division of Extramural Research, NINDS.

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 \$43,463. The estimated annual person-years of staff support required is 0.3 at an estimated annual cost of \$52,096.

DESIGNATED FEDERAL OFFICER

The Director, NIH, will assign a full-time or permanent part-time NINDS 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 NINDS 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 Director, NIH, or the Director, NINDS.

ESTIMATED NUMBER OF FREQUENCY OF MEETINGS

Meetings of the full Committee will be held not less than once 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 function, 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

Continuing. This Committee is mandated with no specified end date.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for the Muscular Dystrophy Coordinating Committee will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee will consist of not more than 15 members, including the Chair, appointed by the Secretary. Two-thirds of the members will represent governmental agencies, including the directors or their designees of each of the national research institutes involved in research with respect to muscular dystrophy and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to these diseases, including the Centers for Disease Control

and Prevention, the Health Resources and Services Administration, the Food and Drug Administration, and representatives of other governmental agencies that serve children with muscular dystrophy, such as the Department of Education. One-third of the members will represent the public, including a broad cross section of persons affected with muscular dystrophies including parents or legal guardians, affected individuals, researchers, and clinicians.

Public members will be invited to serve for a term of three years, and may serve for an unlimited number of terms if reappointed. Terms more than two years are contingent upon the renewal of the Committee by appropriate action prior to its termination. Members may serve after the expiration of their terms until their successors have taken office.

The Chair of the committee will serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and will provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of the Food and Drug Administration, and the heads of other relevant agencies. The Committee will select the Chair for a term not to exceed two. The Chair of the Committee will be appointed by, and be directly responsible to, the Secretary. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members.

SUBCOMMITTEES

As necessary committees 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

The Committee will submit biennially to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that describes the research, education, and other activities on muscular dystrophy being conducted or supported through the Department. Each report will include (1) the research plan developed by the national research institutes, or revisions to the plan, as the case may be; (2) the amounts expended by the Department with respect to muscular dystrophy; and (3) recommendations of particular projects or types of projects that should in the future be considered by the national research institutes or other research entities on all forms of muscular dystrophy.

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

will be handled in accordance with General Records Schedule 26, Item 2 or other approval 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

August 15, 2012

APPROVED:

7/26/2012

Date

Dr. Francis Collins, M.D., Ph.D.

Director, NIH