



## NATIONAL CANCER INSTITUTE CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE

### **COMMITTEE'S OFFICIAL DESIGNATION**

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 (PHS) 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. 2).

### **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 NCI.

### **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. The Committee's advice will encompass 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, 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 \$150,323. The estimated annual person-years of staff support required is 0.5 at an estimated annual cost of \$97,923.

### **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 as DFO and carry out 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 official to whom the committee reports.

### **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 by the Secretary of Health and Human Services (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 Committee's functions, dates and places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year.

### **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 non-federal members appointed by the Director, NCI as well as federal ex officio members as discussed below. The non-federal members must be eligible to serve as Special Government Employees (SGEs) and will serve as SGEs, as defined by 18 U.S.C. § 202. The Chair will be selected by the Director, NCI, from among the non-federal members. When necessary, five members will hold concurrent membership on either the National Cancer Advisory Board, Board of Scientific Advisors, NCI Board of Scientific Counselors, 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. Non-federal members will be invited to serve for overlapping five-year terms. Members serving concurrently as members of the National Cancer Advisory Board, Board of Scientific Advisors, NCI Board of Scientific Counselors, or NCI Council of Research Advocates will serve no longer than the duration of their terms as members of their respective boards/committees. An appointed member may serve after the expiration of that member's term if a successor has not taken office. A quorum for the conduct of business by the full Committee will consist of a majority of currently appointed non-federal members.

Non-voting ex officio members may include NCI Deputy Directors, select NCI Division Directors, an NCI intramural scientist engaged in clinical research, and officials from the Food and Drug Administration, Centers for Medicare and Medicaid Services, the Department of Defense and Department of Veterans Affairs, and such other Federal officials as appointed by the NCI Director.

## **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/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. Ad hoc consultants are not 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.

## **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 any applicable exemptions under the Freedom of Information Act, 5 U.S.C. 552(b) and 41 C.F.R. 102-3.170.

## **FILING DATE**

April 14, 2022

## **APPROVED:**

4/07/2022

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Date



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Director, NCI