Clinical Trials and Translational Research Advisory Committee

Amendment to the Charter Summary

AUTHORITY

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.

MEMBERSHIP AND DESIGNATION

The Committee will consist of 25 members, who may include the Director, NCI as Chair or a designee appointed by the NCI Director will chair the Committee. At least 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 Director□s Consumer Liaison Group. 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, 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 four-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, the Director, Division of Extramural Activities, NCI, the Director, Division of Cancer Treatment and Diagnosis, 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), and Director□s Consumer Liaison Group 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 until a successor has taken office.

DESCRIPTIONS 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 management and administration program, including needs and opportunities across disease sites, patient populations, translational developmental pathways, and the range of molecular mechanisms responsible for cancer development. The Committee will advise on the appropriate magnitude for dedicated translational research priorities and recommend allocation of translational research operations across organizational units, programs, disease sites, populations, developmental pathways, and molecular mechanisms. The Committee will ensure that appropriate emphasis is placed on rare cancers, medically underserved populations, and historically lower-resourced pathways to clinical goals.

The goal is to foster an open, collaborative system involving all the critical stakeholders in the prioritization process bringing diverse institutions and individuals together into an integrated and efficient, but innovative and responsive effort, thus moving discoveries to benefit cancer patients.

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 shall be provided to the Department Committee Management Officer.