U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
21st VIRTUAL NATIONAL CANCER ADVISORY BOARD

Summary of Meeting
10 June 2025

Virtual Meeting
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

NATIONAL CANCER ADVISORY BOARD
BETHESDA, MARYLAND
Summary of Meeting
Previously Scheduled for 13 February 2025

The National Cancer Advisory Board (NCAB) convened for its 21st virtual meeting on 10 June 2025. The meeting was open to the public on Tuesday, 10 June 2025, from 11:00 a.m. to 12:05 p.m. and closed to the public from 12:05 p.m. to 1:00 p.m. The Acting NCAB Chair, Dr. Christopher R. Friese, Vice Provost, Academic and Faculty Affairs, Elizabeth Tone Hosmer Professor of Nursing, Professor of Health Management and Policy, Associate Director, Cancer Control and Population Sciences, Rogel Cancer Center, presided during both the open and closed sessions.

NCAB Members

Dr. John D. Carpten (Chair)
Ms. Margaret Anne Anderson
Dr. Nilofer S. Azad
Dr. Richard J. Boxer (absent)
Dr. Callisia N. Clarke
Ms. Ysabel Duron
Dr. Karen M. Emmons
Ms. Tamika Felder
Dr. Christopher R. Friese
Ms. Julie Papanek Grant
Dr. Amy B. Heimberger
Dr. Ana Navas-Acien
Dr. Edjah K. Nduom
Dr. Kimberly Stegmaier
Dr. Fred K. Tabung
Dr. Ashani T. Weeraratna
Dr. Karen M. Winkfield

President's Cancer Panel

Dr. Mitchel S. Berger (absent)
Dr. Carol L. Brown

Alternate *Ex Officio* NCAB Members

Dr. John Gordon, CPSC (absent)
Dr. Michelle L. Heacock, NIEHS (absent)
Dr. Michael Kelley, VA (absent)
Dr. Matthew J. Memoli, NIH (absent)
Dr. Richard Pazdur, FDA (absent)
Dr. Craig D. Shriver, DoD (absent)
Dr. Kerry Souza, NIOSH (absent)

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Oliver Bogler, Director, Center for Cancer Training
Dr. Philip E. Castle, Director, Division of Cancer Prevention
Dr. James H. Doroshow, Director, Division of Cancer Treatment and Diagnosis
Dr. Satish Gopal, Director, Center for Global Health
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Warren A. Kibbe, Deputy Director for Data Science and Strategy
Ms. Amber Lowery, Deputy Director for Management and Executive Officer
Dr. Douglas R. Lowy, Principal Deputy Director
Ms. Anne Lubenow, Chief of Staff
Dr. Margaret Mooney, Chief, Clinical Investigations Branch
Dr. Krzysztof Ptak, Director, Office of Cancer Centers
Mr. Weston Ricks, Budget Officer, Office of Budget and Finance
Dr. Dinah S. Singer, Deputy Director, Scientific Strategy and Development
Dr. Sanya A. Springfield, Director, Center to Reduce Cancer Health Disparities and Acting Deputy Director for Strategic Engagement Director, Center to Reduce Cancer Health Disparities
Dr. Shamala K. Srinivas, Associate Director, Office of Referral, Review, and Program Coordination, Division of Extramural Activities
Dr. Peter Wirth, Special Assistant to the Director, Division of Extramural Activities

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TUESDAY, 10 JUNE 2025

I. CALL TO ORDER AND OPENING REMARKS—DR. CHRISTOPHER R. FRIESE

Dr. Christopher R. Friese called to order the 21st virtual meeting of the National Cancer Advisory Board (NCAB). Dr. Friese welcomed members of the Board, *ex officio* members, President's Cancer Panel members, liaison representatives, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA) and Executive Secretary, NCAB, National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Friese reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

II. FUTURE BOARD MEETING DATES—DR. CHRISTOPHER R. FRIESE

Dr. Friese called Board members' attention to the future meeting dates listed on the agenda.

III. NCI PRINCIPAL DEPUTY DIRECTOR'S REMARKS—DR. DOUGLAS R. LOWY

Dr. Douglas R. Lowy, Principal Deputy Director, NCI, welcomed NCAB members and attendees to the 21st virtual meeting. Dr. Lowy reported on NCI grant funding and progress in cancer mortality rates.

NCI Grant Funding. Dr. Lowy noted that NCI will continue to use previously negotiated and approved indirect cost rates, except for awards under which facilities and administrative costs are reimbursed at a fixed rate. Early stage investigators have been granted automatic extensions of their eligibility due to delays in grant application submissions, peer review, and/or award processing between the beginning of January and the end of May 2025.

Cancer Mortality Rates. Dr. Lowy remarked that the three-decade decrease in cancer mortality rates has continued for 2023. He expressed appreciation to patients, researchers, NCI advisory committees, and Congress for their roles in this progress. Dr. Lowy noted that these data are available in the Surveillance, Epidemiology, and End Results (SEER) Program tool, SEER*Explorer. In 2023, the annual mortality rate decreased by 1.5 percent, a total decrease of more than one third since 1992. Dr. Lowy underscored the importance and urgency of supporting cancer research to reduce deaths.

Questions and Answers

Ms. Ysabel Duron, Founder and Executive Director, The Latino Cancer Institute, requested access to the mortality report and demographic data. Dr. Lowy responded that the report is available through the *Annual Review on Cancer*.

Dr. Ashani T. Weeraratna, Bloomberg Distinguished Professor of Cancer Biology, E.V. McCollum Chair of Biochemistry and Molecular Biology, Johns Hopkins Bloomberg School of Public Health, Co-Program Leader, Cancer Invasion and Metastasis, Sidney Kimmel Cancer Center, Johns Hopkins School of Medicine, expressed appreciation to Dr. Lowy and all NCI staff for their recent efforts.

Dr. Karen M. Emmons, Professor, Department of Social and Behavioral Science, Harvard T.H. Chan School of Public Health, inquired about NCI's decision-making process during times of transition. Dr. Lowy noted that NCI's decision-making is conducted by consensus as much as possible. NCI is currently working to prioritize key topics in cancer research. NCI has appointed two special advisors,

Drs. Brigitte Widemann and Satish Gopal, who offer clinical expertise. Dr. Lowy also underscored the strength of NCI's team, noting that all staff play a critical role.

NCAB Chair Dr. John D. Carpten, Director, Comprehensive Cancer Center, Director and Chief Science Officer, Beckman Research Institute of City of Hope, inquired about anticipated changes to NCI's funding for extramural and intramural research. Dr. Lowy emphasized that this matter is under careful consideration, and NCI anticipates communicating with extramural researchers as more information is available.

IV. ANNUAL DELEGATIONS OF AUTHORITY—DR. SHAMALA K. SRINIVAS

Dr. Shamala K. Srinivas, Associate Director, Office of Referral, Review, and Program Coordination, DEA, NCI, outlined two Delegations of Authority to the Director of the NCI. She described the delegations and provisions in the Statement of Understanding. Delegation A allows the Director to obtain the services of not more than 151 special experts or consultants who have scientific or professional qualifications. Dr. Srinivas also explained that Delegation B specifies that the NCAB delegates authority to the NCI Director to appoint one or more advisory committees composed of private citizens and officials of federal, state, and local governments to advise the Director with respect to his or her functions.

The Statement of Understanding with NCI Staff on Operating Principles in Extramural Grants also falls within the Delegations of Authority to the Director, NCI. NCAB operations are conducted in accordance with management and review procedures described in the NIH Manual Issuance 4513. Concurrence of the NCAB with recommendations of initial review groups (IRGs) will be required, except for the following: (1) Training grants and fellowships and other non-research grant applications are not subject to NCAB review and approval and, without other concerns, may be awarded without presentation to the NCAB for concurrence, with the exception of Ruth L. Kirschstein National Research Service Awards. (2) Applications above the 20th percentile will not have summary statements presented to the NCAB unless the Institute is considering an award of such an application, or other special consideration is requested or required by NCI or NIH policy, or for special consideration by an appointed member of the Board. (3) For applications assigned raw scores that are not percentiled, the cutoff will be a priority impact score of 50 for all mechanisms except R41, R42, R43, and R44 awards; for the latter, all scored applications will be included.

Expedited Concurrence. (1) For R01 and R21 applications with percentiled or raw scores that fall within the NCI paylines for that mechanism, a process of expedited concurrence will be used. (2) The Executive Secretary will alert Board members with responsibility for expedited concurrence when review outcomes for eligible applications are available on the Electronic Expedited Concurrence portion of the Electronic Council Book.

Administrative Adjustments. (1) Permission is delegated to the Director, NCI, to allow staff to negotiate appropriate adjustments in dollars or other terms and conditions of grant and cooperative agreement awards. (2) Administrative requests for increases in direct costs that are the result of marked expansion or significant change in the scientific content of a program after formal peer review will be referred to the Board for advice and recommendation. (3) Actions not requiring Board review or advice—such as change of institution, change of principal investigator (PI), phaseout of interim support, or additional support—need not be reported to the Board. (4) NCI staff may restore requested time and support that were deleted by the IRG when justified by the PI in an appeal letter or when restoration is in the best interest of NCI and the project is of high NCI programmatic relevance. As circumstances require, after programmatic consideration and consultation with the NCAB Chair, the Director of NCI may make exceptions to these guidelines.

To continue responsible stewardship of public funds, NIH has instituted a policy of Special Council Review of applications from well-funded investigators. Applications from PIs who have $2 million (M) or more in direct costs from active NIH Research Project Grants (RPGs) must be given additional consideration. Immediately following this meeting, applications from PIs in that category will be provided with that additional consideration. The $2 M is a threshold for review, and investigators who have additional research support may still receive additional awards as warranted.

V. TRIENNIAL REPORT ON MONITORING ADHERENCE TO THE NIH POLICY ON THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH— DR. MARGARET MOONEY

Dr. Margaret Mooney, Chief, Clinical Investigations Branch, Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), presented the *Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research*. NIH is mandated by the Public Health Service Act to ensure the inclusion of women and minority groups in all NIH-funded clinical research in the manner appropriate to the scientific question under study. The primary goal of this law was to ensure that research findings can be generalizable to the entire population. The NIH Revitalization Act of 1993, amended by the 21st Century Cures Act, also requires that the advisory boards of each NIH institute prepare a triennial report describing how the institute has complied with the NIH inclusion guidelines and tracking requirements.

NIH-funded researchers must collect information on participant sex, race, and ethnicity for studies involving human subjects that meet the NIH definition of clinical research. This includes patient-oriented research, epidemiological and behavioral studies, and outcomes and health services research. Grantees must report this information annually as part of their annual research performance progress reports. Contracts and intramural program researchers also report annually. NCI's portfolio for this report includes studies supported by both intramural and extramural research programs.

Implementation of inclusion guidelines involves participation of review, program, policy, and grants management staff. Reviewers evaluate applications for the appropriateness of the inclusion plans and analyses, and NCI staff work with investigators to resolve any issues. Program staff monitor enrollment progress in annual progress reports and address concerns as necessary. Grants management staff ensure appropriate terms and conditions are included and documented for the grant. Intramural investigators provide inclusion plans that are considered during scientific review. Enrollment progress is reviewed as part of the annual scientific and institutional review board review, and any issues are resolved. Regular inclusion training is provided to program and review staff.

Dr. Mooney acknowledged key limitations associated with the triennial report's data. She emphasized that the data are intended to serve as a broad overview of general inclusion trends rather than a precise count of trials or participants. First, Inclusion Data Records (IERs) do not represent a count of total studies or trials. Multiple IERs may be submitted for a single study. For studies taking place both in the United States and internationally, a separate IER must be submitted for domestic enrollment and international enrollment. Additionally, the inclusion data do not represent the enrollment for a single year. The data represent cumulative reports submitted by grantees, contractors, and intramural researchers and cover the entire span of the project, rather than a single year. Furthermore, grants that are recompeted in a fiscal year are not included in the data for that year. Type 2 grant applications provide only planned data, not actual enrollment data for that year, so their records and enrollment are not included in the recompetition fiscal year. Dr. Mooney also noted that graphs and charts showing percentages may not add up to exactly 100 percent due to rounding.

NCAB members were informed about overall reporting data for the three-year period. Dr. Mooney first presented the inclusion records and enrollment numbers for all clinical research by fiscal

year. She pointed out that a slight increase in the number of IER records was observed, as well as a slight decrease in total enrollment. She noted that several large-cohort studies help account for that finding. Approximately 85–86 percent of patients are from the United States. Inclusion data by sex remained stable over the reported period. Inclusion data by race and ethnicity showed an increase in the proportion of minority participants during this period. Dr. Mooney explained that some of these data reflect a large intramural cohort study that closed in fiscal year 2023. The data were also compared with those from SEER Census population estimates.

NIH-defined phase 3 clinical trials must also be designed to permit valid analysis of group differences on the basis of sex, race, and ethnicity, unless there is clear evidence that such differences are unlikely to be seen. The following definition is used for NIH-defined phase 3 clinical trials: An NIH-defined phase 3 clinical trial is a broadly based prospective phase 3 clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention compared with a standard or controlled intervention or comparing two or more existing treatments. Often, the aim of such investigation is to provide evidence leading to a scientific basis for considering a change in health policy or standard of care. The definition includes pharmacologic, nonpharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included. Because of the additional requirements for NIH-defined phase 3 trials, NCI and NIH conduct additional analyses of the inclusion data for these trials.

Dr. Mooney presented total IERs and enrollment for NIH-defined phase 3 clinical research reported and the proportion of enrollment by U.S. site. She noted that the percentage of U.S. enrollment was 76.5 percent in 2024 but started at 82.2 percent in 2022. The higher proportion of non-U.S. participants largely was driven by a large international cancer screening study. The number of female participants increased during this period, reflecting significant enrollment in a large breast cancer screening study during this period. Additionally, a higher percentage of Hispanic/Latino patients was largely driven by significant Latin American enrollment in a large cancer screening trial that occurred during this period. The data also were compared with those from SEER Census population estimates. Dr. Mooney expressed appreciation to NCI staff for their efforts in preparing the report, as well as to NCI investigators for their efforts in ensuring the accuracy of the data.

Questions and Answers

Dr. Fred K. Tabung, Associate Professor, Division of Medical Oncology, Department of Internal Medicine, The Ohio State University Comprehensive Cancer Center, James College of Medicine, The Ohio State University Wexner Medical Center, underscored the importance of collecting inclusion data to understand the effectiveness of the therapies and preventive measures associated with clinical studies. He asked how compliance is evaluated in the new framework for peer review, which has been reorganized from five criteria to three factors. Dr. Mooney clarified that these components are still present within the peer-review process.

Dr. Amy B. Heimberger, Jean Malnati Miller Professor of Brain Tumor Research, Vice Chair for Research, Department of Neurosurgery, Northwestern University Feinberg School of Medicine, inquired about mechanisms for monitoring privatized clinical trials. Dr. Mooney responded that this reporting mandate applies only to publicly funded NIH trials. She noted that the U.S. Food and Drug Administration asks companies for this information as part of its review and decision-making process, even if the trial was conducted privately. Dr. Heimberger stated that funding mechanisms likely will be needed for these monitoring efforts.

Motion. A motion to accept the *Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research* was approved unanimously.

VI. ONGOING AND NEW BUSINESS—DR. CHRISTOPHER R. FRIESE

NCAB *ad hoc* Working Group on Extramural Research Concepts and Programs

Dr. Friese introduced the need for an NCAB *ad hoc* Working Group on Extramural Research Concepts and Programs, which will consider concepts and other related programs. NCAB members had previously received a document on this matter.

Questions and Answers

In response to a question from Dr. Emmons, Dr. Lowy noted that the Trump Administration recently eliminated three of NCI's Federal Advisory Committee Act committees, and the Board of Scientific Advisors had reviewed new concepts as part of its remit. This Working Group would provide flexibility and a wide range of represented expertise.

In response to a question from NCAB Chair Dr. Carpten, Dr. Gray clarified that members of the Working Group will bring forward their recommendations, and the final vote would be conducted by the NCAB. The ultimate authority for recommendation would rest with the NCAB.

Dr. Kimberly Stegmaier, Professor of Pediatrics, Harvard Medical School, Ted Williams Investigator, Dana-Farber Cancer Institute, Vice Chair of Research, Pediatric Oncology, Co-Director, Pediatric Hematologic Malignancies Program, Dana-Farber/Children's Hospital Cancer Center, Institute member, Broad Institute of Harvard and MIT, asked about the selection of Working Group members. Dr. Gray explained that the process will be the same as with any other working groups; NCI leadership will recommend individuals for membership.

Motion. A motion to concur on establishing an NCAB *ad hoc* Working Group on Extramural Research Concepts and Programs was approved unanimously

Future Agenda Items. Members suggested that future discussions address internal processes for reviewing mechanisms and notices of funding opportunities that have been removed from the NIH website. NCAB members were asked to forward any additional suggestions for future agenda items to Drs. Friese and Gray.

VII. ADJOURNMENT OF OPEN SESSION—DR. CHRISTOPHER R. FRIESE

Dr. Friese adjourned the open session. Only Board members and designated NCI staff remained for the closed session.

VIII. CLOSED SESSION—DR. CHRISTOPHER R. FRIESE

"This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c)(4), 552b(c)(6), Title 5 U.S. code, and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2)."

There was a review of grants and a discussion of personnel and proprietary issues. Members absented themselves from the meeting during discussions for which there was potential conflict of interest, real or apparent.

The Board was informed that a comprehensive listing of all grant applications to be included in the **en bloc** vote was in the Special Actions package. Those grant applications, as well as those announced during the closed session, could be considered for funding by the institute.

The NCAB **en bloc** motion to concur with IRG recommendations was unanimously approved. During the closed session, a total of 2,653 NCI applications were reviewed requesting direct cost support of $1,118,126,824.

IX. ADJOURNMENT—DR. CHRISTOPHER R. FRIESE

Dr. Friese thanked all the Board members, as well as the visitors and observers, for attending. There being no further business, the 21st virtual meeting of the NCAB was adjourned at 1:00 p.m. on Tuesday, 10 June 2025.

Date	Christopher R. Friese, Ph.D., RN, Acting Chair, NCAB
Date	Shamala Srinivas, Ph.D., Executive Secretary