Board of Scientific Advisors

Meeting Minutes

March 5, 2001

Conference Room 10, C Wing, Building 31
Bethesda, Maryland 20892

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The Board of Scientific Advisors (BSA or Board), National Cancer Institute (NCI), convened for its 17th regular meeting on Monday, March 5, 2001, in Conference Room 10, Building 31C, National Institutes of Health (NIH), Bethesda, MD. Dr. Frederick Appelbaum, Director, Clinical Research Division, Fred Hutchinson Cancer Research Center, presided as Chair.

The meeting was open to the public from 10:00 a.m. until adjournment for opening remarks from the Chairman; ongoing and new business; Subcommittee on Training Report; and Requests for Applications (RFA)/Cooperative Agreement (Coop. Agr.) concepts.

Board Members present:	**Board Members absent:**
Dr. Frederick R. Appelbaum (Chair)	Dr. David B. Abrams
Dr. David S. Alberts	Dr. Esther H. Chang
Dr. Hoda Anton-Culver	Dr. Neil J. Clendeninn
Dr. Virginia Ernster	Dr. Thomas Curran
Dr. Waun Ki Hong*	Dr. Mary Beryl Daly
Dr. Tyler Jacks*	Dr. Suzanne W. Fletcher
Dr. Kenneth W. Kinzler	Dr. Susan B. Horwitz
Dr. Herbert Y. Kressel*	Dr. William G. Kaelin, Jr.
Dr. Caryn E. Lerman	Ms. Amy S. Langer
Dr. W. Gillies McKenna	Dr. Christine A. Miaskowski
Dr. Enrico Mihich	Dr. Nancy E. Mueller
Dr. John D. Minna	Dr. Joseph V. Simone
Dr. Franklyn G. Prendergast	Dr. Louise C. Strong
Dr. Richard L. Schilsky	Dr. Peter K. Vogt
	Dr. Alice S. Whittemore

Dr. Ellen V. Sigal
Dr. Daniel Von Hoff
Dr. Barbara Weber
Dr. William C. Wood*
Dr. Robert C. Young
Dr. Elias A. Zerhouni

NCAB Liaison:
TBN

Others present: Members of NCI's Executive Committee (EC), NCI Staff, Members of the Extramural Community, and Press Representatives.

* proxy

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I. CALL TO ORDER AND OPENING REMARKS; DR.

FREDERICK APPELBAUM

Dr. Appelbaum called to order the 17th regular meeting of the BSA and welcomed members of the Board, NIH and NCI staff, guests, and members of the public. Members were told that in view of the bad weather, he would move through the agenda as quickly as possible so the meeting could be adjourned by 3:00 p.m. He noted that the next BSA meeting is scheduled for 25-26 June 2001. [Note: Sixteen members were in attendance and another four members were represented by proxy. A quorum for BSA business is 18. Present and proxies = 20; this attendance made it possible for the board to proceed with its work.]

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II. CONSIDERATION OF NOVEMBER 16-17, 2000, MEETING MINUTES; DR. FREDERICK APPELBAUM

Motion: The minutes of the 16-17 November 2000 meeting were unanimously approved.

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III. ONGOING AND NEW BUSINESS; DR. FREDERICK APPELBAUM

Dr. Appelbaum noted that dates and participants for "NCI Listens" sessions were listed in the Board books for meetings of the American Society of Preventive Oncology (ASPO), Society of Behavioral Medicine (SBM), American Association for Cancer Research (AACR), and Oncology Nursing Society (ONS). Reports will be given at the next BSA meeting.

Dr. Appelbaum stated that the list of acronyms requested by members was in their Board books. Comments about the list should be sent to Dr. Paulette Gray, Executive Secretary, BSA.

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IV. SUBCOMMITTEE ON TRAINING REPORT: COMMUNICATING TRAINING OPPORTUNITIES; DR. ROBERT YOUNG

Dr. Robert Young, President, Fox Chase Cancer Center, expressed appreciation for the contributions of Drs. Alice Whittemore, Professor and Chief, Division of Epidemiology, Department of Health Research and Policy, Stanford University School of Medicine; and Hoda Anton-Culver, Professor and Chief, Epidemiology Division, Department of Medicine, University of California, Irvine, in preparing the Subcommittee's report on NCI training opportunities. Dr. Young told the Board that the report responded to two concerns frequently heard at "NCI Listens" sessions conducted at national meetings of specialty societies. Specifically, that (1) young investigators are not aware of available NCI support, particularly through the "K" training awards; and (2) K awards are at a competitive disadvantage because the indirect cost is only 8 percent. He noted that institutions prefer funding with greater indirect cost support.

The subcommittee's recommendations to address the issues were that:

- A letter of inquiry should be sent to national cancer-related societies as to whether their journals would be interested in publishing a document (in letter form or a one page announcement) outlining the "K" Awards for young investigators. The letter should be signed by BSA members who have participated at "NCI Listens" sessions.

- A draft letter or a one-page announcement outlining the "K" Awards for young investigators should be developed for subsequent publication in national society journals.

- Members should encourage the leadership of the cancer-related societies with which they are affiliated to schedule a "How Young Investigators Secure a Grant" training session during their annual meetings. The sessions should be similar to the programs that NCI currently sponsors at the AACR

and ASCO meetings.

- A letter, on behalf of the BSA, should be sent to academic institutions and, in particular, Deans of Schools of Medicine and Vice Chancellors of Research, indicating the importance of training young investigators and announcing the availability of "K" Awards. Members of the BSA Subcommittee on Training should co-sign the letter.

- A letter should be sent to the Director, NCI on issues related to indirect cost rates for "K" awards. The reasons why the indirect costs should be revised, the need to minimize the rates impact on young investigators, and the negative incentive to institutions, especially less advantaged institutions, should be clearly stated. The letter should then be sent to the NIH.

In subsequent discussion, the following points were made:

- Members asked whether increases in indirect cost rates would result in fewer awards. Staff responded that the money for both indirect costs and direct costs comes from the same pool, and increasing the percentage for indirect costs would result in a dollar-for-dollar reduction in direct costs. Moreover, K awards are an NIH-wide funding mechanism.

- Grants with insufficient indirect cost rates may preferentially benefit some institutions because those institutions have the resources to absorb the costs. Smaller institutions that lack such resources, including many minority-serving institutions, find it more difficult to accept these grants.

- **Motion:** A motion to accept the Subcommittee on Training's Position Paper entitled "NCI Listens Training Report" was unanimously approved.

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V. PROPOSED RFA/COOPERATIVE AGREEMENT CONCEPTS; PRESENTED BY NCI PROGRAM STAFF

Division of Cancer Treatment and Diagnosis

Pilot Program for Underserved Medical Institutions: Radiation Oncology Partnerships (RFA). Dr. Norman Coleman, Associate Director, Radiation Research Program (RRP), Division of Cancer Treatment and Diagnosis (DCTD), described the concept as an extramural pilot program designed to help develop partnerships with institutions serving underserved and/or minority communities. The intent is to help these institutions develop into capable partners in clinical research and high-quality treatment by assisting in the training and capacity-building necessary to successfully conduct clinical trials. Dr. Coleman indicated that the Underserved Partnerships Program (UPP) is specifically designed to help institutions that have limited NCI funding establish long-term relationships with cancer research entities, such as, Cancer Centers, Cooperative Groups, and major teaching institutions. The long-range challenges are to: assist health care institutions serving underserved areas to develop and sustain a clinical trials effort and become a permanent part of the national cancer research enterprise; increase the number of clinical and translational scientists pursuing biomedical careers in those institutions; and improve cancer mortality outcomes. He noted that radiation oncology is an appropriate discipline in this context because it spans clinical and translational science, its technical base lends itself to field training and network arrangement, and it can use both the Telesynergy Telemedicine Workstation and the NCI Clinical Trials Information System. While radiation oncology is the starting point, the program is designed to bring the whole oncology sphere together. Both short- and long-term metrics to establish baselines and monitor progress are included in the overall design.

The UPP would be funded as a cooperative planning grant (U56). The proposed length of award for this one-time solicitation would be 6 years, and the estimated cost of the program over that period would be approximately $18.9M. Six institutions would be selected to participate, three in the first year and three in the second year. The average cost per institution per year is estimated at approximately $525,000.

In subsequent discussion, the following points were made:

The Board indicated that the revised concept should (1) include a better definition of the term "underserved"; (2) rearrange the chronological order of the required metrics and request that baseline metrics be in place before participation in clinical trials; (3) consider requesting eligible institutions to establish partnerships with more experienced cancer research institutions at an earlier, rather than at a later stage of the program; (4) include a concrete example of the type of partnerships that the UPP is trying to establish (e.g., partnerships with Cooperative Groups, etc.); and (5) include more narrowly focused outcomes.

Motion: A motion to defer the RFA/Cooperative Agreement concept entitled "Pilot Program for Underserved Medical Institutions Radiation Oncology Partnership" so that the concept could be revised to address concerns expressed by the Board was unanimously approved. A BSA subcommittee (Drs. Anton-Culver, Virginia Ernster, Herbert Kressel, Gillies McKenna, Richard Schilsky, and Elias Zerhouni) will work with program staff to address the Board's concerns. The concept will be revisited at the June 2001 BSA meeting.

Division of Cancer Prevention

Chemoprevention of Tobacco-Related Cancers in Former Smokers: Preclinical Studies (RFA/Coop. Agr.). Dr. Vernon E. Steele, Project Leader, Tobacco Research Opportunity Team (TROT), Chemopreventive Agent Development Research Group, Division of Cancer Prevention (DCP), stated that the purpose of this initiative is to encourage the development of animal models using protocols that mimic former smokers. The goals are to identify new chemopreventive agents, and to develop and validate relevant cancer-related surrogate endpoints for use in clinical trials of former smokers to prevent or diminish the risk of cancer in this population. Dr. Steele noted that only one animal model parallels clinical trials with former-smoker exposure protocols to test known, promising agents and to screen new mechanistic classes of agents. Former smokers have significant elevated cancer risk compared with people who have never smoked, and more than 44 million people in the U.S. are former smokers. The RFA would invite investigator-initiated grant applications that propose developing and evaluating chemopreventive strategies pre-clinically, the research results of which would rapidly translate to

clinical studies with former smokers. Applicants would be especially encouraged to apply a number of newly identified molecular targets for tobacco-related cancers to validate these markers in response to chemopreventive therapy in synergy with NCI's Early Detection Research Network (EDRN). Moreover, studies funded under this initiative could take advantage of animal models for human cancer developed by the Mouse Models of Human Cancer Consortium.

The estimated set aside for 6-8 awards is $3M for the first year, for a total of $9.4M over the proposed 5-year project period. Applications will be accepted for R01 and R21/R33 grants, and for competitive supplements to existing awards. Reissuance for 2 years was requested.

In discussion, the following point was made:

- Animal models of cancer mimicking former-smoker conditions will aid greatly in the investigation of novel biomarkers for precancerous lesions; investigators' creativity should be encouraged in identifying precancerous lesions.

Motion: A motion to approve the RFA/Coop. Agr. concept entitled "Chemoprevention of Tobacco-Related Cancers in Former Smokers: Preclinical Studies" was approved unanimously.

Chemoprevention of Tobacco-Related Cancers in Former Smokers: Clinical Studies (RFA/Coop. Agr.): Dr. Eva Szabo, Chief of the Lung and Upper Aerodigestive Cancer Research Group, DCP, articulated the need for identifying clinically useful chemopreventive agents for use in former smokers. Dr. Szabo stated that the purpose of this initiative is to stimulate the conduct of short-term clinical trials that would test the effectiveness of chemopreventive strategies in former smokers. Currently, almost one-half of all new cases of lung and bladder cancer occur in former smokers, and an estimated 30 percent of all cancers can be attributed to smoking. The identification of molecular and imaging markers of risk and early neoplasia, and the testing of agents that can prevent the development of invasive cancers in this group, are of high public health importance. Short-term pilot clinical studies provide an efficient means to examine the effects of interventional

agents on molecular, imaging, and histologic endpoints in populations at high risk for developing invasive cancers, such as patients with the precursor to cancer of the mouth (oral leukoplakia) and superficial bladder cancer. The proposed RFA would solicit investigator-initiated grant applications and would particularly encourage application of newly identified molecular targets for tobacco-related cancer to validate these markers clinically. A supportive infrastructure is available through the NCI-sponsored EDRN and Specialized Programs of Research Excellence (SPOREs).

The first year set-aside for the 5 year award will be approximately $4M. A total cost of approximately $16.9M for an estimated five to six R01s, U01s, and competitive supplements is anticipated. The option to reissue this RFA for 2 years was requested.

In discussion, the following points were made:

- Consideration should be given to contacting Dr. Steve Lamb in Vancouver to address recruitment issues unique to former smokers. Dr. Lamb has successfully recruited former smokers into lung cancer chemopreventive trials.

- Because former smokers often resume smoking, relapse prevention strategies may need to be incorporated into the studies to minimize attrition.

Motion: A motion to approve the RFA/Coop. Agr. concept entitled "Chemoprevention of Tobacco-Related Cancers in Former Smokers: Clinical Studies" was approved unanimously.

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Adjournment: The meeting adjourned at 1:45 p.m. on Monday, 5 March 2001.

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