

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
3rd VIRTUAL NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
February 12, 2015**

**Virtual
Building 31C, Conference Room 10
National Institutes of Health
Bethesda, Maryland**

**NATIONAL CANCER ADVISORY BOARD
BETHESDA, MARYLAND
Summary of Meeting
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The National Cancer Advisory Board (NCAB) convened for its 3rd virtual regular meeting on 12 February 2015. NCAB members attended virtually, and NCI staff attended in Conference Room 10, C Wing, Building 31, National Institutes of Health (NIH), Bethesda, MD. The meeting was open to the public on Thursday, 12 February 2015, from 9:00 a.m. to 9:50 a.m., and closed to the public from 9:50 a.m. to 10:30 a.m. The NCAB Chair, Dr. Tyler E. Jacks, Director, Koch Institute for Integrative Cancer Research, David H. Koch Professor of Biology, Massachusetts Institute of Technology, presided during both the open and closed sessions.

NCAB Members

Dr. Tyler E. Jacks (Chair)
Dr. David C. Christiani
Dr. Marcia R. Cruz-Correa
Dr. Kevin J. Cullen
Dr. Judy E. Garber
Dr. Elizabeth M. Jaffee
Dr. Beth Y. Karlan
Dr. Olufunmilayo I. Olopade (absent)
Dr. Mack Roach, III
Dr. Jonathan M. Samet
Dr. Charles L. Sawyers (absent)
Dr. William R. Sellers (absent)

Alternate *Ex Officio* NCAB Members

Dr. Michael A. Babich, CPSC (absent)
Dr. Vincent J. Cogliano, EPA (absent)
Dr. Michael Kelley, VA (absent)
Dr. Aubrey Miller, NIEHS (absent)
Dr. Richard Pazdur, FDA (absent)
Dr. Craig D. Shriver, DoD (absent)
Dr. Michael Stebbins, OSTP (absent)
Dr. Marie Sweeney, NIOSH (absent)
Dr. Lawrence Tabak, NIH (absent)
Dr. Richard Thomas, DOL (absent)
Dr. Sharlene Weatherwax, DOE (absent)

Members, Scientific Program Leaders, National Cancer Institute, NIH

Dr. Harold Varmus, Director, National Cancer Institute
Dr. Jeff Abrams, Co-Director, Division of Cancer Treatment and Diagnosis
Dr. Lynn Austin, Executive Officer, Deputy Director for Management
Dr. Stephen J. Chanock, Director, Division of Cancer Epidemiology and Genetics
Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences
Dr. James Doroshow, Deputy Director for Clinical and Translational Research
Dr. Daniela S. Gerhard, Director, Office of Cancer Genomics
Dr. Paulette S. Gray, Director, Division of Extramural Activities
Dr. Peter Greenwald, Associate Director for Prevention
Dr. Ed Harlow, Special Assistant for Science Planning
Dr. Lee Helman, Scientific Director for Clinical Research, Center for Cancer Research
Dr. Warren Kibbe, Director, NCI Center for Bioinformatics and Information Technology
Dr. Barry Kramer, Director, Division of Cancer Prevention
Dr. Douglas R. Lowy, Deputy Director, National Cancer Institute
Dr. Alan Rabson, Deputy Director, National Cancer Institute
Dr. Dinah Singer, Director, Division of Cancer Biology
Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
Dr. Louis Staudt, Director, Center for Cancer Genomics
Dr. Joseph Tomaszewski, Co-Director, Division of Cancer Treatment and Diagnosis
Dr. Ted Trimble, Director, Center for Global Health
Mr. Michael Weingarten, Director, Small Business Innovation Research
Dr. Linda Weiss, Director, Office of Cancer Centers
Dr. Jonathan Wiest, Director, Center for Cancer Training
Dr. Robert Wiltrout, Director, Center for Cancer Research
Ms. Joy Wiszneauckas, Executive Secretary, Office of the Director
Dr. Robert Yarchoan, Director, Office of HIV and AIDS Malignancy

Liaison Representatives

Ms. Carolyn Aldige, Cancer Research and Prevention Foundation
Dr. Carolyn Best, American Urological Association
Ms. Paula Bowen, Kidney Cancer Association
Dr. Susan Braun, National Cancer Institute, Director's Consumer Liaison Group
Mr. William Bro, Kidney Cancer Association
Dr. Carol Brown, Society of Gynecologic Oncologists
Mr. Matthew Farber, Association of Community Cancer Centers
Dr. Margaret Foti, American Association for Cancer Research
Dr. Francis Giardiello, American Gastroenterological Association
Dr. Mary Gullatte, Oncology Nursing Society
Ms. Shandi E. Hill, American Society of Therapeutic Radiology and Oncology
Ms. Ruth Hoffman, Candlelighters Childhood Cancer Foundation
Dr. Gerald F. Joseph, Jr., American College of Obstetricians and Gynecologists
Ms. Rebecca A. Kirch, American Cancer Society
Dr. Steven Klein, National Science Foundation
Ms. Laura Levit, American Society of Clinical Oncology
Dr. W. Marston Linehan, Society of Urologic Oncology
Ms. Margo Michaels, Education Network to Advance Cancer Clinical Trials
Dr. Patricia Mullan, American Association for Cancer Education
Ms. Christy Schmidt, American Cancer Society

Ms. Susan Silver, National Coalition for Cancer Survivorship
Ms. Barbara Duffy Stewart, Association of American Cancer Institutes
Dr. Johannes Vieweg, American Urological Association
Ms. Pamela Wilcox, American College of Radiology
COL (Ret.) James E. Williams, Jr., Intercultural Cancer Council

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THURSDAY, FEBRUARY 12, 2015

I. CALL TO ORDER AND OPENING REMARKS—DR. TYLER E. JACKS

Dr. Tyler E. Jacks called to order the 3rd virtual NCAB meeting. Dr. Jacks welcomed members of the Board, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Jacks reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Motion. A motion to approve the NCAB meeting dates for 2016 was approved unanimously.

Motion. A motion to accept the minutes of the December 2, 2014, Joint Boards meeting was approved unanimously.

II. FUTURE BOARD MEETING DATES—DR. TYLER E. JACKS

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

III. NCI DIRECTOR'S REPORT—DR. HAROLD E. VARMUS

Dr. Harold E. Varmus, Director, NCI, welcomed members and expressed congratulations to Dr. Jacks on his reappointment as NCAB Chair. Dr. Varmus said that the fiscal year (FY) 2015 appropriations increased by one-half of a percent over the FY 2014 level. The FY 2016 President's Budget (PB) proposes a 2.3-percent increase for the NIH overall, which would restore the NIH budget to the FY 2012 level. Members were told that the PB includes \$200 million (M) for the new Precision Medicine Initiative (PMI), of which approximately \$130 M would fund a proposed Cohort Study to enroll 1 million members. The nature of the Cohort Study is under discussion, and will be overseen by an external committee under the leadership of Dr. Richard Lifton. He said that the proposed PMI budget designates \$70 M for oncology work in precision medicine and will encompass expanded efforts in genomics activities; a pediatric Molecular Analysis for Therapy Choice (MATCH) trial and other trials focused on certain common cancers; improved understanding of cancer biology, such as through support for preclinical models, to better match drug therapies to cancers; and accelerated development of tools to assist with the processing and use of large amounts of genomic and clinical data. Members were told that the House Appropriations Subcommittee will meet on March 3 regarding FY 2016 appropriations.

Dr. Varmus stated that the NCI-designated Cancer Centers Directors met on February 10 and discussed ways to share Cancer Centers' core facilities, the use of supplementary funding to support global health, and budget reallocation. He noted the upcoming retirement of Dr. Linda Weiss, Director, Office of Cancer Centers, and expressed thanks for her years of service.

Questions and Answers

In response to a query by Dr. Jacks regarding the PMI plans for preclinical model designs for new platforms for drug testing, Dr. Varmus said that efforts will build on existing initiatives to develop patient-derived xenografts (PDXs) and grants for studies of organoids and induced cancer stem cell cultures. The implementation of the ideas is under discussion and involves input from the White House, Office of Science and Technology Policy (OSTP), and the U.S. Food and Drug Administration (FDA), with topics of interest including therapeutic combinations to address drug resistance, and diagnostic testing regulations to support the development of genetic platforms. He noted the need for appropriations to be made for the PMI to commence and remarked on the bipartisan support for precision medicine.

IV. BIENNIAL INCLUSION REPORT—DR. JEFF ABRAMS

Dr. Jeff Abrams, Co-Director, Division of Cancer Treatment and Diagnosis (DCTD), explained that the NIH policy on the inclusion of women and minorities in all clinical research studies, particularly Phase III clinical trials, was mandated by Congress in 1993 (P.L. 103-43), in espousal of the ethical principle of justice and of the importance of balancing research burdens and benefits. Dr. Abrams stated that the policy requires that women and minorities be included in all clinical research studies, including Phase III clinical trials, and that cost is not allowed as an acceptable reason for exclusion. The NIH Revitalization Act of 1993 requires the preparation of biennial reports that describe the NIH Institutes and Centers' (IC) compliance with this requirement. He described the process for preparing the biennial report and the role of the DEA in implementing the policy.

Dr. Abrams described the NCI's implementation procedures. During the pre-award phase of the grant application process, peer reviewers receive instructions and evaluate inclusion plans for all applications. Where concerns are noted, bars to award are put in place. NCI staff work with applicants to ensure appropriate revisions are made. Applications with bars are identified in a closed NCAB session, and a subsequent resolution is reported. During the post-award phase, awardees report cumulative accrual annually, with Program Directors reviewing progress of studies and cumulative accruals. This information is entered into the NIH Population Tracking application. Staff provide oversight, advice, and assistance and work with awardees to disseminate findings and encourage new studies. Inclusion of women and minorities sections must include subject selection criteria and rationale, rationale for any exclusions, enrollment dates (start and end), and outreach plans for recruitment. The NCI is required to aggregate these data whether the clinical trial is a treatment or behavioral trial or an epidemiological observation trial, as well as subset analyses by race, ethnicity, and sex/gender for all Phase III clinical trials with initial funding after 1995. The current report cycle covers data reported in FY 2013–2014, which represents subjects enrolled in FY 2012–2013.

Members were informed about overall reporting data, including data specifically for cancer treatment trials. NCI enrollment by gender during 2013–2014 showed an aggregate of more than 4 million per year, which is dominated by large observational cohorts. Based on U.S. cancer incidence, a higher percentage of women is enrolled than men, a trend that also is seen when gender-specific studies are excluded. Enrollment data by racial composition compared to the U.S. cancer incidence show highest minority accrual of the Asian and African American populations, with a little underrepresentation of the Hispanic population. The NCI intramural research studies enrolled approximately 3.7 million cases in 2013 and 3 million cases in 2014, including close to 1.5 million cases of unknown race/ethnicity from ongoing studies. Enrollment data for Cancer Therapy Evaluation Program (CTEP) treatment trials show a drop in accrual by race in 2014, with a cancer incidence rate that matches the U.S. population. For the Division of Cancer Prevention (DCP), trial data indicate relative balance by gender but a slight underrepresentation of Hispanics and Asian Americans during 2013–2014. The Division of Cancer Control and Population Sciences (DCCPS) accrual to large epidemiologic studies, including social networks and the spread of cancer care practices studies, totaled nearly 13 million patients enrolled in 2014, with both genders represented, as well as reasonable proportions of African Americans, Hispanics, and Asians.

Questions and Answers

Dr. Cullen [For consistency with other minutes, SCG should include his full name, title and affiliation]asked about the constitution of CTEP treatment trials. Dr. Abrams confirmed that the CTEP trials reported are interventional trials and not correlative studies.

Dr. Roach re[For consistency with other minutes, SCG should include his full name, title and affiliation requested information about trends in the inclusion of women and minorities in NCI's clinical research to indicate improvements or issues during the past 2 years. Dr. Abrams stated that although some fluctuation occurs between years, accrual percentages have remained mostly the same during the past 6 years.

Motion. A motion to accept the report of the Biennial Review of Inclusion of Women and Minorities in Clinical Research was approved unanimously.

V. ANNUAL DELEGATIONS OF AUTHORITY—DR. PAULETTE S. GRAY

Dr. Gray r[For consistency with other minutes, SCG should include her full name, title and affiliation requested concurrence by the NCAB on two Delegations of Authority to the Director of the NCI. She described the delegations and the 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. Gray also said that Delegation B specifies that the NCAB delegates to the NCI Director can appoint advisory committees composed of private citizens and officials of Federal, state, and local governments to advise the Director with respect to his 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 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 over the 50th 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 required, 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; and (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 PI, phase-out 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 initial review group when justified by the PI in an appeal letter or when restoration is in the best interest of the NCI and the project is of high NCI programmatic relevance.

In an effort to continue responsible stewardship of public funds, the NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators. Applications from PIs who have \$1 M or more in direct costs from active NIH Research Project Grants (RPGs) must be given additional consideration.

Motion. A motion to approve the NCI Annual Delegations of Authority was approved unanimously.

VII. CLOSED SESSION—DR. TYLER E. JACKS

“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).”

Members were instructed to exit the room if they deemed that their participation in the deliberation of any matter before the Board would be a real conflict or that it would represent the appearance of a conflict. Members were asked to sign a conflict-of-interest/confidentiality certification to this effect.

En bloc: The NCAB en bloc vote for concurrence with IRG recommendations was unanimous. During the closed session, a total of 2,563 NCI applications requesting direct cost support of \$778,867,825 were reviewed.

X. ADJOURNMENT— DR. TYLER E. JACKS

Dr. Jacks thanked all of the Board members, as well as all of the visitors and observers, for attending.

There being no further business, the 3rd virtual meeting of the NCAB was adjourned at 10:30 a.m. on Thursday, 12 February 2015.

Date

Tyler E. Jacks, M.D., Chair

Date

Paulette S. Gray, Ph.D., Executive Secretary