



CHARTER

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES ADVISORY COUNCIL

- 1. Advisory Committee's Official Designation.** National Center for Advancing Translational Sciences Advisory Council.
- 2. 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. §§ 1001-1014).
- 3. Objectives and Scope of Activities.** The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) 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.
- 4. Description of Duties.** In addition to the general advisory functions identified in the above section, 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 on 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 and 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 as to the diseases, disorders, or other aspect of human health with respect to which the Center was established and, with the approval of the Director of 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, as amended, which sets forth requirements addressing the inclusion of women and members of minority groups as subjects in clinical research conducted or supported by the National Institutes of Health (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, as amended. Each triennial report prepared by the Council shall include each of the following:

- A. 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.
- B. 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.
- C. For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—
 - i. have been completed during such reporting period; and
 - ii. are being carried out during such reporting period and have not been completed.
- D. 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, as amended.

- 5. Agency or Federal Officer Receiving the Advisory Committee's Advice/ Recommendations.** The Council will advise the Secretary and the Director, NCATS.
- 6. Support.** Management and support services will be provided by the Division of Grants Management and Review, NCATS.
- 7. Estimated Annual Operating Costs and Staff Years.** The estimated annual costs to operate the Council include the following:
 - i. Federal personnel (based on full-time equivalent (FTE) usage basis) and other Federal internal costs. The estimated annual person years of staff support required is 1.0, at an estimated annual cost of \$255,456. The estimate for other Federal internal costs is \$4,242.
 - ii. Proposed payments to members and number of members. The estimated payments for three non-Federal members is \$2,400; the estimated prorated salary of three Federal members is \$2,244.
 - iii. Reimbursable costs. The estimate for reimbursable costs, including members' travel expenses, is \$18,221.
- 8. Estimated Number and Frequency of Meetings.** Meetings of the full Council will be held at the call of the Chair (with approval of the Designated Federal Office (DFO)) or upon request of the Director, NCATS, at least three times within a calendar year. Meetings will be open to the public except as determined by the Secretary at the request of the DFO in accordance with 5 U.S.C. 552b(c) and 41 C.F.R. 102-3.155 including specifying the specific exception(s) that justifies closure. 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, an annual report of closed or partially-closed meetings will be prepared which will contain, at 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.

- 9. Duration.** The duration of the Council is continuing, subject to the Termination section below.
- 10. Termination.** Unless renewed by appropriate action, prior to its expiration, the National Center for Advancing Translational Sciences Advisory Council will terminate two years from the date the charter is filed.
- 11. Membership and Designation.** The Council will consist of not 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; a representative from the Centers for Medicare and Medicaid Services; a representative from the Food and Drug Administration; 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, as defined by 18 U.S.C. § 202. Two-thirds of the appointed members will be selected from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the NCATS. One-third of the appointed 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. The Secretary shall make appointments in such a manner as to ensure that the terms of the appointed members do not all expire in the same year. 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.

- 12. Subcommittees.** As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice/recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee/working group may not report directly to the agency or any Federal officer.

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 are not considered subcommittee members, 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.

13. Filing Date. February 7, 2026.

APPROVED:

1/30/2026

Date

Principal Deputy Director, NIH