

CHARTER

CURES ACCELERATION NETWORK REVIEW BOARD

AUTHORITY

Required by 42 U.S.C. 287a(d), section 480(d) of the Public Health Service (PHS) Act (formerly 42 U.S.C. 282d(d), section 402C(d) of the PHS Act), as redesignated by section 221(c)(1), Tit. II, Div. F., Public Law 112-74 (the Consolidated Appropriations Act, 2012). The Cures Acceleration Network Review Board (Board) 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 Cures Acceleration Network Review Board will advise the Director, National Center for Advancing Translational Sciences (NCATS), on the conduct of the activities of the Cures Acceleration Network.

DESCRIPTION OF DUTIES

The Board will advise, and provide recommendation to, the Director, NCATS, with respect to (1) policies, programs, and procedures for carrying out the duties of the Director, NCATS, under section 480 of the PHS Act; and (2) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

In the case that the Board identifies a significant barrier, as described above, the Board will submit to the Secretary a report regarding such barrier.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Board reports to the Director, NCATS.

SUPPORT

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

ESTIMATED ANNUAL OPERATING COST AND STAFF YEARS

The estimated annual cost for operating the Board, including compensation and travel expenses for members, but excluding staff support is \$4,567. The estimated annual person-years of staff support required is 0.4, at an estimated annual cost of \$37,612.

DESIGNATED FEDERAL OFFICER

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

The DFO will approve all of the Board's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Board 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, NCATS.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Board will be held at the call of the Chair (with the DFO's approval) or upon request of the Director, NCATS not less than four times per calendar year. Meetings will be open to the public except as determined otherwise by the Secretary of DHHS 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 Board's functions, dates and places of meetings, and a summary of the Board's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

A quorum will consist of a total of 13 members of the Board, excluding ex officio members, with diverse representation as defined as not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization. Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

DURATION

Continuing.

TERMINATION

Unless renewed by appropriate action, prior to its expiration, the Charter for the Cures Acceleration Network Review Board will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Board will be comprised of 24 members who are appointed by the Secretary, Department of Health and Human Services (HHS), and who serve at the pleasure of the Secretary. The Secretary will appoint individuals to the Board based solely upon the individual's established record of distinguished service in one of the areas of expertise described in the paragraph below. Each individual appointed to the Board will be of distinguished achievement and have a broad range of disciplinary interests.

The Secretary will select individuals based on the following requirements: (1) for each of the fields of (a) basic research, (b) medicine, (c) biopharmaceuticals, (d) discovery and delivery of medical products, (e) bioinformatics and gene therapy, (f) medical instrumentation, and (g) regulatory review

and approval of medical products, the Secretary will select at least 1 individual who is eminent in such fields; (2) at least 4 individuals will be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing; and (3) at least 8 individuals will represent disease advocacy organizations.

The Secretary will designate, from among the 24 members appointed, as described above, one Chairperson of the Board and one Vice Chairperson.

Each member will be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed will be appointed for the remainder of such term. A member may be appointed to serve no more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

In addition to the 24 Board members described above, the Secretary will appoint as ex officio members of the Board (1) a representative of the National Institutes of Health, recommended by the Secretary, HHS, (2) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense; (3) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs; (4) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and (5) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

Each ex officio member will serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex officio members in order to provide for a staggered term of appointment for all such members.

All non-Federal members serve as either Special Government Employees or Representative Members.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Board'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

Meetings of the Committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee 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, 2016

APPROVED:

Date

Director, NIH