



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Office of the Director, Notice of Charter Renewal**

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102-3.65(a), notice is hereby given that the charter for the National Cancer Institute Clinical Trials and Translational Research Advisory Committee (CTAC) is being renewed for an additional two-year period on April 14, 2026.

It is determined that the CTAC is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

The Public Interest Determination follows:

#### **National Institutes of Health**

#### **National Cancer Institute Clinical Trials and Translational Research Advisory Committee**

#### **(CTAC)**

#### **Public Interest Determination**

Pursuant to 41 CFR § 102-3.60(a), to establish, renew, reestablish, or merge a discretionary (agency discretion) advisory committee, an agency must first consult with the General Services Administration's Committee Management Secretariat (the Secretariat) and, as part of the consultation, provide a written public interest determination approved by the head of the agency to the Secretariat with a copy to the Office of Management and Budget. In addition, pursuant to 41 CFR § 102-3.35, an agency shall follow the same consultation process and document in writing the same determination of need before creating a subcommittee under a discretionary committee that is not made up entirely of members of a parent advisory committee.

Information on the following factors for the committee is provided to the Secretariat to demonstrate that renewing the committee is in the public interest:

1. Annual budget

The projected total committee cost for FY 2026 is \$121,213.

a. Federal personnel on a full-time equivalent (FTE) basis

The estimated annual person-years of staff support required is 0.4 FTE at an estimated annual cost of \$83,355

b. Other Federal internal costs

The estimated annual cost of other Federal internal expenses is \$4,727.

c. Proposed payments to members

The estimated annual payments for 19 non-Federal members are \$4,600. The estimated prorated salary of two Federal members is \$1,496.

d. Proposed number of members

The committee will consist of up to 25 non-Federal members, in addition to Federal ex officio members.

e. Reimbursable costs

The estimated reimbursable costs, including members' travel expenses, are \$27,035.

2. If applicable, the total dollar value of grants expected to be recommended during the fiscal year

N/A

3. Criteria for selecting members to ensure the committee has the necessary expertise and fairly balanced membership

The Committee will consist of up to 25 non-Federal members appointed by the National Cancer Institute (NCI) Director as well as Federal ex officio members. 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 NCI Director from among the non-Federal members.

When necessary, up to four members may hold concurrent membership on the National Cancer Advisory Board and/or the NCI Board of Scientific Counselors.

Members will be recognized authorities knowledgeable in fields including community oncology; surgical, medical, radiation, and pediatric oncology; patient advocacy;

extramural clinical investigation; regulatory agencies; pharmaceutical industry; public health; clinical trial design, management, and evaluation; drug development and developmental therapeutics; cancer education; cancer information services; community outreach; vaccine development; cellular and molecular oncology; clinical, basic, and translational research; cancer center administration; cancer biology and diagnosis; cancer epidemiology; chemotherapy; oncology health care delivery; pharmacology; pathology; biostatistics; quality of life; health care outcomes; pain management; cancer treatment and restorative care; and education of health professionals.

Non-Federal members, including the Chair, may serve overlapping five-year terms.

Members serving concurrently on the National Cancer Advisory Board or the NCI Board of Scientific Counselors will serve no longer than the duration of their respective board terms. An appointed member may continue to serve after term expiration until a successor is appointed.

Non-voting ex officio members may include officials from the Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), Department of Veterans Affairs (VA), and other Federal officials as appointed by the NCI Director.

4. List of all other Federal advisory committees of the agency

- Advisory Committee on Research on Women's Health
- Advisory Committee to the Director, National Institutes of Health
- Advisory Council on Parkinson's Research, Care and Services
- Aging and Neurodegeneration Integrated Review Group
- AIDS Research Advisory Committee, NIAID
- Applied Immunology and Disease Control Integrated Review Group
- Applied Therapeutics for Cancer Integrated Review Group
- Biobehavioral and Behavioral Processes Integrated Review Group
- Bioengineering Sciences & Technologies Integrated Review Group
- Biological Chemistry and Macromolecular Biophysics Integrated Review Group

- Board of Regents of the National Library of Medicine
- Board of Scientific Counselors Eunice Kennedy Shriver National Institute of Child Health and Human Development
- Board of Scientific Counselors National Human Genome Research Institute
- Board of Scientific Counselors of the National Heart, Lung, and Blood Institute
- Board of Scientific Counselors of the NIH Clinical Center
- Board of Scientific Counselors, Division of Translational Toxicology
- Board of Scientific Counselors, National Cancer Institute
- Board of Scientific Counselors, National Center for Complementary and Integrative Health
- Board of Scientific Counselors, National Eye Institute
- Board of Scientific Counselors, National Institute of Arthritis and Musculoskeletal and Skin Diseases
- Board of Scientific Counselors, National Institute of Biomedical Imaging and Bioengineering
- Board of Scientific Counselors, National Institute of Dental and Craniofacial Research
- Board of Scientific Counselors, National Institute of Diabetes and Digestive and Kidney Diseases
- Board of Scientific Counselors, National Institute of Environmental Health Sciences
- Board of Scientific Counselors, National Institute of Mental Health
- Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke
- Board of Scientific Counselors, National Institute on Aging
- Board of Scientific Counselors, National Institute on Alcohol Abuse and Alcoholism
- Board of Scientific Counselors, National Institute on Deafness and Other Communication Disorders
- Board of Scientific Counselors, National Institute on Drug Abuse

- Board of Scientific Counselors, National Institute on Minority Health and Health Disparities and National Institute of Nursing Research
- Board of Scientific Counselors, National Library of Medicine
- Brain Disorders and Clinical Neuroscience Integrated Review Group
- Cardiovascular and Respiratory Sciences Integrated Review Group
- Cell Biology Integrated Review Group
- Center for Scientific Review Special Emphasis Panel
- Council of Councils
- Cures Acceleration Network Review Board
- Digestive, Kidney and Urological Systems Integrated Review Group
- Division of Intramural Research Board of Scientific Counselors National Institute of Allergy and Infectious Diseases
- Emerging Technologies and Training Neurosciences Integrated Review Group
- Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group
- Fogarty International Center Advisory Board
- Genes, Genomes, and Genetics Integrated Review Group
- Healthcare Delivery and Methodologies Integrated Review Group
- Infectious Diseases and Immunology A Integrated Review Group
- Infectious Diseases and Immunology B Integrated Review Group
- Integrative, Functional and Cognitive Neuroscience Integrated Review Group
- Interagency Autism Coordinating Committee
- Interagency Pain Research Coordinating Committee
- Interdisciplinary Molecular Sciences and Training Integrated Review Group
- Molecular, Cellular and Developmental Neuroscience Integrated Review Group
- Muscular Dystrophy Coordinating Committee
- Musculoskeletal, Oral, and Skin Sciences Integrated Review Group
- National Advisory Allergy and Infectious Diseases Council

- National Advisory Board on Medical Rehabilitation Research
- National Advisory Child Health and Human Development Council
- National Advisory Council for Biomedical Imaging and Bioengineering
- National Advisory Council for Complementary and Integrative Health
- National Advisory Council for Human Genome Research
- National Advisory Council for Nursing Research
- National Advisory Council on Aging
- National Advisory Council on Alcohol Abuse and Alcoholism
- National Advisory Council on Drug Abuse
- National Advisory Council on Minority Health and Health Disparities
- National Advisory Dental and Craniofacial Research Council
- National Advisory Environmental Health Sciences Council
- National Advisory Eye Council
- National Advisory General Medical Sciences Council
- National Advisory Mental Health Council
- National Advisory Neurological Disorders and Stroke Council
- National Arthritis and Musculoskeletal and Skin Diseases Advisory Council
- National Cancer Advisory Board
- National Cancer Institute Clinical Trials and Translational Research Advisory Committee
- National Cancer Institute Council of Research Advocates
- National Center for Advancing Translational Sciences Advisory Council
- National Deafness and Other Communication Disorders Advisory Council
- National Diabetes and Digestive and Kidney Diseases Advisory Council
- National Heart, Lung, and Blood Advisory Council
- National Science Advisory Board for Biosecurity
- National Toxicology Program Board of Scientific Counselors
- National Toxicology Program Special Emphasis Panel

- NIH Clinical Center Research Hospital Board
  - Office of AIDS Research Advisory Council
  - Office of Research Infrastructure Programs Special Emphasis Panel
  - Oncology 1-Basic Translational Integrated Review Group
  - Oncology 2-Translational Clinical Integrated Review Group
  - Population Sciences and Epidemiology Integrated Review Group
  - President's Cancer Panel
  - Risk, Prevention and Health Behavior Integrated Review Group
  - Scientific Advisory Committee on Alternative Toxicological Methods
  - Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities
  - Scientific Management Review Board
  - Sickle Cell Disease Advisory Committee
  - Sleep Disorders Research Advisory Board
  - Social and Community Influences on Health Integrated Review Group
  - Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group
  - Vaccine Research Center Board of Scientific Counselors National Institute of Allergy and Infectious Diseases
  - Vascular and Hematology Integrated Review Group
5. Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source
- CTAC is essential to the conduct of NCI and NIH agency business because it provides independent, expert scientific and programmatic advice to the NCI Director on the conduct, oversight, and implementation of the clinical trials and translational research enterprise, which is one of NCI's largest and most complex investment of public funds. It is the only programmatic cancer-related advisory committee whose sole focus is clinical trials and translational research. CTAC was formed pursuant to a 2005 recommendation

from the National Cancer Advisory Board for NCI to establish a committee dedicated to clinical trials, given NCI's large investment in this area of research. Other NCI boards and committees do not have the expertise needed to provide in-depth, enterprise-wide advice to ensure accountability and optimal use of taxpayer dollars for NCI's clinical trials networks and associated infrastructure.

CTAC integrates key stakeholders to provide advice that will foster a collaborative, efficient, and innovative system that enables the timely translation of discoveries into benefits for cancer patients. No other Federal advisory committee has the same sole focus on NCI's clinical trials and translational research enterprise or provides coordinated, external advice in this area.

CTAC's current work strengthens the clinical trials enterprise by providing advice to help advance streamlined data collection, real-world data integration, and pragmatic trial design, supporting NIH priorities to reduce burden, improve efficiency, and accelerate innovative cancer prevention, early detection, and treatment approaches. CTAC serves the public interest by providing a transparent, independent forum through which advice is provided to the NCI Director, and visibility into NIH's cancer research activities is ensured. Meetings are open to the public, and membership includes a broad range of experts, including patient advocates.

6. If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue

Since its inception, CTAC has played a central role in modernizing and improving the efficiency of NCI's federally funded clinical trials system. The committee has provided invaluable advice on the restructuring of NCI's clinical trials networks, establishing timelines for initiating trials, harmonizing guidelines across programs, and evaluating clinical trials portfolios to enhance NCI's already-productive clinical trials program.

As the conduct of clinical trials has continued to evolve, CTAC has helped NCI to address emerging challenges through a continuous improvement approach and made important recommendations to NCI. CTAC recommendations have focused on

operational efficiency, trial cost and complexity, prevention and symptom management, and health-related quality of life across the portfolio, while also reviewing NCI's clinical and translational research portfolios to identify gaps in recalcitrant cancers such as pancreatic, lung, gastric, and glioblastoma cancers. CTAC's recommendations have also informed scientific frameworks, strengthened programs in cancer screening, radiation oncology, quantitative imaging, and clinical trials informatics, and revolutionized government-sponsored clinical trials, enabling faster and more efficient delivery of outcomes to the American public.

CTAC's impact extends beyond NCI by advancing collaboration and improving clinical research practices across NIH and other federal agencies. The scientific framework CTAC recommended for pancreatic cancer led to cross-NIH collaborations, particularly for the early diagnosis of pancreatic cancer and understanding the role of diabetes in cancer etiology. NIH adopted principles of efficiency and centralized trial operations advanced by CTAC to strengthen clinical trial conduct. CTAC's advice also helped NCI to establish the NCI-VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE), which contributed approximately 400 enrollments to NCI trials in 2025 and expanded Veterans' access to cancer clinical trials.

If CTAC were discontinued, key stakeholders in clinical trials and translational research would lose a voice in providing input on NCI's scientific programs and initiatives, creating a void in NIH's ability to better serve the public and achieve the administration's goal of understanding and lowering chronic disease rates across the cancer control spectrum, including prevention, early detection, and treatment.

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business

CTAC is essential to the conduct of NCI and NIH agency business because it provides independent and expert advice that directly informs how NCI manages its clinical trials and translational research enterprise, an area that represents one of NCI's largest and most complex investments of public funds. CTAC provides advice to the NCI Director on

the conduct, oversight, and implementation of clinical trials and translational research across the Institute by providing broad scientific and programmatic advice on the investment of taxpayer dollars.

CTAC supports NCI's statutory mission and aligns with the current administration's priorities by supporting a strong and efficient cancer clinical trials research enterprise. Through independent, expert advice on NCI-supported clinical trials and translational research across the cancer control continuum, CTAC advances efforts to reduce the burden of chronic disease, enhances transparency and stewardship of NIH's cancer research investments, and promotes research aimed at lowering cancer rates and improving population health.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

Inquiries may be directed to Patricia Brandt Hansberger, Acting Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496-2123, or [patricia.hansberger@nih.gov](mailto:patricia.hansberger@nih.gov).

Dated: March 20, 2026.

**David W. Freeman,**

*Supervisory Program Analyst,*

*Office of Federal Advisory Committee Policy.*