



CHARTER

NATIONAL CANCER INSTITUTE CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE

AUTHORITY

Authorized by 42 U.S.C. 285a-2(b)(7), section 413(b)(7) of the Public Health Service Act, as amended. The National Cancer Institute Clinical Trials and Translational 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 Cancer Institute (NCI), NCI Deputy Directors, and the Director of each NCI Division, on matters related to the conduct, oversight, and implementation of clinical trials and translational research across the Institute.

DESCRIPTION OF DUTIES

The Committee makes recommendations on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. This encompasses oversight of all trials both extramural and intramural. The Committee will provide broad scientific and programmatic advice on the investment of tax payer dollars in clinical trials and supportive science. This will lead to enormous potential for more specific cancer treatment, coupled with the complexity of evaluating new, highly specific agents integrating knowledge, insights, and skills of multiple fields into a new kind of cross-disciplinary, scientifically-driven, cooperative research endeavor.

In addition, the Committee makes recommendations regarding the effectiveness of NCI's translational research. The committee will advise on translational research opportunities with the greatest potential clinical value and feasibility, strategies for moving high priority translational research opportunities rapidly and efficiently through the development process, streamlining handoffs of translational research projects to early phase clinical trial programs, and optimizing collaboration and communication among NCI's translational research and clinical trials programs.

The goal is to foster an open, collaborative system involving all the critical stakeholders that is integrated and efficient, yet innovative and responsive; thus moving discoveries to benefit cancer patients.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

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

SUPPORT

Management and support services will be provided by the Coordinating Center for Clinical Trials, NCI.

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 \$92,061. The estimated annual person-years of staff support required is 0.6% at an estimated annual cost of \$92,067.

DESIGNATED FEDERAL OFFICER

The Director, NCI, will assign a full-time or permanent part-time NCI 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 NCI 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, NCI.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Committee will be held approximately 3 times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary of Health and Human Services (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 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 by appropriate action, the National Cancer Institute Clinical Trials and Translational Research Advisory Committee will terminate two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee will consist of up to 25 members, including the Chair, appointed by the Director, NCI. When necessary, five members will hold concurrent membership on either the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology), or NCI Council of Research Advocates. Members will be authorities knowledgeable in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life,

health care outcomes, pain management, cancer treatment and restorative care, and education of health professionals. All non-Federal members serve as Special Government Employees. Members and the Chair will be invited to serve for overlapping five-year terms. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed members.

Ex officio members include NCI Deputy Directors, select NCI Division Directors, an NCI intramural scientist engaged in clinical research, and representatives from the Food and Drug Administration, Centers for Medicare and Medicaid Services, the Department of Defense and Department of Veterans Affairs.

Members of the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology), or NCI Council of Research Advocates will serve for the duration of their terms as members of their respective Boards/Committees.

A member may serve after the expiration of that member's term if a successor has not taken office.

SUBCOMMITTEES

As necessary, subcommittees 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 consist of a majority of currently appointed 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

April 14, 2016

APPROVED:

3/1/16
Date


Acting Director, NCI