

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
NATIONAL CANCER INSTITUTE**

**55th Meeting (Virtual)**

**BOARD OF SCIENTIFIC ADVISORS**

**Minutes of Meeting**

**March 6, 2014  
Building 31C, Conference Room10  
Bethesda, Maryland**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
NATIONAL CANCER INSTITUTE**

**BOARD OF SCIENTIFIC ADVISORS**

**MINUTES OF MEETING  
March 6, 2014**

The Board of Scientific Advisors (BSA), National Cancer Institute (NCI), convened for its 55th meeting on Thursday, 6 March 2014, at 12:00 p.m. virtually (for members), and other attendees in Conference Room 10, Building 31C, National Institutes of Health (NIH), Bethesda, MD, for other attendees. Dr. Todd R. Golub, Director, Cancer Program, The Broad Institute of the Massachusetts Institute of Technology and Harvard University, presided as Chair. The meeting was open to the public from 12:00 p.m. until 1:18 p.m. on 6 March for the NCI Director's report, and consideration of requests for application (RFAs) and Cooperative Agreements (Coop. Agr.) concepts: AIDS Malignancy Clinical Trials Consortium (AMC); Centers of Cancer Nanotechnology Excellence; and, Cancer Intervention and Surveillance Modeling Network (CISNET).

**BSA Board Members Present Virtually:**

Dr. Todd R. Golub (Chair)  
Dr. Francis Ali-Osman  
Dr. Dafna Bar-Sagi  
Dr. Ethan M. Basch  
Dr. Graham Colditz  
Dr. Chi V. Dang  
Dr. Daniel C. DiMaio  
Dr. Jeffrey A. Drebin  
Dr. Brian J. Druker  
Dr. Karen M. Emmons  
Dr. Kathleen M. Foley  
Dr. Stanton L. Gerson  
Dr. Joe W. Gray  
Dr. Chanita Hughes-Halbert  
Dr. Joshua LaBaer  
Dr. Maria E. Martinez  
Dr. Luis F. Parada  
Dr. Martine F. Roussel (Sherr)  
Dr. Mary L. Smith  
Dr. Lincoln Stein

Dr. Bruce W. Stillman  
Dr. Frank M. Torti  
Dr. Gregory L. Verdine  
Dr. Irving L. Weissman

**Board Members Absent:**

Dr. Kenneth C. Anderson  
Dr. Sangeeta N. Bhatia  
Dr. Andrea Califano  
Dr. Arul M. Chinnaiyan  
Dr. Curt I. Civin  
Dr. Robert B. Diasio  
Dr. Betty Ferrell  
Dr. Theodore S. Lawrence  
Mr. Don Listwin  
Dr. Kevin M. Shannon  
Dr. Louise C. Strong  
Dr. Cheryl L. Walker

**Others present:** Members of NCI's Scientific Program Leaders (SPL), NCI staff, members of the extramural community, and press representatives.

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### I. CALL TO ORDER AND OPENING REMARKS--DR. TODD R. GOLUB

Dr. Todd R. Golub called to order the 55<sup>th</sup> regular meeting of the BSA and welcomed current members of the Board, NIH and NCI staff, guests, and members of the public to the first virtual meeting of the Board. Dr. Golub reminded Board members of the conflict-of-interest guidelines and confidentiality requirements. Members of the public were invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), in writing and within 10 days, comments regarding items discussed during the meeting.

### II. REPORT OF THE DIRECTOR, NCI-DR. HAROLD VARMUS

Dr. Harold Varmus, Director, NCI, welcomed members and provided information about the Institute's budget and legislative news for the current and upcoming fiscal year (FY) as well as NCI news. Dr. Varmus referred members to the recent National Cancer Advisory Board (NCAB) meeting, a videocast of which is available online and includes remarks from the President's Cancer Panel and an extensive symposium on tobacco research related to cancer. He announced the upcoming departure of Mr. John Czajkowski to a position at Harvard Medical School, and the recruitment of Mr. Peter Garrett, who is the new Director of the NCI's Office of Communications, and Ms. Ann Thomas, who will oversee press relationships for the Office of the Director (OD).

**Budget.** Members were told that the FY 2014 Appropriations Bill, which was passed in January 2014, restored approximately one-half of the reduction to the NCI's budget due to sequestration and raises the NCI budget to its FY 2012 level. Dr. Varmus said that approval from the Office of Management and Budget (OMB) for the FY 2014 budget is expected, and that the President's budget request for FY 2015 includes a slight increase for the NIH. Members were informed that a number of congressman important to the NIH are departing from the Congress, including Senator Tom Harkin (D-IA), Reps. Jack Kingston (R-GA), Rush Holt (D-NJ), Henry Waxman (D-CA), and John Dingell (D-MI).

**NCI and NIH Activities.** Dr. Varmus stated that leadership in the NCI and NIH has discussed new types of awards. NIH Institutes and Centers (IC) Directors view the NCI's proposed Outstanding Investigator Award favorably, although discussions continue with the Department of Health and Human Services (DHHS) about the seven year length of the award rather than five years. In addition, the IC Directors support the development of new awards that would emphasize career development, particularly early stages, as well as a shift in the focus of the NIH biosketch from publications to scientific contribution.

Members were informed that evaluation of all NIH intramural research programs is underway. The NCI will identify improvements to its intramural program, address funding at the NIH Clinical Center,

and identify new projects to conduct, similar to the process executed by the NCI-Frederick Advisory Committee (NFAC) to vet potential projects for the Frederick National Laboratory for Cancer Research (FNLRC). Dr. Varmus also remarked on progress in developing new clinical trials that will be dependent on genomic information, including the Molecular Analysis for Therapy Choice (MATCH) trial and development of a master protocol to study small cell lung cancer (SCLC). Members were encouraged to send topics for future meeting discussions.

### **III. RFA/COOPERATIVE AGREEMENT CONCEPTS-NCI PROGRAM STAFF**

#### **Office of the Director**

##### **AIDS Malignancy Clinical Trials Consortium (AMC) (RFA/Coop. Agr. Reissue)**

**Subcommittee Review.** Dr. Stanton L. Gerson, Shiverick Professor of Hematological Oncology, Director, Case Comprehensive Cancer Center, Director, National Center for Regenerative Medicine, Case Western Reserve University, and Director, Seidman Cancer Center, University Hospitals Case Medical Center, expressed the Subcommittee's support for the one-time reissuance. Dr. Gerson said that 25 members comprise the AMC, which conducts complex trials, serves as a unique resource in the global AIDS malignancies arena, and has achieved a 40 percent increase in the minority accrual rate to AMC trials. The Subcommittee noted the positive mid-term evaluation review and good publication record and recommended that the AMC Behavioral Research Working Group continue to focus on accrual, survivorship, and quality-of-life measures.

#### **In the discussion, the following points were made:**

- The AMC's largest new trial for 2014 will focus on anal dysplasia to study anal cancer prevention. It was approved through the NCI review process in the context of the entire NCI AIDS-related malignancies portfolio. In addition, the NIH Office of AIDS Research (OAR) provides supplemental funding for the trial.
- Accrual rates for AMC are modest and will be tracked carefully.
- AMC accomplishments during the past funding period include defining standard therapy for Kaposi's sarcoma, the use of high-level chemotherapies for lymphomas, and preliminary efforts toward an optimal trial design for anal dysplasia.
- Population science components will be incorporated into the AMC in the Behavioral Research Working Group and the anal dysplasia trial will include quality-of-life measures.
- Members recognized the critical resource that the AMC specimen collection will provide and encouraged the NCI to make it available to the broader community once the AMC determines which patients develop cancer.

The first year cost is estimated at \$21 M for 1 award, with a total cost of \$107 M for 5 years.

**Motion.** A motion to concur on the OD's request for application/cooperative agreement (RFA/Coop. Agr.) entitled "AIDS Malignancy Clinical Trials Consortium (AMC)" with strong consideration given to the recommendations of the mid-cycle evaluation was approved unanimously.

## Centers of Cancer Nanotechnology Excellence (CCNE) (RFA/Coop. Agr. Reissue)

**Subcommittee Review.** Dr. Joe W. Gray, Gordon Moore Endowed Chair, Department of Biomedical Engineering, Director, OHSU Center for Spatial Systems Biomedicine, and Associate Director for Translational Research, Knight Cancer Institute, Oregon Health and Science University, expressed the Subcommittee's enthusiastic support for a one-time reissuance, noting the CCNE's productive support of oncology research and nanoparticle functional characterization *in vitro*, in animal models, and in the clinic, as well as the training of young investigators. The program represents what an RFA does well by encouraging a fledgling field that has resulted in a multidisciplinary research community and outstanding output. It was appreciated that the CCNE has accrued 39 patents, with an additional 100 patent applications in process, as well as robust numbers of publications and clinical trials. The CCNE also received a favorable evaluation report, and it was noted that some aspects of the program should be made available via the web to the broader community. Members were told that the FNLCR had an important role in the nanotechnology materials research and development process and might have a larger role in the program in the future. Dr. Varmus indicated that SPL members were highly supportive of the reissuance. He added that the comments from the Board will aid in developing RFA criteria as this will be CCNE's third reissuance.

### In the discussion, the following points were made:

- Members encouraged a presentation of the program at a future BSA meeting to share the benefits of lessons learned from the development of a multidisciplinary program.
- Members debated the merits of an RFA versus collaborative RO1 mechanism as a measure of this emerging field in cancer research, and encouraged the NCI to consider alternative approaches to foster growth in the nanotechnology field and expedite translation to the clinical setting. It was noted that RO1s may not be a good metric as translation can occur quickly, whereas RFAs are useful to build an area of research that receives less attention than needed and to bring together communities that are multidisciplinary or forming but not ready to self-assemble as RO1s.
- The NCI should continue to coordinate its nanotechnology activities with other NIH nanotechnology efforts, which currently include the National Heart, Lung, and Blood Institute (NHLBI), Common Fund nanomedicine and basic research programs, NCI's Molecular Profiling Based Assignment of Cancer (M-PACT) program, and other platforms.
- Members recommended that the Centers of Cancer Nanotechnology Excellence focus on translating into clinical cancer research applications, as opposed to fundamental technology development.
- The NCI was encouraged to incorporate criteria at the time of program concept that ensures either ascendance or "sunsetting" over time.

The first year cost is estimated at \$15 M for 5-6 awards, with a total cost of \$75 M for 5 years.

**Motion.** A motion to concur on the OD's request for application/cooperative agreement (RFA/Coop. Agr.) entitled "Centers of Cancer Nanotechnology Excellence" incorporating a focus on translational science was approved with 23 ayes, no nays, and two abstentions.

**Division of Cancer Control and Population Sciences (DCCPS)**

**Cancer Intervention and Surveillance Modeling Network (CISNET) (RFA/Coop. Agr. Reissue)**

**Subcommittee Review.** Dr. Karen Emmons, Vice President, Research, and Director, Kaiser Foundation Research Institute expressed the Subcommittee's support for the reissuance. Members were told that the concept is for six cooperative agreement awards to use simulation modeling to improve the understanding of the impact of cancer control interventions on population trends, incidence, and mortality. The six sites are breast, prostate, colorectal, lung, esophageal, and cervical cancers. CISNET employs a wide range of models and methods and is widely viewed as a leader in modeling strategies to reduce the cancer burden. The Subcommittee agreed with the Network's positive evaluation report, which highlighted CISNET's successful efforts in promoting and evaluating new screening strategies; evidence-based guidelines; and policies to influence national, state, and local cancer control planning. The Subcommittee recognized the patient-centered research activities and the level of engagement among model researchers; however, increased effort was suggested in disparities and greater transparency around modeling techniques with more user friendly models.

**In the discussion, the following points were made:**

- Most of CISNET’s activities focus on organ sites because the natural history of disease is cancer site specific. The research on HPV vaccines and cervical cancer will be applicable to other HPV cancers.
- Members encouraged the NCI to emphasize underrepresented groups and coordinate efforts with the Prospective Study of Pravastatin in the Elderly at Risk (PROSPER).
- It was noted that the Affordable Care Act provides growth opportunities for CISNET.
- In the CISNET modeling process, model calibration occurs in one trial, followed by validation against other models. NCI staff described an example of trials on flexible sigmoidoscopy that allows the colorectal group to validate models based on calibration developed during earlier trials.

The first year cost is estimated at \$8.4 M for 6 awards, with a total cost of \$42 M for 5 years.

**Motion.** A motion to concur on the DCCPS' request for application/cooperative agreement (RFA/Coop. Agr.) entitled "Cancer Intervention and Surveillance Modeling Network (CISNET)" was approved unanimously.

**IV. ADJOURNMENT-DR. TODD R. GOLUB**

There being no further business, the 55th regular meeting of the Board of Scientific Advisors was adjourned at 1:18 p.m. on Thursday, 6 March 2014.

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Date

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Todd R. Golub, M.D.  
Chair, Board of Scientific Advisors

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Date

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Paulette S. Gray, Ph.D.  
Executive Secretary, Board of Scientific Advisor