THE CANCER LETTER

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Cooperative Groups Advised To Plan For Future Of Less Funding From NCI

Leaders of the NCI-supported clinical trials cooperative groups should plan on receiving less government funding over the next several years, Institute officials said last week.

The cooperative groups should attempt to forge innovative relationships with the pharmaceutical and biotechnology industries, as well as insurers and health care providers, said Michael Friedman, director of the NCI Cancer Therapy Evaluation Program.

Yet, while budgets are shrinking, research opportunities are

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In Brief

General Motors Cancer Research Foundation Prizewinners: Brock, Li, Fraumeni, Harlow

GENERAL MOTORS Cancer Research Foundation Prizes will be awarded next week to four scientists who made groundbreaking discoveries in molecular biology, epidemiology, and clinical research. The Charles F. Kettering medal for outstanding contributions to the treatment of cancer will be awarded to **Norbert Brock**, former chief of the Dept. of Cancer Research ASTA Werke in Bielefeld, Germany. The Charles S. Mott medal for outstanding research in cancer causation and prevention will be shared by **Frederick Li**, of the Dana-Farber Cancer Institute, and **Joseph Fraumeni Jr.**, of NCI. The Alfred P. Sloan Jr. medal for outstanding basic science contributions to cancer research will go to **Edward Harlow Jr.**, *of Massachusetts General Hospital*. Each GM prize includes a $100,000 award and gold medal. The prizes will be awarded June 21 in Washington. . . . . **ROBERT A. WELCH AWARD** in Chemistry for 1995, presented by The Welch Foundation, has been awarded to **Robert Abeles**, professor of biochemistry at Brandeis Univ., and **Jeremy Knowles**, dean of the Faculty of Arts and Sciences, Harvard Univ. Abeles' work has focused on how enzymes serve as catalysts. Knowles' research centers on understanding the actions of enzymes that speed chemical transformations in humans. . . . **BERNARD WEINSTEIN**, director of the Columbia-Presbyterian Cancer Center, and **Stephen Goff**, Higgins Professor of Biochemistry & Molecular Biophysics, at Columbia-Presbyterian, have been elected Fellows of the American Academy of Arts and Sciences. . . . **DANIEL ZELTERMAN** will join the Yale Cancer Center as director of the Clinical Research Office and professor of public health (biostatistics). Zelterman is on the faculty of Univ. of Minnesota.

Groups Advised To Seek Relationships With Industry

(Continued from page 1)

expanding, Friedman said last week at the semi-annual meeting of the chairmen of the cooperative groups.

"You will have an unmanageable mismatch between what you will want to study and the resources to study it," Friedman said. "We are now looking at perfectly valid questions that we won't be able to answer, and we are going to have to live with that."

Friedman said his remarks were intended to alert the group leaders to the concerns of the NCI. "My goal is to infect you with some of the anxiety we feel," he said.

Plan On Tighter Budgets

The anxiety to which Friedman alluded is created by the following developments:

●Efforts of Congress and the Administration to balance the federal budget are expected to result in tighter budgets for NCI. Appropriations projected for NCI over the next five years by the Administration will not keep pace with the biomedical research price index.

●Richard Klausner, chief of the Cell Biology and Metabolism Branch of the National Institute of Child Health and Human Development, widely regarded as the HHS choice for NCI director, is a basic scientist, who, several NCI officials point out, does not have direct experience with clinical cancer research. The White House is expected to announce his appointment in a matter of weeks.

●Because NCI has never been able to fully fund cooperative group research, the institutions where groups are based have provided substantial support. However, under managed care and cost control measures, these institutions are increasingly unable to provide research funds.

NCI's $77 million cooperative group program supports networks of clinical investigators around the US and Canada. The program's budget was flat in FY95. Under House and Senate budget proposals, NCI as a whole would experience a cut of between 1 to 5 percent.

"There will be a reduced budget and to think otherwise is fantasy," Friedman said. "We should today plan how we will operate with less money."

Groups have been able to "patch together resources" from industry, philanthropy, and from their own institutions, Friedman said. These efforts will need to be strengthened, he said.

"The new director and NCI leadership is going to be less interested in group accomplishments in the past, but what are you doing now and your plans for the future," Friedman said. "Things are going to be science-based. Are you asking clear [research] questions, are the answers useful? We should look fresh at what we do."

Groups that become involved in national efforts, such as tissue banking and prevention studies, will have greater advantage, Friedman said. "The more services you can deliver, the more valuable you will seem," he said.

Large, Simple, Inexpensive Trials

Robert Wittes, acting director of the Div. of Cancer Treatment, said the Institute's intramural program is expected to downsize significantly under the recommendations of the National Cancer Advisory Board's Working Group on the NCI Intramural Program (Bishop-Calabresi report, **The Cancer Letter**, May 19).

However, the extramural program probably will not benefit as a result, Wittes said. "The money probably will go back to the Treasury," he said.

Wittes said the groups should attempt to work with insurers to show that clinical trials are "outcomes" research. "If trials are kept cheap and simple, you can show that trials don't cost much or may be even less than standard care," he said.

Charles Coltman, chairman of the Southwest Oncology Group, said the group chairmen should request a meeting with the new NCI director. "No one can fully represent what we do other than us," he said.

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Recovery of funds: New requirements, or "terms of award," for the cooperative agreements that fund group headquarters will not include a previously proposed section on NCI's authority to recover research funds in the event of scientific misconduct.

NCI officials have said the Institute has the authority under Public Health Service regulations to recover funds provided to the group headquarters in the event that any member of the group has been found guilty of scientific misconduct (**The Cancer Letter**, Dec. 9, 1994).

Group chairmen said their institutions would be uneasy signing an award that included such wording, in effect accepting liability for misconduct at subcontract institutions.

NCI officials said they removed the wording that group chairmen had opposed, because NIH published a statement on awardee responsibilities that supersedes NCI terms of award.

A statement published in the NIH Guide to Grants and Contracts last year described Public Health Service policies on misconduct in science (**The Cancer Letter**, Dec. 9, 1994). Included is a section on recovery of funds:

"Under 45 CFR 74.170, et seq., and the cost principles referenced therein, expenditures of awarded funds for research that is invalid or unreliable because of misconduct in science may be considered unallowable costs for which the awardee institution is liable for repayment to the awarding agency. This is decided on a case-by-case basis."

NCI's authority to recover funds is expected to be tested in a case the US government filed earlier this month against St. Luc Hospital of Montreal (**The Cancer Letter**, June 9).

In another change to the terms of award, NCI requires that institutions receiving the grants assure that group member institutions have procedures in place to contact patients who were research subjects and encourage them to notify the group of address changes.

This provision is to keep patient records current so that they may be contacted and informed of changes in clinical practice or findings of scientific misconduct.

The new terms of award will become active in FY96.

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Group chairmen unanimously approved a change to the NCI guidelines for Data Safety and Monitoring Committees that will allow slow-accruing protocols to be closed sooner.

Under the new guidelines, a group chairman may act immediately on the recommendation of the trial's DSMC to close a trial for lack of accrual. That decision is usually made during a group's membership meeting.

In the past, NCI required the group to consult CTEP staff following the meeting, before informing group members.

ODAC Recommends Ethyol, DaunoXome For Marketing

The FDA's Oncologic Drugs Advisory Committee last week recommended approval for an agent that protects against the toxicity of cisplatin and a liposomal formulation of the anticancer agent daunorubicin as a first-line treatment for Kaposi's sarcoma in HIV-positive patients.

The chemoprotective agent, Ethyol (amifostine), is sponsored by US Bioscience (AMEX: UBS) of West Conshohocken, PA.

Ethyol was approved in an 8-0 vote for cumulative renal injury associated with cisplatin chemotherapy for treatment of ovarian cancer.

ODAC recommended accelerated approval for the drug, making use of a mechanism that allows for marketing of a drug while its sponsor gathers final proof that it works.

The committee did not recommend approval for Ethyol on two previous ocasions, in 1992 and last year.

US Bioscience said it would work with FDA to determine the final labeling for Ethyol. The company also said it is studying the agent's activity in other chemotherapeutic regimens and tumor types as well as its potential to protect from toxicities of radiation therapy.

Ethyol is approved in Britain, Germany, France, Spain and Luxembourg.

Phase III Data For KS Drug

The Kaposi's sarcoma drug, DaunoXome, was sponsored by NeXstar Pharmaceuticals Inc. (Nasdaq: NXTR) of Boulder, CO.

ODAC made its recommendation after reviewing the company's amended New Drug Application, which included data from NeXstar's phase III study

completed in September 1994.

The controlled, randomized study of 227 HIV-positive patients with advanced Kaposi's sarcoma compared the efficacy and side effects profile of DaunoXome and a three-drug regimen of adriamycin, bleomycin and vincristine.

Earlier this month, DaunoXome was approved by Sweden's Medical Products Agency.

RPR Requests Delay For Taxotere

Originally, ODAC was expected to consider the application by Rhone-Poulenc Rorer for the drug Taxotere. However, RPR requested a delay in consideration of the application, a company spokesman confirmed.

The company requested a delay after receiving a set of questions from FDA staff.

"We are still in the process of supplying the analysis of existing data," an RPR spokesman said to **The Cancer Letter**.

The company has not been asked for additional data, he said.

ODAC is expected to consider the Taxotere application later this year, the company said.

ORI Clears Plotkin Of Charge Of Misconduct In NSABP Trials

The PHS Office of Research Integrity found that Los Angeles physician David Plotkin did not commit scientific misconduct in the course of his participation in the clinical trials of the National Surgical Adjuvant Breast & Bowel Project.

"ORI found errors in some cases but did not find falsification, fabrication or deliberate misrepresentation on the part of Dr. Plotkin or his staff," ORI said last week in a press release.

Tribune Found Poor Record-Keeping

Last May, the Chicago Tribune found poor record-keeping and errors in the research files submitted to NSABP by Plotkin's Memorial Cancer Research Foundation of Southern California.

According to the Tribune, Plotkin's foundation had enrolled several patients who later proved ineligible for the lumpectomy study, included several others without their written consent and reported some deceased patients as living (**The Cancer Letter**, May 6, 1994).

Days before the Tribune story was published, Plotkin requested an NCI audit of his files.

That audit found "low overall quality" of research at Plotkin's foundation and criticized Plotkin for allowing John Crewdson, a reporter with the Tribune, to review the research files of patients who had taken part in the trials.

NCI auditors found that the intellectual damage from Plotkin's data to NSABP was minimal since all but one flawed patient file had been discovered by the cooperative group's auditors.

The NCI report presented no evidence of falsification, fabrication or deliberate misrepresentation, the elements of scientific misconduct, as defined by the ORI (**The Cancer Letter**, June 17, 1994).

Allegations "A Result of Incomplete Review"

Sources said that following the publication of the Tribune story and the NCI audit of Plotkin's files, the Institute asked ORI to determine whether any action was warranted in the case.

After reviewing the materials, ORI decided to proceed to an investigation.

"ORI's investigation specifically focused on the accuracy of biopsy dates, tumor size, history of cancer and mortality data or clinical data forms submitted by the foundation to the statistical office of the NSABP," ORI said in a press release.

"The ORI investigators believe the allegations of possible scientific misconduct resulted from a review of incomplete records by the Chicago Tribune and NCI's auditors. ORI had access to additional NSABP and MCRF files which were not available during the earlier reviews," ORI said.

"Thankful This Is Over": *Plotkin*

Plotkin said the ORI findings amount to exoneration.

"I am more than thankful that this is over and I have been exonerated," he said in a statement to **The Cancer Letter**.

"I will forever be upset that this episode ever happened. It only shows what can happen when politics gets the upper hand over good research and good medicine. Now I can again concentrate on what has always been most important to me: I will be attending to the needs of my patients," he said.

Plotkin did not release a copy of the full ORI report.

Cancer Panel Recommends Better Basic Science Funding

The President's Cancer Panel, in its annual report to the White House, recommended improved funding of basic and translational cancer research in order to speed progress in cancer prevention, detection, treatment and support services.

The three-member panel is mandated by law to monitor the cancer research programs of NIH and NCI, known collectively as the National Cancer Program. The National Cancer Act of 1971 requires the panel to bring to the President's attention any "delays or blockages" in the program.

Panel Chairman Harold Freeman said the panel's meetings over the past year had examined issues of access and delivery of care.

"The recurrent theme throughout these meetings has been the need to provide access to and insurance coverage for cancer prevention, diagnosis, treatment and control for all Americans; the need to further delineate the determinants of cancer causation through continued support for basic and applied research; and the need to coordinate the cancer-related research and cancer care activities of the federal, state and local government as well as private industry and voluntary organizations," Freeman said.

Panel's Recommendations

The panel made the following recommendations:

- Augment funding of basic research through NCI and accelerate application of basic research discoveries through translational research to develop improved cancer prevention, detection, treatment and supportive services.
- Pinpoint the obstacles preventing access to *existing cancer prevention, diagnosis,* treatment and support for all Americans and delineate the roles of NCI and other public and private sector participants in the National Cancer Program in ameliorating these barriers.
- Mount a joint cooperative effort among federal, local and voluntary agencies to educate the American public regarding its options in cancer prevention and health care access.
- Coordinate research efforts across federal, local and voluntary organizations in a joint offensive against cancer.

The Report of the President's Cancer Panel is availble from the NCI Office of Cancer Communications, tel: 301/496-6641.

FDA, NIH Agree To Streamline Genetic Study Approvals

FDA and NIH have agreed to streamline approvals for gene therapy studies.

Under regulations signed recently, FDA and the NIH Recombinant DNA Advisory Committee will simultaneously consider applications for gene therapy in patients.

Also, the new regulations remove requirements for RAC to approve certain minor gene-therapy procedures, from some DNA-based vaccines to cancer treatment on cells first removed from the body.

Philip Noguchi, FDA's gene therapy chief, said the field is expected to grow rapidly and the agency wants to prevent bottlenecks. "What we've seen so far is almost trivial compared to what's coming," Noguchi said to a meeting of biotechnology experts in San Francisco last month.

The agreement between FDA and NIH could cut the time companies wait for research approval from about eight months to just 45 days, Noguchi said.

In addition, FDA is setting up a gene-therapy registry to track continuously every American who receives these experimental treatments. He said the registry may solve a vexing problem: how to ensure a treatment that—because of its expense and complexity—is tested only in several hundred patients won't prove to have problems once it is offered to hundreds of thousands.

A prototype of the registry, which will allow scientists to gather extensive data for their own projects, should be ready by December, Noguchi said.

The government has approved 105 gene-therapy trials in people since the first in 1990, for a total of about 400 Americans treated with this still experimental therapy, Noguchi said.

The vast majority, 77 trials, are for cancer, followed by 18 potential treatments for genetic diseases, eight for AIDS and one each for rheumatoid arthritis and peripheral vascular disease.

Getting approval to test gene therapy in patients has been more rigorous than in any other medical area, requiring approval by FDA, Institutional Review Boards at hospitals, and the NIH's RAC.

RAC meets only four times a year and will not consider a test until the hospitals have approved it.

The process meant a minimum of eight months waiting for approval to enroll patients in trials. Those times could drop to just 45 days under new regulations signed last month, Noguchi said.

FDA expects to see some gene therapies on the market within a few years, Noguchi said.

The industry has begun discussing how to protect patients from the improper use of its genetic discoveries, said Carl Feldbaum, president of the Biotechnology Industry Organization.

Top of the list is genetic privacy, as the growing discovery of genes important for the development or mitigation of disease prompts tests to tell who is at risk later in life.

Experts predict that some 150 genetic marker tests could be available within 10 years, Feldbaum said. A law to protect patients from unauthorized testing or illegal use of test results by insurance companies, with criminal penalties, might be appropriate, he said.

"This is something we clearly need to deal with now, while the technology is being developed," he said. "Every single individual is going to have a genetic privacy issue."

Report Criticizes Grant Review At NIH, Suggests Oversight

The NIH Div. of Research Grants is too isolated from the program and staff of the Institutes and is sometimes too confrontational, rather than collaborative, according to a report by a group of intramural and extramural scientists.

The Working Group on the DRG, led by Marvin Cassman, acting director of the National Institute of General Medical Scientists, was appointed by NIH Director Harold Varmus. Varmus named the committee after DRG Director Jerome Green announced plans to retire.

The report affirms a number of criticisms of the NIH peer review process that extramural scientists have made for many years.

According to the report, DRG should continue to exist as a way to separate grant review from programs, and centralized review "remains a signficant asset, particularly given the overlapping scientific interests" of the Institutes.

The report also noted that applications submitted to DRG have increased, but the workload has not been met with an increase in resources.

The report listed the "central concerns" of the committee, followed by recommendations.

Central Concerns:

A. The structure and operation of DRG

●Barriers between DRG and the Institutes. A frequently expressed concern was that, in the name of separation of program operation and review, DRG has become too isolated from program staff of the Institutes and Centers (ICs). This has resulted in what occasionally appears to be a confrontational rather than a collaborative interaction between DRG and the ICs.

●Provision of a stimulating and rewarding work environment in DRG. The logistic demands of the review process appear to have created an assembly line mentality, without providing sufficient opportunities for Scientific Review Administrators to stay abreast of changes in science.

●The structure of DRG and the placement of DRG within the NIH organization. The role and placement of the Information Systems Branch was of considerable interest because of this unit's importance to electronic research administration. Additionally, there were questions about whether DRG should continue as an autonomous unit, given that its primary function is as a service for the funding units of NIH, the ICs.

B. Policies governning review functions

●Consistency and coordination of peer review, as performed both within DRG and between DRG and the ICs. There is a perception, both within NIH and among many in the external scientific community, that neither similar standards nor similar procedures are always applied in the conduct of peer review among DRG study sections or between DRG and IC reviews. This is seen as important for ensuring that the best science is supported across the NIH.

●Distribution of review responsibilities between DRG and the ICs. The application of the criteria for deciding where a grant will be reviewed--whether within DRG or through one of the ICs--seems inconsistent and arbitrary.

●The responsiveness of DRG peer review to changes in science. Concerns were raised repeatedly that study sections, as currently constituted, are not sufficiently responsive to changes in science. This is because they are too narrow in intellectual focus, or because mechanisms (adding reviewers to study sections or creating new study sections) are too cumbersome to allow approriate response to emerging new areas of science.

Recommendations:

1. A new central oversight body, the Peer Review

Oversight Group (PROG), should be established and charged with coordinating, evaluating, and making policy recommendations for all peer review conducted at NIH, both within DRG and in the Institutes and Centers (ICs). It should be chaired by the Deputy Director for Extramural Research and should include scientists from the extramural research community.

2. Peer review should be conducted in both DRG and the ICs. Decisions about whether a particular grant application is reviewed within DRG or in an IC should be based on the science to be reviewed and not on the mechanism (type of award) used or activity involved. In general, grant applications involving broad areas of basic laboratory and clinical research should be reviewed in DRG while clearly mission-related research should be reviewed in the relevant IC. Defining this separation of responsibilities will be subject to debate and should be the province of the PROG.

3. DRG study section membership should be broadened so that the study sections become more diversified, with less attention paid to methodology or to a specific organ or disease. This increased breadth of focus must maintain pace with scientific developments through periodic evaluations involving respected scientists from outside the NIH.

4. The Information Systems Branch of DRG should be abolished and be replaced by a new Office of Extramural Information Systems and Analysis in the Office of Extramural Research in the Office of the Director, NIH.

Additional Considerations:

1. The committee was divided as to whether DRG should remain an autonomous organization reporting to the Director, NIH, or should be part of the Office of the Deputy Director for Extramural Research.

2. Issues related to the role and function of the DRG Scientific Review Administrators (SRAs) are among the most critical concerns affecting the operation of DRG. Thus, although internal issues related to the operation of DRG appropriately reside with its director, some explicit suggestions are provided to strengthen the role of the SRAs in the review process.

Changes Are A "Delicate Matter"

"Altering the peer review structure is clearly a delicate matter," the report concluded. "Any modification of peer review structures...affects the primary locus of interaction between applicants and NIH, and the primary point on which funding depends. The impact of any change is amplified because of the current practice of 'percentiling,' which effectively ensures that applications are only compared to others in that particular study section, rather than to applications reviewed in other panels. In practice, this provides each study section with an 'entitlement' because a fixed percentage of each study section's applications will always fall in the putative 'pay range.'... As a consequence, the loss of a study section or dilution of representation of any segment of the scientific community on a study section will be seen as a direct threat to future funding in that area of science. This is not a trivial issue to consider in implementing changes."

The Report of the Working Group on the Div. of Research Grants is available from the NIH Office of Extramural Research, tel: 301/496-1096.

NIH Policy Requires Meetings To Include Women, Minorities

Scientific meetings sponsord by NIH or using NIH facilities must make "a concerted effort to achieve appropriate representation of women, racial/ethnic minorities and persons with disabilities, and other individuals who have been traditionally underrepresented in science," according to a recently announced NIH policy.

In a notice in the NIH Guide to Grants and Contracts, the Institutes released the "Guidelines On Inclusion Of Women, Minorities, And Persons With Disabilities In NIH Sponsored And/Or Supported Intramural And Extramural Scientific Meetings And Conferences."

"NIH affirms that the value of scientific meetings is enhanced by including participants from all segments of the scientific population and, when appropriate, members of the lay community, in both the planning and conduct of such meetings," the policy stated.

The NIH Revitalization Act requires NIH to "provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act and the Americans with Disabilities Act require reasonable accommodations to be provided to individuals with

disabilities.

Following is the new NIH policy:

It is the NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings. In addition, organizers who name NIH as a sponsor or use NIH facilities must make a concerted effort to achieve appropriate representation in compliance with this policy.

"Appropriate" means representation based on the availability of scientists from these groups known to be working in a particular field of biomedical or behavioral research. The plans to seek appropriate representation should be specified during selection of organizing committees, speakers, and other invited participants, such as session chairs and panel discussants. In addition, efforts should be made to encourage attendance by women, minorities and persons with disabilities at all NIH sponsored and/or supported scientific meetings as a means of increasing their participation in the particular scientific field. The plans to seek appropriate representation will be included as an evaluation criterion during review of the requests for funding for these meetings.

This policy shall apply to all domestic or international scientific meetings sponsored by and/or receiving support from the NIH. "Scientific meetings" include all meetings, conferences, workshops, symposia, seminar series, and lectures that involve organizing/planning committees, expenditure of funds, invited participants, or are nationally or internationally advertised. Such meetings may be initiated by the NIH's institute, center or division (ICD) extramural and intramural programs or by contracts, or may be investigator-initiated requests for grants or cooperative agreements. Reasonable efforts should be made, as well, to fulfill the goal of this policy for single seminars sponsored by NIH laboratories or extramural programs.

All NIH sponsored and/or supported conferences must be held at accessible sites, as outlined by section 504 of the Rehabilitation Act of 1973 and, as applicable, the Americans with Disabilities Act of 1990. Conference registration materials should provide a question that will allow participants with disabilities to voluntarily identify any special needs, so that conference organizers can make plans to accommodate these needs.

When making awards for grants, cooperative agreements, or contracts for scientific meetings, NIH will work with applicants as necessary to assist them to comply with this policy. NIH's extramural and intramural staff who initiate scientific meetings must comply with this policy. It is the responsibility of the ICD Directors to implement this policy. The NIH Director will assure that all extramural and intramural programs comply with this policy.

Inquiries (NCI-related): Marvin Kalt, Div. of Extramural Activities, NCI, Executive Plaza North Rm 600C, Bethesda, MD 20892, tel: 301/496-5147, email: kaltm@dea.nci.nih.gov

RFA Available: CCOPs

RFA CA-95-015

Title: **Community Clinical Oncology Program**

Letter of Intent Receipt Date: July 10

Application Receipt Date: Aug. 29

The NCI Div. of Cancer Prevention and Control invites applications from domestic institutions for cooperative agreements (U10) to the Community Clinical Oncology Program (CCOP). New community and research base applicants and currently funded programs are invited to respond to this RFA as described below.

This issuance of the CCOP RFA seeks to build on the strength and demonstrated success of the CCOP over the past eleven years by continuing the program to support community participation in cancer treatment and cancer prevention and control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI) and utilizing the CCOP network for conducting NCI-assisted cancer prevention and control research. It is anticipated that seven research base awards and eight CCOP awards will be made. Up to $4 million in total costs per year will be set aside to fund applications submitted in response to this RFA. An additional $13 million in total costs per year will be committed to specifically fund several large chemoprevention trials implemented through the CCOP network.

Inquiries: Leslie Ford, Div. of Cancer Prevention and Control, NCI, Executive Plaza North Rm 300-D, 6130 Executive Blvd, MSC-7340, Bethesda, MD 20892-7340, tel: 301/496-8541, fax: 301/496-8667.