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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Cancer Institute

3rd Regular Meeting
BOARD OF SCIENTIFIC ADVISORS
Minutes of Meeting

November 21-22, 1996
Building 31-C, Conference Room 6
Bethesda, Maryland

created: 27sep95 [Lorrie Smith](#) revised: 21jul97

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DCPC;
Chemoprevention
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DCPC;
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Dr. Glynn

ATTENDEES

The Board of Scientific Advisors (BSA), National Cancer Institute (NCI), convened for its third regular meeting at 8:30 a.m. on Thursday, 21 November, in Conference Room 6, Building 31C, National Institutes of Health (NIH), Bethesda, Maryland. Dr. David Livingston, Professor of Medicine, Dana-Farber Cancer Institute, presided as Chair.

The meeting was open to the public from 8:30 a.m. to 6:15 p.m. on 21 November and 8:05 a.m. to 12:32 p.m., 22 November, for introductory remarks from the Chair, discussion of procedural matters, future BSA meeting dates, the NCI Director's report, update on grant pay lines, Program Review Group (P.G.) reports, and review of concepts.

BSA members present:

Dr. David M. Livingston (Chair)

Dr. Frederick R. Applebaum

Dr. Joan Brugge

Dr. Mary Beryl Daly

Dr. Virginia L. Ernster

Dr. Eric R. Fearon

Dr. Suzanne W. Fletcher

Dr. E. Robert Greenberg

Dr. Waun Ki Hong

Dr. Tyler Jacks

Ms. Amy S. Langer

Dr. Caryn E. Lerman

Dr. Joan Massague

Ms. Deborah Mayer

Dr. W. Gillies McKenna

Dr. Enrico Mihich

Dr. John D. Minna

Dr. Sharon B. Murphy

Dr. Allen I. Oliff

Dr. Franklyn Prendergast

Dr. Stuart L. Schneiber

Dr. Joseph V. Simone

Dr. Louise C. Strong

Dr. Peter K. Vogt

Dr. Daniel D. Von Hoff

Dr. William C. Wood

Dr. Robert C. Young

BSA members absert:

Dr. David D. Ho

Dr. Nancy E. Meuller

Dr. Barbara L. Weber

Dr. Alice S. Whittemore

NCAB liaison:

Ms. Zora Brown (absent)

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

**CALL TO ORDER AND OPENING REMARKS
DR. DAVID LIVINGSTON**

Dr. David Livingston called to order the 3rd regular meeting of the Board of Scientific Advisors and welcomed members of the Board, NIH/NCI staff, guests, and members of the public.

Dr. Livingston called to the members' attention the minutes from the previous meeting and items included in the notebook, for example, a listing of currently active NCI program announcements, NCI contract obligations for FY96, a bibliography of chemoprevention publications, and BSA action items from the August 1996 meeting.

**CONSIDERATION OF THE AUGUST MEETING MINUTES
DR. DAVID LIVINGSTON**

The minutes of the 7-8 August 1996 BSA meeting were approved with the following corrections: Dr. Peter Vogt as present and Dr. E. Robert Greenberg as absent.

REPORT OF THE DIRECTOR, NATIONAL CANCER INSTITUTE

DR. RICHARD KLAUSNER

Dr. Richard Klausner discussed the status of the budget and new program initiatives.

Budget: In a brief discussion of the budget, Dr. Klausner indicated that the FY97 NCI budget of \$2.38B represented a 6 percent increase of approximately \$130M over the FY96 appropriation, The NIH appropriation increased overall by 6.1 percent (excluding the \$90M targeted for the Clinical Center). Dr. Klausner stated that the FY97 appropriation reflect strong support for the NIH/NCI as a biomedical research enterprise.

Members were told that approximately 80 percent of NCI's \$130M increase for FY97 will be allocated to the research project grants (RPGS) programs. Funding for intramural research will represent approximately 17 percent of NCI's budget, a 4 percent decrease from FY95.

The overarching principle in allocating the FY97 budget to fund the best science, without regard to the mechanism of funding, was reaffirmed. The Board was told that approximately \$16M will be dispersed through grant mechanisms other than ROIs and POIs. There will be increased funding for training grants, the new Temin Awards, and support for a new minority medical oncology program; a reduction in the percentile for R01 grants from the 23rd to the 22nd percentile; and the Accelerated Executive Review (AER) and exceptions grants process will be continued. The AER pool, which was approximately \$6.7M in FY96, will increase in FY97, reflecting a full year of funding.

Additionally, a legislative requirement for the small business programs has resulted in a \$12M increase in the amount of monies awarded; NCI has allocated approximately \$25M to fully fund R29s (FIRST awards), thereby increasing by \$20M the amount in the RPG pool earmarked for forward funding.

Under NCI's new approach to grant exceptions, each division will be allocated a budget with the authority to make exception funding decisions on applications outside the payline for R29, R21, and R03 grants, as well as to make funding decisions to Provide interim funding and administrative supplements without further review by the Executive Committee (EC). In addition, divisions will be able to fund R01 grant exceptions outside the payline, provided the applications do not exceed \$350,000 in total direct costs for the first year and are within 10 percentile points of the payline. All other grant applications that fall outside the established payline and do not meet the above criteria will be brought to the EC.

New Programs and Initiatives: The Board was informed that staff concepts for new programs and initiatives covering a broad range of topics will be presented to the BSA. If approved, most of the initiatives would be funded in the RPG line from reserved funds.

Dr. Klausner noted that the NCI continues to pursue interactions with the Department of Defense (DoD). The NCI has also signed an agreement with the Veteran's Administration (VA). Forty percent of NCI

cancer centers are at institutions with VA medical centers. The VA agreement is for all clinical trials, Phase I through Phase IV, prevention, diagnostics, as well as treatment. Under the new agreement, the VA will extend the opportunity for all of its patients to participate in clinical trials.

Changes in the AIDS program include: 1) redistribution of funds that increased the percentage for extramural grants from 12 percent in 1995 to approximately 50 percent; and 2) an increase in funding to the AIDS Malignancy Consortium and AIDS Malignancy Bank for basic and translational research and clinical trials. Other initiatives under way are the review of the NCI's clinical trials programs and extensive changes in the NCI AIDS program, including the decision to create a biology-based AIDS drug discovery program built upon the important biologic, pharmacologic, biochemical, and genetic issues of resistance. This area is central to the future of understanding the development and optimization of drugs,

In answer to questions from Board members, the following points were made:

- Regarding the DoD and VA collaboration agreements, shorter clinical trials were discussed as an important goal for the success of these programs.
- Initiatives have begun with many of the third party carrier leaders (e.g., HMO Research Network) interested in research. The NCI will determine if a common agenda exists for possible collaboration.
- When asked how many individuals the NCI would like to see on clinical trials, staff responded that there is not a specific target.
- Additional detailed data on changes in AIDS grant monies will be presented at the March 1997 BSA meeting.

UNFINISHED BUSINESS:

THE BSA AT SCIENTIFIC MEETINGS - DR. ROBERT YOUNG

Dr. Robert Young informed the Board that four national scientific organizations had agreed to host "NCI Listens" sessions. Those organizations are the: American Society for Clinical Oncologists (ASCO), American Society of Hematology (ASH), American Society of Preventive Oncology (ASPO), and American Association for Cancer Research (AACR). Dr. Young indicated that the "NCI Listens" sessions provides an opportunity to obtain Positive and useful feedback from members of these organizations. Evaluations of these discussions will be ongoing and updates will be presented at future meetings.

Following a brief discussion, the following point was made:

- The BSA will consider expanding this activity to other organizations.

NCI PRESENTATION OF CONCEPTS TO BSA - DR. FREDERICK APPELBAUM

Dr. Appelbaum briefly updated the Board on the new Request for Applications (RFA) and Request for Proposal (RFP) concept guidelines. Comments related to the guidelines should be sent to Dr. Appelbaum.

**NEW BUSINESS:
DR. DAVID LIVINGSTON**

Members were reminded of the quadrennial reviews of NCI extramural divisions, Division Directors, and the units within the Office of the Director, NCI. Following a brief discussion, it was agreed that a retreat of a subset of BSA members and NCI staff to develop procedures for the quadrennial reviews would be scheduled. Recommendations for carrying out the reviews will be presented to the full Board at a future BSA meeting.

A brief discussion resulted in the following points:

- Division reviews should be postponed until the BSA has more experience working together.
- Reviews of this nature are probably handled best by the division directors staff, with the BSA being called on as ad hoc participants in the process.
- External analysis can serve to validate important internal analysis, and review processes must be built-in early on.
- Staff site visits are needed for extramural programs. The intramural side has been successfully following a similar system.

NCI AND THE CONGRESS
MS. DOROTHY TISEVICH

Ms. Dorothy Tisevich, Director, Office of Legislation and Congressional Activities presented an update on congressional matters. In a series of slides, Ms. Tisevich briefly summarized the: Kennedy Kassebaum Bill; the results of the recent election, the change in the congressional leadership and the makeup of its committees; the NIH Revitalization Act; and the various bills introduced by the 105th Congress, i.e., the One-Stop Shopping Bill and a Genetic Information Bill (S. 1 898).

UPDATE ON GRANT PAYLINES/DISTRIBUTION OF GRANT FUNDS MR. STEVEN HAZEN

Mr. Steven Hazen, Chief, Extramural Financial Data Branch (EFDB), stated that the process used by the NCJ to allocate the RPG funds starts with a specific budget. Authorized allocations are then set aside for the small business programs (\$50M), noncompeting commitments, including administrative supplements (\$25M), and special initiatives. Multiyear funding of competing grants (\$795M) are then set aside.

The NCI generally starts with well over \$1 B and, after the above allocations, approximately \$250M remains for discretionary funding. Of this amount, \$15M goes to RFAs published in prior years, and \$235M goes to ROIs, POIs, R29s, and the exceptions. Efforts are made to achieve a balance among the ROIs, POIs, and R29s, the three major grant mechanisms. Policy assumption is that the payline and the number of grants remain as close as possible to the previous year. Given that the NCJ does not know when all grant applications will be submitted or the actions of the reviewers, funding projections are often made.

Regarding the quarterly report, Mr. Hazen noted that the August and November 1996 pay lines are comparable to those of the same months in FY95.

In response to questions from Board members, the following points were made:

- When queried about the funding levels for R01 and P01 grants, staff responded that the levels reflect general principles established at the beginning of the fiscal year when the budget is known with certainty and the application pool is approximated. Because there may be large differences in numbers of applications from one year to the next, allocations must often be conservative at the beginning of the year.

NCI STRATEGIC PLANNING DR. EDWARD HARLOW

Dr. Edward Harlow, Associate Director, Office of Science Policy (OSP), informed the Board that OSP is organizationally under the direction of the NCI Director. Dr. Harlow presented an overview of the various activities within the scope of OSP.

By-Pass Budget: The OSP's basic responsibility is to develop a strategic plan and to focus on facilitation rather than implementation. OSP is involved in the construction and writing of the By-Pass budget, a document which is submitted directly to the President. Through this document, which will be rewritten every 3 years, NCI has an opportunity to explain its broad mission.

Working Groups: Four think-tank Working Groups, which correspond to areas of opportunity highlighted in the By-Pass budget, have been formed: 1) Cancer Genetics, 2) Developmental Diagnostics, 3) Preclinical Models, and 4) Early Detection. Working Groups are charged to: develop a statement of goals based on what the scientific world should be like in 15 to 20 years; and recommend how activities might proceed forward towards those goals.

Progress Review Groups: The Progress Review Groups (PRGS) will be charged to look at the present state of cancer research and design national priorities. The PRGs will begin with breast and prostate cancer; other site specific disease opportunities will follow.

Science Information System: The OSP is presently designing an electronic database information system that will provide an opportunity to examine the details of NCI operations. This system will be a resource to identify what is happening within the NCI, how opportunities are being met, and what questions are being investigated.

Strategic Technology Group: Drs. Robert Strausberg and Carol Dahl informed the Board that the Strategic Technology Group (STG) is a focal point at the NCI for technology issues in cancer research that cut across the Institute. Dr. Dahl stated that the key issue of integrating biotechnology or technology development into NCI programs include three critical components: 1) increasing the access to existing and developing technologies; 2) supporting and stimulating the development of critical technologies needed for cancer research; and 3) thinking futuristically about technology research.

In response to questions from Board members, the following points were made:

- The goal statements of the Working Groups are available on the NIH web page, and the implementation ideas of the OSP will be published in the National Registry.
- The Developmental Diagnostics Working Group is identifying how to deal with clinical samples in ways that avoid traditional and Institutional Review Board (IRB) barriers.

- Dr. Strausberg clarified that the OSP is coordinating technology exchanges with the Genome Institute, as well as other government organizations, such as the National Institute of Allergy and infectious Diseases (NIAID).

PROGRAM REVIEW GROUP REPORTS:

DR. JAMES ARMITAGE, DR. JOSEPH SIMONE, and DR. EDWARD BRESNICK

Drs. James Armitage, Joseph Simone, and Edward Bresnick presented updates on the three BSA program review groups.

Clinical Trials Program Review Group (CTPRG) : Dr. Armitage reported that the Group's five subcommittees are currently addressing how to: 1) attract outstanding clinical scientists to a project; 2) identify the priorities for clinical trials; 3) make research allocation decisions; 4) convince patients to participate in clinical trials; and 5) link clinical scientists with scientists from industry and academia. He indicated that the CTPRG draft of the Program Review Group report is expected by February 1997.

Questions from Board members resulted in the following points:

- When queried about alternative models for doing large national cancer clinical trials, Dr. Armitage stated that a single laboratory would be needed for the United States to answer questions about cancer therapy and large national clinical trials.
- Given that only 2 percent of cancer patients in the United States participate in national clinical trials, a registry monitoring the other 98 percent would be ideal to help plan and improve clinical trials. This registry could be similar to the Surveillance Epidemiology and End Results Program database or the Community Clinical Oncology Program (CCOP) mechanism.

Cancer Centers Program Review Group (CCPRG) Report: Dr. Simone reported that the Group's charge was to evaluate the design, achievements, best evaluation methods, funding, flexibility, and accountability of cancer centers. Dr. Simone stated that the Review Group's report was developed around two guiding principles: 1) to develop a process for reviewing the added value that the Cancer Center Support Grant (CCSG) provides scientifically; and 2) to provide increased flexibility and accountability, both financially and programmatically, for the functioning of the cancer centers. He noted that CCPRG members believe that centers should have a substantial, broad portfolio of peer reviewed, cancer-focused research in place and that the core grant should produce added value to the cancer research effort and not serve as the initiator of a base of cancer-related activities.

CCPRG recommendations were: 1) There should be only two types of NCI-designated centers: cancer research centers and comprehensive cancer research centers@ 2) The word "research" should be included in all center designations; 3) Comprehensive cancer research centers should be left fundamentally intact; 4)The criteria for cancer control activities should be clarified; 5) Population-based research should be more broadly defined; 6) There should be no separate review for comprehensiveness; 7) There should be no unfunded mandates; 8) The quality of science and the added scientific value resulting from the C@'SG should be the main review criteria; 9) CCSG guidelines should be revised to permit greater programmatic and budgetary flexibility; 10) The paperwork should be reduced by

requiring less detail in core records and simplifying requirements for noncompeting renewals to include only changes and advances; 1) During the review process, the leadership and direction of a center should be evaluated; 2) Reviewers should be chosen with broad vision and experience; and 3) Senior cancer center directors and administrators should be encouraged to participate as reviewers.

Other recommendations were that the NCI: 1) devise alternative approaches to funding competitive grant renewals to encourage the admittance of new types of centers; 2) develop a process to phase out the lowest-ranked centers; 3) establish a flat dollar amount (i.e., "dollar cap") at the time of competitive renewal; 4) authorize the use of up to 25 percent of the CCSG's first year budget as developmental funds; and 5) allow rebudgeting of up to 25 percent of funds within the cancer center group if review scores for those areas rated outstanding or excellent.

NCI's Response to the CCPRG Report: Dr. Robert Wittes, Director, Division of Cancer Treatment, Diagnosis and Centers, informed the Board that NCI's response to the report will be a set of rewritten guidelines that describe the underlying philosophy of the program, together with a section devoted to the actual policies and procedures for submitting the grant application. Dr. Wittes stated that a very early draft of the new guidelines has received helpful responses from CCPRG members. The development of the new guidelines will be an interactive process between NCI and the community, as represented by the Review Group, with the goal of ensuring that the Cancer Centers Program reflects the philosophy and tone of the report. A February 1997 deadline is targeted for review of the final version of the guidelines.

Recommendations that NCI could agree to implement include: 1) a more precise definition of the criteria for cancer-control research; 2) two types of cancer centers; 3) no separate review of comprehensiveness; 4) no unfunded mandates; 5) concentrated reviews on quality of science and value added by the CCSG; 6) increased flexibility for the center director in allocating funds among categories; 7) the elimination of excessive record keeping for the CCSG application; 8) use of up to 25 percent of the budget for developmental funds; 9) phase out of the present use of planning grants; 10) development of a robust informatics program; and 11) development of separate funding mechanisms outside the CCSG for support of nonresearch service functions.

The most difficult set of recommendations were those that called for a very explicit merit-based system for funding centers. Potential modifications proposed were: First, establish a payline for the centers line each year that would make a distinction between substantially meritorious grants and those that did not deserve long-term support. Second, either phase out competing applications that fall below the payline over 1 to 2 years, if they are recompeting, or do not fund them at all if they are new. Third, implement a sliding scale based on priority score for competing applications failing above the payline to determine the level of funding as a percent of the peer review-recommended level. Fourth, consider no cap on the increase that institutions could ask for when they recompute as long as the total request does not exceed the cap on the size of the total award request.

In response to questions from Board members, the following points were made:

- Growth opportunities for smaller centers may be diminished.
- Phasing out the least successful centers could be beneficial in that the overall level of excellence would be raised and opportunities made for new centers.
- Phasing out smaller centers should be the active decision of the peer review group and not simply the result of failing below a payline.
- One approach to achieving excellence in site visit reviews would come from a cooperative, multidisciplinary approach with the leadership of the cancer centers.

Prevention Program Review Group (PPRG) Update: Dr. Bresnick reported that the Group's subcommittees are addressing diet and nutrition, lifestyle, animal model systems, early detection, behavioral research, chemopreventive drug development, and the training of manpower in cancer prevention. A report may be completed by February 1997.

DIVISION OF CANCER BIOLOGY
DR. FAYE AUSTIN

Dr. Faye Austin, Director, Division of Cancer Biology (DCB), presented an overview of the newly structured division. Dr. Austin stated that the DCB's mission is to stimulate, identify, and support new knowledge about the basic biology of cancer. DCB supports primarily investigator-initiated research through R01, R29, and P01 grants. The division is relatively homogeneous. It is made up of the three Carcinogenesis Branches that were formerly in the Division of Cancer Etiology: the Biological Carcinogenesis Branch, the Chemical and Physical Carcinogenesis Branch and the Radiation Effects Branch; and two branches formerly in the Division of Cancer Biology Diagnosis and Centers: the Cancer Biology Branch and the Cancer Immunology Branch.

Research supported by each branch is as follows: The Biological Carcinogenesis Branch -the role of biological agents, primarily viruses, in the causation of cancer, either as primary factors or cofactors; Chemical and Physical Carcinogenesis Branch - the metabolism, activation and mechanism of action of chemical carcinogens and their metabolites in DNA mutagenesis and the effects of transformation. It also supports basic studies of the mechanism of action of natural and synthetic inhibitors of chemical carcinogens; and Radiation Effects Branch - the molecular mechanisms of DNA mutagenesis in neoplastic transformation induced by ionizing and nonionizing radiation.

In addition to the Extramural Grant Program, the Radiation Effects Branch manages three cooperative studies in Belarus and Ukraine, countries of the former Soviet Union, to study the health consequences of the Chernobyl nuclear power plant accident ten years ago. These studies include the incidence of thyroid cancer in children in Belarus and Ukraine, and studies of hematologic disorders, especially leukemia, in the cleanup workers in Ukraine. The studies are cofunded by NCI, DOE and the Nuclear Regulatory Commission.

The Cancer Biology Branch, also known as the Tumor Biology Program, supports basic studies of the pathogenesis of cancer at the molecular and cellular levels. The Cancer Biology Branch is the largest single grant program in the NCI.

Finally, there is the Cancer Immunology Branch which supports research on the role of the immune system in controlling the growth and spread of tumors. This branch also supports studies of the immune mechanisms and bone marrow and other stem cell transplantations and the biology of leukemias and lymphomas, including AIDS lymphomas.

DCB staff responsibilities include managing a portfolio of grants, facilitating investigator-initiated research, identifying and addressing needs in cancer biology, communicating areas of special interest, and reporting on scientific progress and program accomplishments.

The total DCB active grant portfolio of unsolicited grants was 1,631 grants at the end of FY96.

Fiftyseven percent of all of the NC[unsolicited R01 grants and about the same proportion of R29 grants were funded by DCB. Thirty-seven percent of the NCI POIs are supported by the division. DCB funded at the end of FY96 1,761 awards for a total funding level of \$458 M.

DCB's overall goals for 1997 include: 1) enhancing communication within DCB, across NIH, and with the scientific community; 2) increasing the number of workshops, resources, and innovative approaches; 3) formation of trans-DCB scientific interest groups; and 4) establishing a basic Cancer Genetics Branch (CGB) to provide a better focus for currently supported research and increased interaction with genetics-based programs in other divisions.

In response to questions from the Board, the following points were made-

- Decisions about funding are based entirely on priority scores. While there are no separate program paylines, there is some flexibility in what staff can bring forward as exceptions.
- The percentage of funded grants as exceptions is small.
- The AER process is based solely on merit and not on program priorities.
- When queried about the rationale for having a Cancer Genetics Branch in DCB when there is a Division of Cancer Genetics, Dr. Austin stated that this is only an organizational realignment of staffing because the division already funds grants that deal with studies of cancer genes at the molecular and cellular level.

RFA AND CONTRACT MECHANISMS
DR. MARVIN KALT

Dr. Marvin Kalt, Director, Division of Extramural Activities (DEA), presented an overview of RFA/RFP concept reviews and informed the Board that ideas for the concepts come from strategic planning, portfolio analysis, meetings and workshops, public health emergencies, executive and legislative mandates, and unmet needs. Dr. Kalt explained that cooperative agreements are investigator-initiated but are solicited via an RFA and require concept review by the BSA. RFAs and Cooperative agreements require a set aside of funds. Only cooperative agreements include government staff in participatory roles. Solicitations through program announcements (PAs) are also investigator-initiated. PAs differ from RFAs and cooperative agreements in that there are no funds set aside, nor do they require concept review by the BSA.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER EPIDEMIOLOGY AND GENETICS
DR RUTHANN GIUSTIS**

Cancer Genetics Network (Cooperative Agreement) - Dr. Ruthann Giusti reported on the general guidelines developed by the Cancer Genetics Working Group for the Cancer Genetics Network (CGN). Using a series of slides, Dr. Giusti provided background information on the importance of genetics testing and the need to develop novel approaches to communicating high quality and up-to-date information about cancer genetics to health care providers and to consumers. She explained that the Cancer Genetics Network is a research resource that would be funded as a resource-related (U24) cooperative agreement.

The network was described as a dynamic infrastructure with the objectives to: 1) enroll individuals who are potential participants in cancer genetic studies; 2) develop and disseminate current comprehensive, high quality information about cancer genetic susceptibility and testing; 3) enhance participation in clinical cancer genetics research; 4) develop and assess approaches to risk communication and informed decisionmaking in laboratory testing procedures; and 5) collect outcome data linking specific mutations with phenotypes. These objectives will be achieved through two primary network functions, a communication or education function and a registry function.

The CGN will consist of the following centers: 1) Network participating centers which will recruit and follow participants and will provide core data to the network registry. Up to eight participating centers will be funded at \$250,000 to \$300,000 per site annually; 2) an Informatics and Data Management Center - a center of technical excellence funded at a level of \$600,000 annually to develop and maintain the network registry database; and 3) a Communications Coordinating Center - funded at a level of \$500,000 annually and will coordinate the communications, education, and outreach functions of the network. The funding level requested is \$3.5M annually for a 5-year period.

In response to questions from Board members, the following points were made:

- When queried as to whether the Communications Coordinating Center and the Information Data Management Center would be established in the same location, Dr. Giusti explained that the two centers are conceived as having two separate technical and scientific functions. As such, the centers would be competed individually to maximize competition.
- In response to concerns raised that there were too many specifics presented, Dr. Giusti stated that there would be less specification in the final RFA.
- In response to a concern that the proposal was limited to only eight centers, Dr. Klausner stated that the idea was to start with a Phase I that would begin to develop the infrastructure. Phase I would include a limited number of centers that would be competed for by single sites or a

consortium. In future years, the infrastructure would grow to include more sites nationally.

- With regard to a question relating to the lack of funding for testing minority populations, Dr. Guisti stated that this issue would be further explored. Presently, the network could not support the cost of testing.
- When asked how this infrastructure will interface with the organ-specific registries that are already in the process of being established, Dr. Giusti responded that the proposed network would be complementary to a number of existing efforts, including the organ-specific registries. The major difference between the registries and the network is that the network is targeted primarily to individuals. Additionally, because it is streamlined, it has the potential to be broad based and expandable.
- In response to a question on how confidentiality of genetic information would be ensured, Dr. Klausner responded that, in Phase I, the centers would develop a plan for creating a system that allows communication and allows registration that satisfies the issues of confidentiality, encryption, and protection. The NCI would participate in establishing and ensuring the appropriateness of the criteria.
- Prior to proceeding with the final RFA, staff should address the difficulty in conducting annual followups; feasibility of obtaining reimbursement; the question of overlap with other existing registries; and whether smaller, more targeted demonstrations should be conducted.

Motion: A motion was made to approve the concept with the following recommendations: 1) the RFA should be reviewed by the NCI Executive Committee before it is issued; the removal of all specifics regarding the number staffing positions that would serve in individual centers and what their jobs will be; and clearly indicate that confidentiality and privacy aspects will be securely protected. The motion was seconded and approved, with two members opposed and two abstentions.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF EXTRAMURAL ACTIVITIES
DR SANYA SPRINGFIELD**

Career Development and Mentored Peer Review Award (RFA): Dr. Sanya Springfield, Program Director, Comprehensive Minority Biomedical Program (CMBP), DEA, in a series of slides, provided background information on the subject of research grants for underrepresented minorities. Dr. Springfield stated that trend data show that very few underrepresented minority researchers have applied and received F32, R29, and R01 grants.

The three goals of this RFA are to: 1) establish independent research careers for underrepresented minorities; 2) increase the number of nontargeted research grant applications from underrepresented minority scientists; and 3) increase the pool of qualified underrepresented minority reviewers and advisory members. Support will be for those underrepresented minority research scientists who: 1) have been the recipient of an NIH Research Supplement for Underrepresented Minorities award; and 2) need an extended period of sponsored research as a way to gain experience while bridging the transition from a mentored research environment to an independent research/academic career.

The mechanism of support will be the Research Scientist Development Award (K01). Support will be for up to 5 years at a direct cost level of approximately \$150,000 per year. The total cost projected over 5 years, for approximately 10 awards and two annual competitions, would be \$7M.

In response to questions from Board members, the following points were made:

- When asked about the requirement that limits candidates to recipients of a minority supplement award, Dr. Springfield explained that initially the idea would be to support supplement awardees, but that the eligibility will be opened to others, depending on the success of the program.
- A member indicated that the program should be expanded to include more candidates and should also extend across multiple elements of the NIH. Dr. Kalt responded that there is a defined number of investigators who would be considered for this award, and that the intent was to look at expanding the program in future years. Additionally, if these individuals are successful, then they are likely to start applying for R01s before the fifth year, so maximum award level might not be achieved.
- In response to a question regarding the level of a candidate's involvement in peer-review activities, Dr. Springfield explained that the candidates would begin by observing study sections; some could be qualified to serve on study sections as temporary members. There will also be a mock study section(s) workshop for those individuals who have never participated in peer-review activities.

- Consideration will be given to a member's suggestion that the name of the award be changed to Career Development Award.

Motion: A motion to postpone action on the concept pending budget clarification carried with one abstention.

Motion: Following receipt of the budget information, a motion was made to approve the concept. The motion was seconded and unanimously approved.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER TREATMENT, DIAGNOSIS AND CENTERS
DRS VINCENT CAIROLI and ELLEN FEIGAL**

AIDS - Oncology Clinical Scientist Development Program (RFA): Drs. Vincent Cairoli, Chief, Clinical Training Branch, and Ellen Feigal, Clinical Investigations Branch, presented this RFA concept. Currently, there is no specific subspecialty of medicine in the area of HIV/AIDS, nor any formal, nationally recognized training program integrating the specialized skills in hematology, oncology, and infectious diseases needed to address AIDS-related malignancies. The purpose of this program, therefore, is to support institutional, multidisciplinary, training programs focused on the HIV/AIDS oncology field with the goal being to train a cadre of clinicians with the highly specialized skills necessary to address the clinical and research problems associated with AIDS-related malignancies. The training requirements would demand an interdisciplinary program that includes didactic research and patient components, as well as requiring an advisory committee that would have oversight authority for selection of the candidates, mentoring, and review of the critical nature of each research project.

A K12 funding mechanism was chosen because it is an institutional type mechanism that affords better salary support, with no payback obligation; and is helpful in recruiting clinicians. Information from principal investigators and department heads suggested that this type of program cannot be supported as a single award made to one person.

The total cost projected over 4 years for 45 awards, beginning September 1997, would be \$9M. This will be a 2-year training program for each trainee, with an average cost per trainee of approximately \$95,000/year.

In response to questions from Board members, the following points were made:

- Eligibility for this program is not necessarily targeted to those who have already completed fellowships in oncology or infectious diseases. In reality, most clinicians have 3 to 4 years of training prior to their application for clinical fellowships. As many boards now allow 1 or 2 years of research as part of a clinical fellowship, this program would fit nicely into that timeframe. The design of the program provides sufficient flexibility to allow the applicant organization to identify the target candidates and offer a program that is commensurate with the background of the candidates selected.
- Applicants who responded to the NCI quick-response letter of February, involving applications for supplements to the cancer centers for basic research or training, would still be eligible for this program. No distinction would be made between those who had already received the 1-year funding and those who had not.
- To determine the number of positions that the applicant institute is requesting, one of the peer-

review criteria addresses the applicant pool size and the type of candidates in the pool from each institution. Peer review can result in a reduction of the number of positions, if it is thought that the applicant pool size does not justify the numbers requested.

- In response to a concern that there will not be a sufficient amount of quality applicants to make the program worthwhile, Staff discussed the average applicant numbers for each year that are anticipated during the 4-year program, three, six, six, and three. It was emphasized that 18 was only an average and, currently, the plan is to issue about 5 awards that would include 45 people in 4 years. Staff acknowledged that the requirement that the applicant organization must have the requisite number of patients was highly restrictive and would result in the exclusion of a certain number of centers.
- Each institution does not have to provide "three" or any specific number of individuals to train in AIDS oncology per year. The institution can propose the number of applicants that they can reasonably recruit and train in terms of resources and availability.
- In response to members' concern that there may be prejudice against institutions applying for awards, if they could not produce the "three" investigators yearly, Dr. Cairoli assured them that no fixed numbers exist. The intent of the RFA is to be as flexible as possible to mesh with the programmatic thrust of the institution. The NCI will not dictate to the institutions how many applicants must be submitted.

Motion: A motion was unanimously approved to support the RFA concept as proposed.

Dr. Livingston adjourned the open session of the 21 November meeting at 6:15 p.m. and called the 22 November meeting of the BSA to order at 8:05 a.m.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER TREATMENT, DIAGNOSIS AND CENTERS
DR GORDON CRAGG**

National Cooperative Biosynthesis-Directed Drug Discovery Groups (RFA): Dr. Gordon Cragg, Chief of the Natural Products Branch, stated that the Developmental Therapeutics Branch of the Division of Cancer Treatment, Diagnosis, and Centers (DCTDC) has, for many years, emphasized the investigation of natural products as a source of potential new therapeutic agents. Over 60 percent of the anticancer drug candidates currently in clinical and preclinical development are naturally-derived and include agents from marine, microbial, and plant sources.

Dr. Cragg stated that this concept aims to apply combinatorial biosynthesis processes to drug discovery through the generation and screening of expanded polyketide and/or other biosynthetic pathway libraries, and the elaboration of these libraries through the use of tailoring enzymes and other appropriate biologic strategies. The objective is to foster multidisciplinary approaches to the discovery and/or optimization of novel anticancer drugs using combinatorial biosynthesis. This concept proposes the establishment of drug discovery groups, assembled by a Principal Investigator, to form a multidisciplinary and multiinstitutional consortium of individuals with the skills needed to pursue the proposed lead discovery compounds and their optimization successfully. The inclusion of industrial partners to carry out such efforts will be strongly encouraged.

A cooperative agreement mechanism was chosen because significant involvement of NCI staff and the award recipients in the conduct of the investigations will be required. This partnership would facilitate technology transfer from government-owned databases and repositories and the use of appropriate contract resources to enhance the Group's efficiency and effectiveness.

The total cost projected over 5 years, beginning September 1997, would be \$13.5M. It is anticipated that there will be three to four awards, although the number is flexible. The cost for this concept is \$2.5M for year 01.

In response to questions from Board members, the following points were made:

- A 5-year plan was recommended, because it is anticipated that it will be 1 to 2 more years before molecules with significant activity begin to emerge. It is envisioned that these lead compounds could then be further elaborated by techniques such as combinatorial chemistry, which overall could take 3 to 5 years. No clinical candidates are expected from this program.
- A cooperative agreement was chosen, because the input of the NCI in the discovery process is very important, i.e., in terms of providing added screening capability and devoting NCI resources to preclinical development, formulation, and pharmacology and can expedite discovery.

- The thrust of this plan is to determine if it is possible, within a structural class already known to be rich in compounds with both demonstrated pharmaceutical uses and potential, to determine whether the additional diversity that can be generated using engineered organisms would be productive. Such diversity might serve as a foundation for further studies in synthetic combinatorial chemistry, further elaborating the diversity to a degree that cannot be achieved using more conventional engineered biosynthetic pathways.
- A member indicated that, using combinatorial chemistry, it is possible to achieve structural diversity in the area of polyketides greater by orders of magnitude than that achieved through the use of microorganisms.
- With regard to the issue of structural diversity, a Board member suggested that the microbial technique has a number of shortcomings; the first one is the slow pace. The number of molecules anticipated from such a strategy might be tens of thousands over 5-years. However, over 2-years the number is almost zero. In contrast, existing methods in combinatorial chemistry now have capability to synthesize molecules in unlimited quantities; for example, the number of nonoligonucleotide, nonpeptide, organic molecules that have been synthesized in the laboratory of the Board member since January 1996 is about 80 million.
- The second shortcoming is in screening these molecules. It is essential to develop combinatorial methods in concert with new screening approaches. Radically new screening approaches are needed to incorporate new technical advances, to use smart assays and knowledge of cell biology, and to define pathways and methods to implement the screens, using millions of molecules.
- A Board member questioned the feasibility of using marine and plant-based systems, given their complex nature from the point-of-view of genetic control as well as the product enzyme interaction and related metabolism. Members inquired as to how empirical the choice of targets would be and how the targets would be designed, particularly in this area of plant and marine organisms? Dr. Cragg acknowledged that these systems are considerably more complex and require some very basic research. He informed members that the targets would be approached through cell culture, emphasizing that this was the core of the second concept scheduled for presentation.
- A Board member summarized his review of the concept by stating that both new agents and clinical trial candidates are needed. In this regard, the National Cooperative Drug Discovery Group (NCDDG) has a good track record. One reason for their success appears to be the use of both biochemists and biologists to determine if screening problems exist. Also, biologic targets are selected by the client group. Generation of clinical candidates is needed. The concept does not provide a clinical candidate approach. With that in mind and the lack of strong evidence of the new technology over combinatorial chemistry, as it was presented, the recommendation was to revise the agreement to include the goal of producing viable clinical candidates.

- As a result of the discussion, Dr. Wittes suggested that both RFA concepts be tabled for reconsideration and reformulation by the DCTDC.

Motion: It was moved and seconded that Drs. Wittes, Cragg, Sausville, Schreiber, Mihich, Von Hoff, and Oliff form a discussion group to resolve the issue of whether developmental therapeutics is appropriate at this time as an intramural program and, if so, to determine the mechanisms needed to stimulate research in this area. The motion was unanimously approved.

A future agenda item should be a presentation on the NCDDG program, exploring its track record for drug development and the program's operations and organization.

Motion: It was moved that a committee, organized by Dr. Wittes, be formed to explore how the NCI might participate in, collaborate with, or present opportunities in combinatorial biosynthesis to the granting community. The motion was unanimously approved.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER TREATMENT, DIAGNOSIS AND CENTERS
DR JAMES JACOBSON**

Technologies for Generation of Full-Length Human cDNA Libraries (RFAs): To provide conceptual background and an introduction to two related RFA concepts, Dr. Klausner presented a summary of the Cancer Genome Anatomy Project (CGAP), describing the mechanisms and expected achievements of the project. He stated that CGAP is an example of an intramural initiative that will interface with in house resources. The goal of CGAP is to find unique niches where genetic research can make an impact and fill a need. The RFA concepts fulfill the needs for: 1) high-quality, characterized, usable cDNA libraries; and 2) the creation and dissemination of robust technologies that can move into the NCI research enterprise.

In response to questions from the Board members, the following points were made:

- In response to a Board member's concern about duplication of efforts and cost effectiveness issues, Dr. Klausner emphasized that, because these are investigations into the unknown that use an empirical approach, much testing will be required.
- CGAP is an intramural effort and is part of an infrastructure that consists of developing functional libraries. The information will then be available for everyone.
- Although an explosion of ideas about technological approaches has occurred, most approaches have limitations. Fostering the development of useable technologies will help to overcome the limitations that are now faced by researchers.

Dr. James Jacobson, Program Director for Biochemistry and Immunodiagnosis, Cancer Diagnosis Program, presented the two RFA concepts. Dr. Jacobson stated that the goals of the CGAP are to: 1) establish a complete index of all genes that are expressed in tumors; and 2) develop novel technologies (e.g., scanning) to facilitate the comprehensive evaluation of the molecular profile of human tissues.

*The first concept, **Technologies for Generation of Full-Length Human cDNA Libraries**, will request applicants to propose the development of efficient, cost-effective technologies that will facilitate the replacement of expressed sequence tags (EST) libraries with cDNA libraries consisting of clones that contain the full coding sequences of the represented genes. In addition, applicants will be asked to define milestones and a realistic timeline for accomplishing the proposed research. Continued funding will depend on progress toward meeting the proposed milestones, which will be assessed by administrative review.*

Support will be through the Exploratory/Developmental (R21) mechanism, which allows grants to be submitted when limited preliminary data exists and there are time limitations. The total cost projected

over 3 years, beginning September 1997, would be \$7.5M. It is anticipated that there will be 10 awards. The cost for this concept is \$2.5M for year 01.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER TREATMENT, DIAGNOSIS AND CENTERS
DR JAMES JACOBSON**

The second concept, Novel Technologies for Evaluation of Molecular Alterations in Tissue, will encourage the development of integrated systems that support all aspects of these analyses, including sample preparation, sample analysis, and appropriate informatics systems for data collection and analysis. These technologies are intended to facilitate the discovery process in cancer biology research at the level of both gene discovery and molecular cellular biology.

Support for this research program will be through the R01 (traditional investigator-initiated grant) and R21 mechanisms (pilot project/feasibility study). To accommodate investigators with ideas that currently are ready to submit as well as those who may need time to develop their ideas, applications will be solicited for two receipt dates, approximately April 1, 1997 (funded in FY97), and November 1, 1997 (funded in FY98). Total costs, projected over 4 years, for 4-6 awards would be \$6M per the two receipt dates.

In response to questions from Board members, the following points were made:

- A Board member noted that some of the terms used in the concepts may either lack specific definition or raise other issues. For example, does "tumor" mean epithelial, lymphoma, mesenchymal, etc.; also, what specific factors are included under "quality control?" Staff stated that these are issues for the applicant. Although the purposes of the concepts are to stimulate technologies, these issues will have to be addressed as the technology develops and is actually applied. Considerable dialogue with investigators prior to project initiation is anticipated.
- The R21 mechanism allows the NCI to target the review of applications through an ad hoc group of individuals who are familiar with such technology.
- In response to a Board member's suggestion that it may be better at this time to fund more applications rather than fewer, Dr. Jacobson stated that 10, the number of awards for the first concept, is not absolute, but a suggested average.
- Technology development is an important area for NCI involvement and coordination. A variety of areas of technology development are in the planning stages at this point. A workshop is scheduled that will begin to identify and gather the appropriate people to discuss how to achieve some of the technology goals of interest. A report of the progress and evolution of such programs and grants will be presented to the Board in approximately 6 months.

Motion: A motion was made and unanimously approved to support the two RFA concepts as proposed.

- o A Board member observed that, because the BSA is a large, diverse group, there was not enough time to make judgements about the scientific merit of some of the concepts. The member, however, thought that the Board is uniquely qualified to address three questions that are not always considered, given the manner in which the concepts are presented. First, why is there a gap in the funding mechanism that results in funding issues being addressed in unconventional ways? Second, how was the budget determined? Third, how was the budget justified? The Board needs to consider these questions. Concept presentations should, perhaps, focus less on the science and more on the issues that the Board needs to consider. Another member noted that the Board's recent decision to divide into two subcommittees for concept evaluation may allow time to present both aspects as an interrelated approach.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER PREVENTION AND CONTROL
DR. GARY KELLOFF**

Pivotal Clinical Trials for Chemoprevention Agent Development: Dr. Gary Kelloff, Chief of the Chemoprevention Branch, stated that the RFA will be used to fund small end Phase III trials with approximately 300 patients. The trials will last 6 months to 5 years, be of sufficient size to identify disease endpoints, using biomarkers, in each arm of the trial, and presumably lead to larger trials. Through cooperation and assistance from the NCI and liaison with the Food and Drug Administration (FDA), there will be a systematic development of agents to their next logical step. These will be investigator-initiated protocols involving a multidisciplinary approach; a variety of target populations will be viewed, and biochemical and genetic markers will be validated.

Dr. Kelloff noted that the controlled trials will evaluate efficacy of agents in controlled populations; the agents, sites, and populations will be selected by the investigators. He stressed the importance of validating biochemical and genetic markers and of being able to measure these markers. Six or 7 cooperative agreement awards will be funded for 3 to 5 years beginning in September 1997. An average trial will cost from \$800,000 to \$1M per year, with a total cost per trial of \$4M.

In response to questions from Board members, the following points were made:

- In response to questions concerning the targeted organs and the availability of appropriate agents, Dr. Kelloff stated there were numerous agent candidates that are ready for testing. The DCPC envisions funding a colon, lung, and prostate application, but the choice of agent and site in the trial will be the investigator's decision.
- In response to a member's suggestion to defer a decision until the Prevention Program Review report was received and reviewed by the BSA, members were informed that the EC has decided to proceed with all program area activities and not to delay any action(s) while waiting for PRG reports.
- When queried as to why the RFA was selected as the funding mechanism, staff stated that the RFA mechanism is less expensive in the aggregate than many R01s.
- With regards to the difference between the proposed concept and the one presented at the August 1996 BSA meeting, Dr. Kelloff stated that the intent of the current concept is to identify disease endpoints; the August RFA addressed trials that will examine biomarker developments and correlations of existing precancer endpoints.
- When asked about the size of the trials, several hundred people on multidisciplinary collaborative randomized studies, and quality assurance, safety, and validity, Dr. Greenwald stated that

independent data safety monitoring boards will be part the trials. Tissue-based endpoints will be built into the trial design.

- In response to a member's concern about the lack of supporting data for the agents and endpoints listed, the large dollar amount, and the detailed site and agent listings in the RFA, Dr. Greenwald responded that it will be up to the investigators to establish the case for agents and valid reproducible biomarkers and endpoints.

Motion: A motion was made to approve the RFA concept with minor changes in wording so that the listings for agents and sites is not so restrictive and a 50% reduction in the budget to \$15M. Renewals would compete from the R01 pool. The motion was unanimously approved.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER PREVENTION AND CONTROL
DR. GARY KELLOFF**

Chemoprevention in Genetically Identified High-Risk Groups: Interactive Research and Development Grants (RFA): Dr. Kelloff stated that this RFA, a cooperative agreement, is designed to focus on, define, and evaluate chemoprevention strategies in asymptomatic individuals at very high risk for cancer. The trials will consist of 50-100 patients, call for an interactive and multidisciplinary approach, and be investigator initiated. Each award will fund at least three independent research projects with a shared common focus. Examples of studies and trials that may be conducted through this funding mechanism were given. Each trial will include three investigators for five years at a level of approximately \$300,000 annually.

In response to questions from the Board, the following points were made:

- A member questioned the similarity between the RFA being reviewed and the funding request presented to the BSA in August 1996. Staff responded that the focus of the previous RFA was to determine efficacy leads as efficiently as possible. Detailed basic mechanistic research had not been included in the previous RFA. Availability of human tissue before and after drug dosage is included in the present RFA. It is expected that basic molecular biology and translational research will be conducted.
- In response to a member's concern about the lack of animal models, Dr. Greenwald stated that consideration will be given to including animal models in the RFA.
- When queried whether the three investigators would be in the same or different scientific area at one institution, Dr. Greenwald stated that it could be a program project at one site with a strong team. Dr. Kelloff added that applications would not be restricted to investigators from just one institution.
- Funding for genetic testing and counseling of high-risk individuals is not included in the RFA, but investigators could request funding in their individual submissions.
- When asked if DCPC was concerned about insufficiently large cohorts, Dr. Greenwald stated that only those applications with a strong statistical argument for the study design would be funded.
- A member questioned the lack of efficacy in high-risk groups, considering animal data, and whether a pilot study would be more appropriate at this stage. Dr. Greenwald responded that data are available, and it is the investigators' responsibility to present the appropriate data.
- A member commented that additional fundamental research should be required prior to

undertaking this project. Staff responded that this method provides an opportunity to obtain information on high-risk individuals and develop a mechanistic understanding.

- A member requested that the RFA be written to allow for pilot work, and that a trial component be included. Staff concurred.
- A member noted that this RFA, except for the involvement of high-risk populations, is related to the first RFA and suggested that the funding be reduced by 50 percent.

Motion: A motion was made to approve the RFA with modifications to address concerns raised by the Board with a 50% reduction in the budget (\$15M) . The motion was approved with one abstention.

**RFA CONCEPTS PRESENTED BY NCI PROGRAM STAFF
DIVISION OF CANCER PREVENTION AND CONTROL
DR. THOMAS GLYNN**

Prevention of Tobacco Use by Children and Youth in the U.S. (RFA): Dr. Thomas Glynn, Chief of the Prevention and Control Extramural Research Branch (PCERB), stated that nothing has changed during the past 14 years regarding cigarette smoking being the chief single avoidable cause of death in our society, the most important health issue of our time. Dr. Glynn reviewed the tobacco statistics.

The intent of the RFA is to support innovative research in new areas that have the potential to foster a significant and prolonged reduction in the use of tobacco by youth in the United States. Dr. Glynn stated that school-based tobacco prevention programs have had modest success and the RFA will focus on applying what has been learned. Primary research needs identified included: psychopharmacology, i.e., how dependent youth can be helped to stop; behavioral genetics; health care policy effects; sensitivity to price increases; health care delivery methods and changes; tobacco prevention counseling within the managed care structure; age and setting for intervention and treatment; tobacco prevention messages and their delivery system; and effective use of school-based intervention data.

Dr. Glynn stated that the RFA mechanism was chosen because of the need for a focused coordinated research effort. The RFA will be released in 1997 and 1998, with a set aside of \$4M per year. Eight to 10 awards will be made with a cap of \$500,000 per year. He added that public interest is high, and it is important for the NCI to take a lead on this issue.

In response to questions from Board members, the following points were made:

- In response to a question regarding intramural support for the RFA, Dr. Glynn stated that there had been meetings with the National Institute of Child Health and Human Development (NICHD) and the National Heart, Lung and Blood Institute (NHLBI) staff. A meeting with a trans-NIH tobacco group is planned.
- The RFA title be changed to reflect cessation of tobacco use among children.
- The innovative requirements and the preventive opportunities of the RFA should be reinforced and the peer-review groups be constituted in a manner to encourage innovative research.
- When queried about the announcement methods and the inability of the NCI Home Page, the primary notification vehicle, to reach a wide, interested audience, Dr. Glynn stated that DCPC had received a mailing list from Head Start, and was looking at other groups in an effort to expand the RFA notification process to groups and individuals not previously targeted.

Motion: A motion was approved unanimously to support the concept.