THE CANCER LETTER

Vol. 19 No. 20
May 14, 1993

Price $225 Per Year US, Canada.
$250 Per Year Elsewhere

P.O. Box 15189 Washington, D.C. 20003 Telephone 202-543-7665

NCI's FY95 Bypass To Justify $3.47 Billion, Includes $490 Million For Breast Cancer Research

NCI's bypass budget for fiscal 1995 is expected to describe how the Institute could use $3.47 billion, a 62 percent increase over President Clinton's budget request for FY94.

Draft figures for the Institute's professional needs budget were released to the National Cancer Advisory Board at its meeting last week. The National Cancer Act of 1971 requires the NCI director to submit an annual budget estimate "directly to the President for review and transmittal to Congress." The law allows NCI to "bypass" the layers of

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In Brief

San Antonio's ICRC Gets A New Name, SACI; Blum Is Deputy Oncology Director At Kaplan

SAN ANTONIO'S NCI-designated cancer center has changed its name. The former Institute for Cancer Research and Care is now the San Antonio Cancer Institute (SACI). The former name "failed to tell people anything about where we are located," said **Charles Coltman**, director of the Institute. SACI is a collaboration of the Cancer Therapy and Research Foundation of South Texas and the Univ. of Texas Health Science Center at San Antonio. The Institute will sponsor the "Third Annual Syposium on Cancer Research in San Antonio" July 23. For information, contact Kathy Johnson at SACI, Tel. 210/677-3850. . . . **RONALD BLUM** has been named deputy director for clinical oncology at the New York Univ. Medical Center's Kaplan Comprehensive Cancer Center. Blum also is professor of medicine at NYU School of Medicine and director of its medical oncology division. . . . **NO FREEBIES:** U.S. Bioscience Inc. will not hand out free items to participants at the American Society of Clinical Oncology annual meeting in Orlando, FL, next week. Instead, the company will give $5,000 to the Orlando Cancer Center for research on strategies to assist patients in coping with residual effects of cancer treatments. The money will fund baseline and post treatment neuropsycological evaluations for pediatric patients with leukemia, lymphoma and brain tumors. . . . **PRESIDENT'S CANCER** Panel Special Commission on Breast Cancer will meet June 25 at the Hollywood Roosevelt Hotel, Hollywood, CA, to discuss "Information Dissemination and the Role of the Media." The meeting is open from 11 a.m.-5 p.m. . . . . **JOHN BROOKS** has been named chairman of the pathology department at Roswell Park Cancer Institute. Brooks, of Univ. of Pennsylvania School of Medicine, will join RPCI June 1.

'95 Bypass: Fund 50% Of Grants, Double CCOPs, Raise Prevention

(Continued from page 1)

NIH and HHS to openly discuss funding needs of the National Cancer Program.

The FY95 bypass budget is scheduled for release in mid-September. The NCAB requested the draft figures because the board does not plan to meet again until October.

"The bypass budget is a very useful tool to NCI, providing a forum for the presentation of the needs as set by professional judgement for the entire Cancer Program," NCI Director Samuel Broder said to the board.

Double CCOPs, Fund 50% Of Grants

Under the estimates presented to the board last week, the FY95 bypass will recommend:

▶ $342 million for cancer prevention and control, $204 million above the President's FY94 budget, a 148 percent increase.

This amount would allow NCI to double its support to the Community Clinical Oncology Program, currently comprised of 51 CCOPs and 10 Minority-Based CCOPs nationwide. NCI also would expand research on nutrition and dietary effects of cancer, augment studies of cancer among the underserved and rural populations, construct an intramural cancer prevention research facility to expand research on biomarkers and molecular biology, and expand research on intermediate endpoints for the early detection of cancer.

▶ $1.34 billion for research project grants, nearly $400 million above the President's budget, to fund 50 percent of approved grant applications.

▶ $191 million for cancer centers, $62 million above the President's budget. The amount would allow NCI to supplement centers for pilot studies in high priority research areas, expand outreach and prevention and control initiatives, fund "Regional Enhancement" centers in geographic areas currently underrepresented, and award planning grants to develop additional centers.

▶ $72 million for the Specialized Programs of Research Excellence, $42 million above the President's budget, allowing NCI to award more P50 center grants to support SPOREs in breast, ovarian, prostate, lung, brain, melanoma and gastrointestinal cancers.

▶ $25 million for research career programs, $10 million over the President's budget.

▶ $14 million for the Cancer Education Program, $5 million above the President's budget.

▶ Nearly $140 million for the clinical cooperative groups, $52 million over the President's budget, allowing NCI to increase the number of patients accrued onto clinical trials to approximately 45,000 with a focus on lung, breast, colon, and prostate cancers, women's health, and underserved populations.

▶ $77 million for National Research Service Awards, $38 million over the President's budget.

▶ $375 million for research and development contracts, $154 million over the President's budget.

▶ $523 million for intramural research, $135 million over the President's budget.

▶ $132 million for research management and support, $36 million over the President's budget, allowing for the expansion of the Cancer Information Service and information dissemination to underserved populations, rural poor, and others.

▶ $182 million for construction, $162 million over the President's budget, allowing modernization and construction of extramural cancer research facilities nationwide. The emphasis would be on facilities for research on breast cancer, vaccine development, prevention, and high technology clinical research.

NCI is expected to propose that $125 million be available as a two-year appropriation.

The bypass also is expected to include provisions for initiating "large scale cross cutting program project grants" funding research on environmental carcinogenesis, prevention, gene therapy and computational analysis research.

$490 Million For Breast Cancer

NCI will propose spending $490 million on breast cancer research, a $127 million increase over the FY94 President's budget. Some of the funds are proposed to be spent over two years.

The amount would allow NCI to increase the number of breast cancer SPOREs, expand most areas

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Subscription rate $225 per year North America, $250 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

of research, and fund the "Trans-NIH Breast Cancer Initiative" proposed in the FY94 bypass budget.

Prostate cancer research would receive $135 million, a $90 million increase over the President's budget, expanding prevention trials and screening.

The bypass also will propose $251 million for AIDS research, $38 million over the President's budget.

Bypass Budget: The 'One Book'

The bypass budget has been criticized by some in the cancer community as too long and scientific, lacking a clear focus--not a quick summary of NCI's needs suitable for dropping on the desk of a Member of Congress.

In 1991, Harold Moses, then president of the American Assn. for Cancer Research, called for simplification of the 400-page document. In a speech before the NCAB, Moses called the bypass "an unusable document that is difficult to comprehend if you do not have a scientific background" (**The Cancer Letter**, Dec. 6, 1991).

Also that year, Albert Owens, then president of the National Coalition for Cancer Research, called the bypass "about as appealing to the public as a telephone book" (**The Cancer Letter**, Aug. 16, 1991).

In recent years NCCR has prepared materials that present a quick summary of the bypass budget and NCCR's request to Congress for cancer research funding.

Others have said the document's funding request--averaging 40 to 60 percent above the President's budget--should be scaled back to take political and economic realities into consideration.

Responding to the criticism, Broder maintained that the bypass is supposed to be a scientific statement of NCI's professional needs. However, he invited cancer organizations to submit comments and suggest changes for future bypass budgets.

Also, Broder appointed his special assistant, Judith Karp, as editor-in-chief of the bypass budget. Karp organized and edited the FY94 bypass and currently is working on the FY95 document.

That change alone is a major improvement, members of the NCAB's Planning & Budget Subcommittee said last week.

"There was no single individual assigned to write the entire bypass, so each of the divisions put in a bypass request," NCAB member Erwin Bettinghaus said to **The Cancer Letter**. "Sometimes things didn't get put in one year that had been included the year before. Now there is a comparison process that a reader can follow year by year."

Bettinghaus told the board that, "The committee agrees completely with Dr. Broder's notion that the bypass be a scientific document, but there is no reason why the presentation of science can't be consistent and clear from year to year."

"Everyone wants something they can carry around without needing a tow truck," Karp said to **The Cancer Letter**. "We call it the 'One Book' [Southwestern Bell's combined yellow and white pages] because you don't need to refer to anything else.

"It would be nice to express all of our initiatives in 100 pages, in the broadest of ways, but that would not explain why we would want to follow those particular paths," Karp continued. "The bypass is, we hope, scholarly and scientifically sound.

"Our job is to present a broad and ecumenical view of the science that has gone on to date, the many questions that remain to be answered, and the questions opened up by new information."

Karp edits the scientific portions of the bypass, while the budget figures are prepared by NCI's budget office.

'A Series Of Markers'

At a Planning & Budget Subcommittee meeting held in Chicago earlier this year, NCAB member and current NCCR President Robert Day suggested that the bypass describe the progress toward NCI's Year 2000 goals for reducing cancer incidence and mortality, possibly by relating funding levels to the attainment of the goals.

AACR President Lee Wattenberg suggested that the bypass include a organ sites section on the needs for research on the ten most frequent cancer, and overviews on the value of basic research, prevention and control research, and a description of the challenge of developing new treatments.

"It was a good idea to get comments from outside groups," Bettinghaus said to **The Cancer Letter**. "I think the end result will be a budget that may eventually serve as a series of markers on cancer research over a number of years.

The bypass budget, Bettinghaus said, "is supposed to be a scientific needs document for the Institute. There have been years in which Congress has taken the bypass and set that as the goal [in authorizing NCI funding].

"It can truly be a scientific needs analysis with no consideration for political process," Bettinghaus said. "Maybe the bypass should be 150 percent above [the President's budget]. If it were, the bypass would say, 'This is what we can legitimately put into cancer research.'"

NCAB Votes To Return P01 Review To Previous Rank Order System

The National Cancer Advisory Board last week voted to return the review of program project (P01) grant applications to the two-tiered system that existed prior to 1987.

The board, with one nay vote, agreed with NCI Director Samuel Broder and the NCAB's Program Project Task Force that P01s should be prioritized and given a rank order. NCAB member Pelayo Correa opposed changing the current system.

Since 1987, P01 review has been done by ad hoc site visit teams formed for each grant application.

Broder likened that review system to a medical school attempting to search for a new dean by forming 10 different search committees to interview 10 candidates. Peer review should be forced to prioritize and rank several grants, he said.

Broder presented a detailed overview of the Institute's program project grant funding to the NCAB at its meeting last September (**The Cancer Letter**, Oct. 2, 1992).

P01 priority scores have compressed closer to the perfect score of 100 since the advent of the post-1987 system, Broder said at that meeting.

P01 Ranking Experiment

Last February, NCI conducted a "P01 ranking experiment" in which a panel, chaired by John Kersey of the Univ. of Minnesota, was asked to resolve differences between applications with roughly equal scores as given by the initial review.

The panel, made up of representatives from each of the P01 initial review groups and two members from each of the NCI Boards of Scientific Counselors, was given the summary statements from the initial review of 20 grants and asked to rank applications in quintiles.

Only one application moved down in rank and one application moved up in rank between the first and second quintiles, according to a report on the experiment written by Marvin Kalt, deputy director of NCI's Div. of Extramural Activities. There were few other position shifts.

In a discussion of the ranking experiment, the panel "recognized the problems caused by compression of scores, but felt that there was no perfect solution," according to Kalt's report. "It was concluded that, above a certain level of merit, NCI should be trusted to choose from among different applications by use of whatever methods meet the needs of the Institute."

The report continued: "Reinstatement of chartered parent committees to review and score applications was felt to have limited potential in improving resolution. It would add substantial cost to the review process and would raise questions where scores were changed from the preliminary verdict of the site visit report. This route would require multiple committees (or subcommittees), each of which still would not be percentiled against their own behavior. The likely outcome of such voting is predicted to be a bimodal pattern where the lower half of the scores worsen, while the upper half remains compressed as amended applications allow the groups to infer funding patterns and vie to fund their own preferences in applications by improving scores."

Three-Year Trial Approved

Citing Kalt's report, Correa said he opposed returning to the two-tiered system. "The problem of score compression is not going to be remedied," he said.

The board voted to accept the task force's proposal for a three-year trial of a two-tiered system.

Following is the task force proposal:

"The first tier would involve site visit teams composed of a combination of ad hoc reviewers and parent committee members similar in nature to the special review committees currently employed.

"All original and competing applications would normally be considered as being eligible to receive a site visit or applicant interview. Site visit teams would score the individual components, and make tentative recommendations on the integration of the program as a whole. Parent review committees would not normally re-review the science in individual components, but would focus on evaluation of the overall scientific program, its integration, synergy, innovation and uniqueness; and then assign the priority score of record.

"Three or four committees would need to be chartered in order to provide the expertise necessary to review all applications. Alternately, one committee with three or four subcommittees could be drawn from a single chartered Special Emphasis Panel depending on what would be permissible under the new Executive Order.

"NCI review staff would be responsible for the material communicated from the first-tier (site visit) committee to the second-tier (parent) review committee. Annual reports would be made to the NCAB to monitor progress."

NCI staff will provide the task force with a proposal for review committee structure for its next meeting, scheduled as a May 24 conference call.

Other NCAB Action

In other action at the meeting last week, the board:

▶ Accepted the recommendation of its Clinical Investigations Task Force to ask the NIH Div. of Research Grants to create a clinical oncology study section (**The Cancer Letter**, May 7).

▶ Drafted a letter to Secretary of Labor Robert Reich supporting the Occupational Safety and Health Administration "in any effort to control smoking in the workplace." The board, the letter said, "will support standards which address indoor air quality and passive smoking in the workplace" and offered to provide scientific documentation or experts willing to testify at hearings on the subject.

DCPC Advisors To Consider Seeking Prevention And Control Study Section

The Div. of Cancer Prevention & Control Board of Scientific Counselors is expected to consider a resolution at its fall meeting asking the NIH Div. of Research Grants to create a new study section on cancer prevention and control.

Board members Carol D'Onofrio and Helene Brown suggested a resolution at the board's meeting last week, following a presentation by staff of the NIH Div. of Research Grants.

Board members were concerned that of the past 41 cancer prevention and control grant applications submitted to DRG's Behavioral Medicine study section, none have been funded.

"Needed research isn't getting done," D'Onofrio said to **The Cancer Letter** this week.

The existing study section is made up primarily of experts in clinical psychology and medicine who may not understand prevention and control issues such as community-based intervention studies, board members said.

DRG staff presented several analyses of the Behavioral Medicine study section's reviews, showing that prevention and control investigators turned down for funding do not resubmit applications. They questioned the need for a new study section.

"They thought there wasn't a problem," D'Onofrio said. "I pointed out that there's no point in resubmitting unless you think you have a chance. So, though DRG doesn't perceive a problem, the BSC does."

The board decided to delay a vote on a resolution until its October meeting so members would have more time to consider it.

"The BSC is going to continue to monitor the success rates of its grant applications that are reviewed by Behavioral Medicine and by other study sections as well," D'Onofrio said to **The Cancer Letter**. "The intent is to keep pushing for a standing study section that deals with community based prevention and control research. It may not be just cancer, it may extend across other institutes."

• • •

Letters Are Invited

NCI advisors, NCI staff, and others in the cancer community have for several years advocated the creation of new study sections for cancer prevention and control as well as clinical cancer research.

The National Cancer Advisory Board last week voted to request DRG to establish a clinical oncology study section.

The Cancer Letter invites readers to submit letters for possible publication in the newsletter discussing the study section issue. Investigators, in particular, are invited to relate their views on any aspect of this issue. Letters from others are welcome as well.

Letters may be submitted to: Editor, **The Cancer Letter**, PO Box 15189, Washington, D.C. 20003, or faxed to 202/543-6879.

Capitol Notes

Breast Cancer Coalition Plans Petition Urging National Strategy

As Washington ponders an overhaul of the nation's health care and as Capitol Hill prepares for another round of battles over appropriations, the National Breast Cancer Coalition is working the hustings to demonstrate that its goal, eradication of breast cancer, has a powerful political constituency.

The coalition, which unites politicized breast cancer patients, already packs a considerable punch on the Hill.

However, the group is likely to enjoy even greater clout if it meets its goal of collecting 2.6 million signatures under a petition calling for a comprehensive strategy for eradication of the disease.

NBCC's plan is to drop the petition on President Clinton's lap later this fall.

Sources said signatures for the petition will be collected nationwide, at the meetings of the 170 groups that comprise the coalition, as well as at churches and grocery stores. It will take about six months to collect the signatures, sources said.

In 1991, the group's campaign to deliver 175,000 letters to the White House and Capitol Hill ended up

generating more than 600,000 letters.

Former President George Bush apparently did not acknowledge the 100,000-plus letters delivered to his White House, coalition leaders said. Clinton, by contrast, is certain to be more attentive to the coalition's constituency and its message.

Before the election, Clinton endorsed the coalition's goal to secure a $300 million increase in appropriations for breast cancer research.

Last summer, as members of the House and Senate appropriations committees walked to closed markup sessions, the coalition lined the halls with its members. Ultimately, new funds were appropriated, but most of the increase, $210 million, was contained in the defense budget.

Coalition Seeks $449 Mil. For NCI

This year, the coalition's goal is to make NCI spend $449 million on breast cancer and to continue the funding of breast cancer research in the Department of Defense. That level of funding is contained in both the House and the Senate versions of the NIH reauthorization package.

In a letter to the White House, the coalition put Clinton on notice about its plans:

"On May 2, the National Breast Cancer Coalition launched a massive grassroots effort to fight breast cancer.

"The goal is to collect 2.6 million signatures, which represents the 1.6 million women who have been diagnosed with breast cancer and the 1 million women who have the dread disease and do not know it.

"Each of these individuals will be urging you to act by declaring the eradication of breast cancer a national priority and developing a comprehensive national strategy.

"Eradication of breast cancer must become a national priority. Presidential leadership can make this happen. The first step is to convene selected leaders from the Executive branch, the Congress, the scientific community, private industry and women with breast cancer.

"Last year Congress [appropriated] the first ever meaningful increase for breast cancer research. This year, the budget you sent to Congress continues this increase for the next five years. Increased funding is critical, but it is not enough...

"A national strategy must be developed and implemented. When our country decided in the 1950s that we wanted a man on the moon, we developed a plan and committed the resources to make it happen. This same determination is what is needed to end the epidemic of breast cancer for us and for our children."

Heath Providers Believe Low-Income Women Lack Mammography Access

The overwhelming majority of health care providers believe that low income women do not have adequate access to mammography when it is indicated, a survey of oncology administrators found.

In a recent presentation before the Special Commission on Breast Cancer of the President's Cancer Panel, Catherine Harvey, president of the American College of Oncology Administrators, said her survey of 140 oncology administrators pointed to the following problems:

▶ Altogether, 80 percent believed the underserved women had limited access to mammography screening and health promotion.

▶ Restricted access to treatment options was identified by 68 percent of the administrators surveyed.

"One problem routinely cited was the ability to find a provider to take care of low income women when the diagnosis was made," said Harvey, the oncology program manager at Hollings Oncology Center in Charleston, SC.

"In South Carolina, we have had this problem because we now have a low income screening program that is beginning to permeate the state. Yet for us, the screening program does not provide treatment services. Thus, we are beginning to confront access problems when a positive diagnosis is made," Harvey said.

"There are frequently limitations on the allowable treatment provided by such entitlement programs and insurance. This often results in high out of pocket expenses, poor outpatient reimbursement and no funding for adjuvant therapy," she said.

▶ 60 percent of respondents said women who lack adequate reimbursement are excluded from clinical trials. "Even cooperative group trials are frequently not covered by low income programs," Harvey said.

According to Harvey, inadequate reimbursement creates the following consequences for the patient:

▶ "Because some insurance companies reimburse 100 percent for mastectomy, but only 80 percent for modified surgery and radiation therapy, women elect mastectomy when lumpectomy might be a better psychological choice," Harvey said.

▶ Many women appear to delay seeking treatment because of reimbursement and high out-of-pocket expenses. "Some of that delay comes from the fact that they are not educated about either their options or the consequences of the delay in treatment,"

Harvey said. "It's hard to encourage them to come in early when they do not understand that long term survival and quality of life are tied to early treatment."

Several administrators said they were troubled by the discrepancy between Medicare payment and the American Cancer Society guidelines on mammography, Harvey said. As a result, health care providers tell their patients to get mammograms every year, while Medicare pays for one mammogram every two years.

Over the past 12 months, the membership of the American College of Oncology Administrators (ACOA) has tripled to about 600 (**Cancer Economics**, May 1992).

The group, which was formed in December 1991, will hold its annual symposium June 3-5 in Nashville, TN. Tuition is $235 for members, $395 for non-members. The group will also co-sponsor several sessions at a meeting of the Society for Radiation Oncology Administrators Oct. 10-14 in New Orleans.

ACOA is a chapter of the American Academy of Medical Administrators. For additional information call ACOA, 313/540-4310.

RFAs Available

RFA CA-93-021

Title: **Prevention clinical trials utilizing intermediate endpoints and their modulation by chemopreventive agents**

Letter of Intent Receipt Date: May 28

Application Receipt Date: Aug. 12

NCI's Div. of Cancer Prevention & Control invites applications for cooperative agreements to support clinical trials that are directed toward examining the role of various chemopreventive agents and/or diet in the prevention of cancer.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations. Applications from minority individuals and women are encouraged.

Applicants funded under this RFA will be supported through the cooperative agreement (U10) mechanism. There will be government involvement with regard to (1) assistance securing an Investigational New Drug (IND) approval from the Food & Drug Administration, (2) monitoring of safety and toxicity, (3) coordination and assistance in obtaining the chemopreventive agent, (4) quality assurance with regard to the clinical chemistry aspects of the study. Project period may not exceed five years. This RFA will be issued annually for three years. Approximately $1.5 million in total costs for the first year will be committed to fund applications. The project period may not exceed five years. It is anticipated that three to five awards will be funded.

The objective is to encourage cancer chemoprevention clinical trials that utilize biochemical and/or biological markers to identify populations at risk and/or to provide intermediate endpoints that may predict later reduction in cancer incidence rates.

These studies may be developed in phases, including a pilot phase, which could later proceed to a full scale intervention. The emphasis should be on small, efficient studies aimed at improving future research designs of chemoprevention trials, providing biologic understanding of what is happening in the trials, or providing better, more quantitative and more efficient endpoints for these trials. After successful completion of the pilot phase (i.e., demonstrated modulation of marker endpoints by the intervention), subsequent studies could include a definitive clinical trial monitoring the test system, a cancer incidence or mortality endpoint, and a designated agent.

Investigators may apply at this time for the pilot phase, or submit an application for both the pilot and definitive trial studies. However, if the application is for the pilot phase only, the proposed study must describe its relevance to a clinical application and utilize a chemopreventive agent, marker test system, and study population that could later be the subject of a full scale, double-blind, randomized, risk reduction clinical trial. Intermediate marker trials of breast cancer chemoprevention are especially encouraged.

Inquiries may be directed to Dr. Marjorie Perloff, Chemoprevention Branch, NCI, Executive Plaza North Suite 201, Bethesda, MD 20892, Tel. 301/496-8563.

RFA CA-93-025

Title: **Community Clinical Oncology Program**

Letter of Intent Receipt Date: June 25

Application Receipt Date: Aug. 24

NCI's Div. of Cancer Prevention & Control invites applications from domestic institutions for cooperative agreements to the Community Clinical Oncology Program (CCOP). New community and research base applicants and currently funded programs are invited to respond to this RFA. This issuance of the CCOP RFA seeks to build on the strength and demonstrated success of the CCOP over the past ten 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.

New applicants and currently funded programs are eligible as described below. Two types of grantees are eligible to apply: community programs and research bases. Community applicants may be a hospital, a clinic, a group of practicing physicians, a health maintenance organization or a consortium of these. Community programs (CCOPs) will be required to enter patients onto NCI-approved treatment and cancer prevention and control clinical trials through the research base(s) with which each CCOP is affiliated.

Research base applicants must be either an NCI-funded clinical trials cooperative group or cancer center. Research bases will be required to provide clinical research treatment and cancer prevention and control protocols, monitor the quality research and follow CCOP accrual.

Support will be through the cooperative agreement (U10). Project period for applications submitted in response to this RFA may not exceed three years for new applicants and five years for applicants currently supported under this program. Currently supported applicants will be funded for three, four, or five years depending upon priority score/percentile, review committee recommendations, and programmatic considerations. Up to $4.2 million in total costs per year for five years

will be committed to fund applications. Of the total, approximately $1.8 million will be committed to research bases and approximately $2.4 million to CCOPs. It is anticipated that up to three research base awards and up to 15 CCOP awards will be made.

Over 80 percent of patients with cancer are treated in the community. The CCOP was initiated in 1983 to bring the benefits of clinical research to cancer patients in their own communities by providing support for physicians to enter patients onto treatment research protocols. The second RFA, issued in 1986, expanded the focus to include cancer prevention and control research. In 1992, there were 51 programs in 27 states involving over 300 hospitals and over 2,800 physicians. Approximately 5,000 patients were entered onto treatment trials and 4,000 subjects per year on cancer prevention and control studies.

Cancer prevention and control research in the CCOPs is aimed at reducing cancer incidence, morbidity, and mortality through the identification, testing, and evaluation of interventions in controlled clinical trials. The 80 protocols activated to date cover the full spectrum of cancer prevention and control research, including chemoprevention and marker studies for future prevention interventions, smoking cessation studies, screening and early detection, and pain control and other symptom management interventions.

The CCOP initiative is designed to bring the advantages of state-of-the-art treatment and cancer prevention and control research to individuals in their own communities by having practicing physicians and their patients/subjects participate in NCI-approved treatment and cancer prevention and control clinical trials. The CCOP also provides a mechanism to increase the involvement of primary health care providers and other health care specialists in treatment and cancer prevention and control research and provides an opportunity for education and exchange of information on new technologies.

Review criteria for CCOP applicants include the ability to accrue a minimum of 50 credits per year to cancer prevention and control clinical trials and at least 50 credits to cancer treatment clinical trials. Review criteria for Research Bases include the ability to design appropriate treatment and/or prevention and control clinical trials.

Inquiries may be directed to Dr. Leslie G. Ford, Community Oncology and Rehabilitation Branch, NCI, Executive Plaza North Room 300-D, Bethesda, MD 20892, Tel. 301/496-8541.

RFA-CA-93-026

Title: **Minority-Based Community Clinical Oncology Program**

Letter of Intent Receipt Date: June 25

Application Receipt Date: Aug. 24

NCI's Div. of Cancer Prevention & Control is interested in continuing the established cancer control effort which involves practicing oncologists who serve large minority populations in the NCI clinical trials program. DCPC invites applications from domestic institutions with greater than 50 percent of new cancer patients from minority populations for cooperative agreements in response to this Minority-Based Community Clinical Oncology Program (MBCCOP) RFA.

This issuance of the MBCCOP RFA seeks to build on the strength and demonstrated success of the MBCCOP over the past three years by: (1) continuing the program as a vehicle for supporting community participation in treatment and cancer prevention and control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI); (2) expanding and strengthening the cancer prevention and control research effort; (3) utilizing the MBCCOP network for conducting NCI-assisted cancer prevention and control research; and (4) evaluating on a continuing basis MBCCOP performance and its impact in the community.

New applicants and currently funded programs are eligible as described below. Community applicants may be a hospital, a clinic, a group of practicing physicians, a health maintenance organization (HMO) or a consortium of these. Applicants must have greater than 50 percent of new cancer patient population from minority ethnic groups. MBCCOPs will be required to enter patients onto NCI-approved treatment and cancer prevention and control clinical trials through the research base(s) with which each MBCCOP is affiliated.

Support will be through the cooperative agreement. Project period may not exceed three years for new applicants and four years for applicants currently supported under this program. Currently supported applicants will be funded for three or four years depending upon priority score/percentile, review committee recommendations, and program considerations.

It is anticipated that up to $2.7 million in total costs per year for four years will be committed. It is anticipated that up to 12 MBCCOP awards will be made.

Overall, cancer incidence and mortality rates for many cancer sites in minority populations are higher compared to whites. Survival rates from cancer in minority populations are also less than in whites. One way to develop and implement effective cancer treatment, prevention and control strategies in minority populations, and thereby reduce disparities in cancer incidence, morbidity, and survival rates between whites and minority populations, is to provide broader access to benefits of clinical research and greater involvement of minority populations in the clinical trials process.

The major NCI program initiatives supporting this network are the Clinical Cooperative Group Program, the Cancer Centers Program, the Cooperative Group Outreach Program, and the Community Clinical Oncology Program. Treatment and cancer prevention and control clinical trials research funded through these programs provides patients and their physicians with access to state-of-the-art cancer care management opportunities, and provides oncologists with a source of continuing education on innovations in cancer therapy, diagnostic techniques, and treatment applications. The MBCCOP is an extension of the clinical trials network with the intent of including populations that have traditionally been unable to access state of the art cancer care.

The MBCCOP, while designed to increase accrual of minority patients to clinical trials, is also an opportunity to identify barriers to minority participation in clinical research and to test intervention strategies in cancer treatment, prevention and control.

Review criteria for MBCCOP applicants include the ability to accrue a minimum of 50 credits per year to cancer treatment clinical trials and a minimum of 30 credits in the first year of funding, 40 credits in the second year, and 50 credits in the third and fourth years to cancer prevention and control clinical trials.

Inquiries: Dr. Otis W. Brawley, Community Oncology and Rehabilitation Branch, NCI, Executive Plaza North Room 300, Bethesda, MD 20892, Tel. 301/496-8541.