



CHARTER

NOVEL AND EXCEPTIONAL TECHNOLOGY AND RESEARCH ADVISORY COMMITTEE

AUTHORITY

Authorized by 42 U.S.C. 282(b)(16), section 402(b)(16) of the Public Health Service Act, as amended. The Novel and Exceptional Technology and Research Advisory 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 provide advice to the Director, National Institutes of Health (NIH), on matters related to the conduct and oversight of research involving emerging technologies in biomedical science (also referred to as emerging biotechnologies).

DESCRIPTION OF DUTIES

The Committee makes recommendations on research involving the use of, and developments in, emerging biotechnologies. The Committee will address scientific, safety, ethical, and social issues associated with areas of emerging biotechnology research for which the NIH requests advice or guidance.

As necessary, and with the approval of the Designated Federal Officer (DFO), the Committee and its subcommittees may call upon special consultants, assemble ad hoc working groups, and convene conferences, workshops and other activities.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee will advise, assist, consult with, and make recommendations to the Director, NIH.

SUPPORT

Management and support services will be provided by the Office of Science Policy (OSP).

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 \$183,228. The estimated annual person-years of staff support is 0.8 at an estimated annual cost of \$132,170.

DESIGNATED FEDERAL OFFICER

The Director, OSP, will assign a full-time or permanent part-time OSP employee as the 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 OSP 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, OSP.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Committee will be held approximately 2 times within a fiscal year and as requested by the DFO. 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, at a minimum, a list of members and their business addresses, the Committee's functions, 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.

TERMINATION

Unless renewed, the Committee will terminate two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee will consist of up to 25 voting members, including the Chair, appointed by the Director, NIH. A majority of the voting members must be knowledgeable in relevant emerging scientific fields (e.g., gene therapy, gene editing, synthetic biology). As needed, the Committee may include persons knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human participants in research, the environment, ethics, law, public attitudes or related fields. Members will not be employees of a federal agency and will serve as Special Government Employees. Members and the Chair will be invited to serve for overlapping four-year terms. A member may serve after the expiration of that member's term until a successor has taken office. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Committee's jurisdiction. The findings/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

June 30, 2019

APPROVED

6/14/19
Date

Jan V. Cal
Director, NIH