

CHARTER

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES ADVISORY COUNCIL

AUTHORITY

Authorized by 42 U.S.C. 217a, section 222 of the Public Health Service (PHS) Act, as amended. The National Center for Advancing Translational Sciences Advisory Council (Council) 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 Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary), the Director, National Institutes of Health (NIH) and the Director, National Center for Advancing Translational Sciences (NCATS, also referred to as Center) on matters related to the activities carried out by and through the Center and the policies respecting these activities.

DESCRIPTION OF DUTIES

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 regarding the advancement of translational sciences and related activities of NCATS for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Center.

The Council may review applications for grants and cooperative agreements for research or training and recommend approval of 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 Center; 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 and, with the approval of the Director, NCATS, make available such 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.

The Council will prepare triennial reports describing the manner in which the Center has complied with section 492B of the PHS Act, which sets forth requirements addressing the inclusion of women and members of minority groups as subjects in clinical research conducted or supported by NIH. Each report shall be submitted to the Director, NCATS, for inclusion in the triennial report submitted to Congress by the Director, NIH, pursuant to section 403 of the PHS Act. Each triennial report prepared by the Council shall include each of the following:

1. The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.
2. The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.
3. For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—
 - (a) have been completed during such reporting period; and
 - (b) are being carried out during such reporting period and have not been completed.
4. The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with section 492B(c)(2)(A) of the PHS Act

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Council will advise the Secretary; the Director, NIH; and the Director, NCATS.

SUPPORT

Management and support services will be provided by the Division of Grants Management and Review, NCATS.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is \$23,312. The estimated annual person-years of staff support required is 1.7, at an estimated annual cost of \$235,860.

DESIGNATED FEDERAL OFFICER

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

The DFO will approve or call all of the Council's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Council 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 Director, NCATS.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Council will be held approximately three 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 Council's functions, dates and places of meetings, and a summary of the Council'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.

TERMINATION

Unless renewed by appropriate action, the National Center for Advancing Translational Sciences Advisory Council will terminate two years from the date this charter is filed.

MEMBERSHIP AND DESIGNATION

The Council will consist of no more than 18 members appointed by the Secretary (appointed members) and the following nonvoting ex officio members: the Secretary; the Director, NIH; the Director, NCATS; and any additional officers or employees of the Department of Health and Human Services as the Secretary determines necessary for the Council to effectively carry out its functions. Appointed members must be eligible to serve as Special Government Employees (SGEs) and will serve as SGEs. Of the appointed members, two-thirds will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social

sciences) relevant to the activities of the NCATS, particularly representatives of the health and scientific disciplines in the areas of drug development and translational sciences. One-third of the members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and management. A quorum for the conduct of business by the full Council will consist of a majority of currently appointed members.

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

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

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice or recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee/working group 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. A quorum for a subcommittee will be three members. Ad hoc consultants do not count towards the quorum and may not vote. 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 Council and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Council and subcommittee records will be handled in accordance with General

Records Schedule 6.2, Federal Advisory Committee Records, 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

February 7, 2020

APPROVED:

Date

Director, NIH