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CCOP Review Completed; 72 Applications Submitted, 23 More For Minority CCOP

Review of Community Clinical Oncology Program applications in the second recompetition (third round) of the program was scheduled to be completed this week, as the last of three review committees wraps up its work. Although more than 100 letters of intent were submitted, the

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In Brief

David Harrington Replaces Zelen At ECOG; Kushner To Receive Ewing Layman's Award

DAVID HARRINGTON has been selected by the Eastern Cooperative Oncology Group Executive Committee as the new group statistician, replacing Marvin Zelen, who resigned Nov. 1. Zelen had held that position since 1971. "His contributions to clinical research will be long remembered," ECOG Chairman Paul Carbone said. . . . **ROSE KUSHNER,** author and cancer patient advocate, will receive the James Ewing Layman's Award at the annual meeting of the Society of Surgical Oncology next May. . . . **EMIL FREI,** director of Dana-Farber Cancer Center, during a discussion at a meeting of the Div. of Cancer Treatment Board of Scientific Counselors, on NCI's Outstanding Investigator Grant program: "In the abstract, I would support it. But if it were to be brought here as a concept proposal, and knowing that it would take money out of the RO1 pool, I would probably vote against it." . . . **KENNETH TREVETT,** assistant to the director and house counsel at the Jackson Laboratory for the past seven years, has accepted a position as corporate counsel for the Dana-Farber Cancer Institute, effective Dec. 1. In the newly created position, Trevett will develop the institute's first in-house legal office. . . . **MARY DALY** has been named associate director of the cancer control science program in Fox Chase Cancer Center's population science division. A lieutenant colonel on active reserve duty with the Air Force, Daly previously was chief of the hematology medical onoclogy service at Wilford Hall Air Force Medical Center in Lackland, TX. . . . **LINDA BIRENBAUM** has been named director of nursing research at Fox Chase. Birenbaum was associate professor in program evaluation at Univ. of Portland School of Nursing. . . . **CHRIS MANUS** was appointed head of the Animal Care & Treatment Div. in Chemotherapy and Toxicology Research at Southern Research Institute. . . . **RESEARCHERS AT** Univ. of Southern California's Kenneth Norris Comprehensive Cancer Center confirmed in an animal model the link between consumption of Chinese salted fish and the incidence of nasopharyngeal cancer among Southern Chinese.

NCI Reviews 72 CCOP Applications, Plus 23 More For Minority CCOPs

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the number of applications totaled 72, including those from all 52 of the existing CCOPs which were up for renewal. Four CCOPs--in Oakland, Milwaukee, San Diego, and Rapid City--were funded only this year, when NCI put additional money into the program, and they will have two more years before they must be recompeted.

The new Minority CCOP has also been reviewed, with 23 applications submitted. NCI expects to make at least eight awards in this program, with a total first year budget of $1.2 million.

For the first time in the program, some CCOP awards will exceed three years. Approximately one third of those with the top priority scores will be funded for five years, the next one third for four years and the rest for three years. When the four which were funded this year are recompeted, each year thereafter will see recompetitions in the program.

That should help spread out the review burden, which was carried by the three committees this year. They were chaired by Alvin Mauer, Univ. of Tennessee (Memphis); Arvin Glicksman, Univ. of Pennsylvania; and Virgil Loeb of Washington Univ. and Geraldine Padilla of UCLA as cochairs.

CCOP research bases (cooperative groups, centers) were also due for recompetition this year, but NCI administratively extended their cooperative agreements for one year. That was done to alleviate the review burden and also to give them more time to get their cancer control efforts with CCOPs up and running. Research base applications will be due next summer.

The budget for the program (not counting the Minority CCOP) is $12.2 million in the current 1990 fiscal year. That probably will not be enough to fund 60 awards as NCI had hoped; it may not even support the existing number of 56.

The CCOP applications and funding recommendations will be presented to the National Cancer Advisory Board at its meeting Jan. 29-30.

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Cancer Training Programs Faring Fairly Well, Considering NCI Budget

The state of cancer training programs at NCI, contrary to the fears of many who have felt that budget cuts threaten to diminish the flow of young scientists into biomedical research, may not be quite so bad after all.

"I'm optimistic," Vincent Cairoli, chief of the Cancer Training Branch, told **The Cancer Letter** this week. "I think we will do reasonably well in 1990, given what is happening elsewhere, with RO1s and other areas."

Cairoli summarized the state of the branch's programs in a presentation to the Board of Scientific Counselors of the Div. of Cancer Biology & Diagnosis, where the branch was moved earlier this year from the Div. of Cancer Prevention & Control.

The outlook for RO1, investigator initiated grants, is grim: only about 20 percent of approved new and competing renewals will be funded. Over the last five years, that figure has been closer to 35 percent, and in mid-1970s, sometimes exceeded 40 percent.

NIH training programs took a hit last year when Congress ordered an increase in National Research Service Award stipends without providing the money to cover the increase. That would have meant a sharp reduction in number of trainees supported, but NIH and the institutes scraped up enough money to restore most of the positions.

Cairoli said that the worst case scenario for NRSA in 1990 would be that the same number of trainees would be supported as in 1989, 1,428. "I think we will be able to do a little better than that."

Career Development Awards will be very competitive, since there have been a large number of applications submitted. The number of awards will be stable, possibly two more or two less than the 123 awards made in FY 1989, Cairoli said.

Cancer Education Grants also will be very competitive, with the budget hard pressed to equal the 45 grants made in 1989.

NRSA, Career Development, and Cancer Education are the three mechanisms for support by NCI's manpower training program. Each mechanism includes important subsets, which are described as follows:

NRSA

Individual predoctoral fellowship for oncology nurses (F31). Registered nurse can be supported for five years to earn doctorate in basic or applied cancer science. Eight awards were supported in 1989, totaling $99,000.

Individual postdoctoral fellowship (F32). Applicant with earned doctorate degree can receive three years of basic, clinical, or behavioral research training. 152 awards were supported in 1989, totaling $3.7 million.

Individual senior postdoctoral fellowship (F33). Experienced scientist can make major changes in research career, get support during sabbatical, acquire new skills. These are for one to two years. Two awards were supported in 1989, totaling $66,000.

Institutional research training grant (T32). Permits any domestic public institution to provide research training in any science relevant to cancer. 171 grants were supported in 1989, totaling $29.3 million. These supported 540 predoctoral and 726 postdoctoral students.

The T32 NRSA mechanism also includes institutional research training grants in surgical oncology. This supports special research training for surgeons and is flexible to take into account variations in surgical residencies. Typically, surgeons work two or more years, in addition to their residencies, in some area of cancer research. Seventeen awards were supported in 1989, totaling $2 million. These supported 62 trainees.

NRSA stipends range from $17,000 a year for postdocs with no experience, and range up to $31,500 for postdocs with seven years experience. Predoctoral students receive $8,500 a year; some of the larger schools find ways to supplement those stipends.

Career Development Awards

Research career development award (KO4). Promising, developing investigators with high research potential are brought to independent research status. This pays salary only, up to $40,000 a year, for three years, nonrenewable. That will increase to $50,000 in 1990. Research support must come from another source, such as RO1s. An investigator's KO4 and RO1 applications are frequently reviewed together. 46 grants supported in 1989, totaling $2.5 million.

Preventive oncology academic award (KO7). To stimulate research and teaching career development in cancer prevention and control. Five year nonrenewable awards, pays up to $40,000 salary support. Eleven grants supported in 1989, totaling $803,000.

Clinical investigator award (KO8). MDs can receive five years of basic, clinical, or behavioral research training. Now five year nonrenewable awards, paying up to $40,000 a year in salary support. Originally for three years; those with three year awards may apply for two additional years. 45 grants supported in 1989, totaling $3 million.

Physician scientist award. MDs can receive five years of research training. They can propose phased program of didactic study and laboratory experience. Pays up to $40,000 a year in salary support. 19 grants supported in 1989, totaling $1.3 million.

The research career award (KO6) has almost been phased out. Those were lifetime awards ("the nearest thing we have had to Social Security," Cairoli said) which paid the salaries of outstanding investigators as long as they were active and had other research support. They were one time awards, with no further review. At the highest point in this program, in the 1960s, there were 16 active KO6s. There is only one left this year.

Cancer Education

These grants (R25) are the successor to the Clinical Education Program, which under the now retired Margaret Edwards helped train so many medical oncologists that many feared the field would be glutted with them. That program was phased out in 1987, replaced by the following components of the new R25s:

Part A--Pre and postdoctoral fellowships in chronic disease prevention and control. Four grants were supported in 1989, totaling $835,000.

Part B--Short research experiences for high school and undergraduate students. These usually are for two to three months in the summer, through schools of medicine, dentistry, nursing, or other health profession schools "where the students can get into cancer labs," Cairoli said. "The intent is to show what a career in biomedical research is like, particularly in cancer research. There is an effort at the high school and college levels to recruit minorities into this program, and quite a few of them do a good job of that." 35 grants were supported in 1989, totaling $1.1 million.

Part C--Nutrition curriculum development. This assists development, implementation, and evaluation of curriculum development related to cancer, in various professional schools. These are nonrenewable five year awards, and applicants must show strong support of their institutions' administration; they must demonstrate that the program will continue after the grant expires. Four grants were supported in 1989, totaling $324,000.

Part D--Short term training courses and workshops. These can be one day to several weeks. Applications may be submitted only when NCI announces its interest in supporting a training course in a particular area. Seven were supported in 1989, totaling $687,000.

NCI advisors and others have agonized over what they see as a failure to invest in the future of biomedical research as reflected by the flat budget for research manpower training in the 1980s. Because of inflation, the flat budget actually means the program has been reduced:

--NRSAs hit their peak in numbers of full time trainee positions in 1979, with 1,542, when the budget for NCI's NRSAs was $20 million. The number remained almost constant for five years, then started to drop in 1983, going under 1,400 in 1986, then climbing back to 1,475 in 1987 and 1,456 in 1988. The total of 1,428 in 1989 required a budget of $33.2 million.

--The total budget for cancer training in 1980 was $42.9 million; in 1989, it was $43.8 million.

NCI Director Samuel Broder has recommended to NIH that it seek legislation allocating a "small but significant percentage" of royalties received by NIH through licensing of patents to research training. That could help stabilize and perhaps increase support for training, provided Congress did not make corresponding decreases in appropriations to NIH.

ASSIST Smoking Intervention To Get Under Way In FY 1991

The largest health promotion effort ever undertaken by NIH was started with the release last week of the RFP for the $110.2 million American Stop Smoking Intervention Trial for Cancer Prevention.

ASSIST, approved by NCI's Div. of Cancer Prevention & Control Board of Scientific Counselors in October 1988, is a collaboration between NCI and the American Cancer Society. Through the project, comprehensive tobacco control programs will be developed in up to 20 states and metropolitan areas based on effective smoking prevention and control methods developed and tested by the Smoking, Tobacco & Cancer Branch.

At least 50 million Americans will be directly served by the program, according to a recent STCP report on the project. The RFP was published in the Nov. 24 issue of **The Cancer Letter.**

"ASSIST will demonstrate that the wide spread, coordinated application of the best available strategies to prevent and control tobacco use will significantly accelerate the current downward trend in smoking and tobacco use, thereby reducing the number and rate of tobacco related cancers in the U.S.," said the report, presented at the recent DCPC Board meeting.

About 15 to 20 contracts will be awarded to health departments, which will join with ACS affiliates to form state or local coalitions. During phase 1, the coalitions will work to define the smoking problem in each state and will develop an smoking prevention and control intervention plan. During phase 2, the plans are to be implemented.

Proposals are due Sept. 25, 1990, and contracts will be awarded in June 1991. Phase 1 will begin in July 1991 and end in January 1993. Phase 2 will begin in January 1993 and end in December 1998.

Phase 1 is estimated to cost $8.5 million and phase 2 about $20 million a year for five years. A followup year will cost an estimated $1.7 million.

As part of the preparation for ASSIST, NCI has developed a set of standards for effective smoking prevention and control which represents a consensus of smoking control experts about the essential activities which comprise and comprehensive smoking prevention and control program. The standards are to be widely distributed to encourage smoking prevention and control intervention.

Jessie Gruman, the project officer for ASSIST, said the goal of the program is to reduce the percentage of Americans who smoke from 28 percent to 17 percent by 1998, just short of the 15 percent in NCI's Year 2000 goal.

Board member William Darity said he was concerned that ACS has a constituency and volunteers "largely concentrated on the middle income, middle class," while health departments are geared to serve persons with low incomes.

"Smoking is not as yet completely concentrated among the low income," Gruman said. "We need ACS involvement--it helps ACS make a stronger and more visible commitment to smoking cessation. We are getting their media expertise, volunteers and reputation. ACS has made an institutional commitment to reaching out to those they haven't in the past."

Terry Pechacek, acting chief of the Smoking, Tobacco & Cancer Branch, said the proposals "must address this issue. We will be able to pick sites with underserved populations--that's why we are giving them (responders) a long time to submit proposals."

ACS is putting $6 million into ASSIST, Gruman said.

Board member Mary Ashton said even though up

to 20 states or metropolitan areas will be funded, "I would be surprised if we don't get applications from 40 states."

COMMIT Completes First Year Of Phase 2

NCI's Community Intervention Trial for Smoking Cessation has completed the first year of its implementation phase and "appears to be fulfilling its potential as a landmark study of the effect of community mobilization on smoking cessation," according to a report by the trial's Policy Advisory Committee.

The eight and a half year trial, the largest smoking intervention trial up until ASSIST, was approved by the DCPC Board in 1985, and began in October 1986. About $2 to $4 million was set aside for the trial.

The trial involves more than 2 million people in the testing of a community based intervention protocol that can be disseminated nationwide to meet NCI's Year 2000 objectives to reduce the percentage of smokers. The trial design encompasses 11 pairs of communities that were matched in size, demographics and location. One community from each pair was selected as the intervention site. The primary endpoint is the annual smoking cessation rate in each community.

"We are impressed with both the quality and quantity of activities and materials that have resulted from the trial at this stage," the PAC report said. The report was presented by board member Virginia Ernster at the board's recent meeting.

"COMMIT has a solid record of accomplishment in the development of a multifaceted intervention for smoking cessation and in community mobilization in diverse geographic areas, whose combined populations equal 2.2 million," the report said.

Phase 1 of the trial, which involved development of the protocol and evaluation plan, was completed in October 1988. Phase 2, which involves community mobilization and implementation of the intervention, began in October 1988 and will continue until June 1993.

The trial will monitor changes in community smoking prevalence and adolescent smoking rates. Also to be monitored are the level of cessation program activity, health professionals' advice to stop smoking, worksite programs, smoke free policy changes and local participation in national smoking control programs.

The protocol required the formation of a community board and task forces in the 11 intervention sites. The boards assumed the responsibility for planning and managing the protocol implementation early this year.

During phase 1, trial investigators defined 40 required interventions involving physicians and dentists, mass media, worksites, community organizations and telephone hotlines. Goals were defined for the intervention areas and quantifiable objectives were set for each of the 40 intervention activities. The four year implementation of the 40 activities will involve more than 1,000 physicians, 700 dentists, 1,400 worksites, 1,000 community organizations, 250 media outlets, 400 schools and 60 cessation service providers.

All of the intervention communities met their deadlines to establish a board, hire a field director and establish a field office, according to a separate report prepared by the Smoking, Tobacco & Cancer Program staff. Each community approved board by-laws, approved a community analysis report and established a site management plan. The task forces established in each community developed specific smoking control plans and action plans defining how the intervention protocol would be implemented in the community. The plans were developed with wide community involvement close to the target dates.

The PAC report listed the following concerns about the trial's progress in three areas:

--"Loss of followup in the first wave of the evaluation cohort study was greater than expected, averaging 15 percent across sites. The investigators are addressing this through more intensive mail follow up and other strategies, and they intend to do analyses to compare baseline data from responders and nonresponders. In the worst case scenario of continued 15 percent attrition, there will still be adequate numbers."

--The PAC was concerned about "the quantity and quality of the effort in the 40 activities that comprise the intervention." The 11 sites produce quarterly reports on their achievement of the minimum goals specified in the protocol for each activity. The PAC has requested that meaningful summary measures of the overall level of compliance with the intervention be developed. The measures will be necessary to correlate "amount" of intervention with smoking cessation at the end of the trial.

--"The PAC emphasized the importance of deriving estimates of the cost effectiveness of the COMMIT strategy. The committee reviewed an approach to an economic analysis that would produce estimates of the incremental cost to a community per additional quitter, based on a comparison of societal cost and number of quitters in the intervention and control sites. The PAC requested that a protocol describing

the actual data to be used in the analysis be presented by an economist to the committee at its February meeting."

"All of us recognize that there will be tremendous imprecision" in such an economic study, Ernster said, but the effort is still worthwhile.

'Strong Justification' For Smoking Research

In the annual report on the Smoking, Tobacco & Cancer Branch, Pechacek told the board that despite a falling percentage of adult smokers, there "still is a strong justification for large amounts of money for research in smoking."

The justification is the number of young adults and adolescents who are starting to smoke, the fact that the lung cancer death rate in women has caught up with deaths from breast cancer, and the fact that the rate of use of snuff and chewing tobacco is flattening, but at a higher level than in the late 1970s and early 1980s.

"Since the national smoking rate is declining anyway, how do we know we need trials at all?" Board member Philip Cole asked. "It seems we are just trying to accelerate (the decline)."

"We'll have a clear answer to that" when COMMIT and ASSIST are completed, DCPC Director Peter Greenwald said.

Pechacek noted that if it is determined that "the cost for extra quits is deemed inappropriately high" once COMMIT is completed, a decision can be made to cancel ASSIST.

Smoking is still "a primary killer," Pechacek said, "even though there are other pressing health issues."

The board unanimously approved a concept for an interagency agreement with the National Center for Health Statistics to conduct a survey on the attitudes and practices of teenagers towards tobacco use. Such a survey has not been done since 1979. The board approved $200,000 for the survey.

Surveillance Program

The report of the Surveillance Program also was presented at the board meeting. The function of the program is to provide a nationwide monitoring system to measure the burden of cancer in the U.S. and to assess progress against cancer. This includes measurement of disease outcomes, such as cancer incidence and survival, indirect indicators such as risk factors, attitudes and knowledge, and the effect of interventions. A core component of the program is the Surveillance, Epidemiology and End Results Program which tracks cancer incidence, patient survival and mortality in the U.S.

The report on the program listed the following plans for the future:

--During the next years the Surveillance Program will continue with the development of data systems and the analysis of databases which provide information on measuring progress against cancer. A major effort in data analysis is needed to more fully utilize the existing data information systems, such as SEER, and to address a number of methodologic issues.

--The program is coordinating a planning effort of the NCI study of patterns of cancer care.

--A new area of emphasis is being developed in health services research and economics. A number of studies are being planned in primary data collection analysis, in analysis of existing databases and in collaborative studies with government agencies.

--In conjunction with the Univ. of Minnesota's clinical trial on fecal occult blood tests, a study is being conducted to determine resources needed and the feasibility of collecting data on the cost of treatment of colon cancer by stage of disease using records from participating HMOs, private practice physicians and the Univ. of Minnesota Hospital. The five month study began in October.

--The Kaiser/Cost of Cancer Pilot Project began this summer to assess the feasibility of abstracting cost of cancer data from the Kaiser HMO database, and whether the records are adequate to make estimates of cost of treatment.

--The program is developing plans for a cost of cancer survey.

--In addition, the program is developing and has underway a number of data analysis projects.

The annual report also listed the following accomplishments in the past year:

--A cancer surveillance plan is being developed which outlines the current surveillance activities underway and the future projects planned to monitor progress in cancer control. A steering committee will be appointed to help set Surveillance Program priorities.

--During the past two years, the program has produced comprehensive reports on incidence, mortality and survival trend information for all major cancer sites. In the past year, the staff wrote a detailed report, "Cancer Statistics Review 1973-1986."

--The peer review for renewal of the SEER contracts has been completed and awards will be made during the next four months.

--Rapid Survey Response, the tracking and evaluation of cancer prevention and control activities in relation to the Year 200 goals, was instituted for more timely and rapid data collection responses.

Biomedical Construction, Pay Raise, Foundation Bills Clear Committee

Three major biomedical related bills have cleared the Senate Labor & Human Resources Committee and are ready to be sent to the floor of the Senate when Congress reconvenes in January.

A facilities construction bill, S 1863, authorizes $150 million for grants in FY 1990 and an estimated $156 million and $163 million for fiscal years 1991 and 1992.

The grants are to be awarded by NIH and the Alcohol, Drug Abuse & Mental Health Administration to public and nonprofit institutions to expand, remodel or renovate existing facilities or to build new research facilities.

The bill, titled the "Biomedical and Behavioral Facilities Construction Act of 1989," was originally introduced as part of S 1392, the "Biomedical and Behavioral Research Act." The committee deleted the provision during budget markup last month. Sen. Edward Kennedy (D-MA) introduced the bill as a separate measure.

Under the provisions of the bill, grant recipients must pay half the cost of construction. However, the NIH director may waive limitations on the awards. The matching requirement could be reduced for an institution "where both the need and the potential contribution were exceptional," according to a report accompanying the bill. In 1987, NIH awarded $6.9 million in construction grants, the report said. Federal support for construction reached a peak in 1965 when NIH grants totaled $63.2 million in current dollars.

The bill requires that an applicant must provide assurance that the facilities will be used for research for 20 years after the grant is provided. The institution must be able to pay for its share of the construction costs and fund the effective use of the facility. The facility must also expand the institution's capacity for research.

The bill also would establish a technical review board within NIH to give advice on facilities construction and to conduct peer review of grant applications. The bill provides that approval of applications is to be based on the relative scientific and technical merit of the facilities, the quality of research or training, the needs of the institution and the age and condition of existing facilities.

The committee cleared the "Foundation for Biomedical Research Act," S 1391, which establishes endowed chairs for biomedical researchers at NIH and ADAMHA. The bill requests that HHS make $500,000 available to get the foundation started, after which it would attempt to be self supporting with private donations.

However, the Congressional Budget Office estimated that if the government were to fund the foundation totally, the cost would be about $5.5 million in FY 1990.

Although the bill does not specify the number of chairs to be funded, committee sources say the goal is to fund approximately 10 chairs. Candidates would be selected by a panel of experts to be appointed by the foundation's board of directors. Four members of congress are ex officio members of the board, as are the NIH director and the ADAMHA administrator. They will select the board chairman and four or five other board members.

The committee also cleared S 1392, the "Biomedical and Behavioral Research Act," which authorizes pay raises for top NIH and HHS scientists. The bill authorizes $13 million for the Senior Biomedical Scientific Service in FY 1990, increasing to $16 million in 1994.

The bill would raise the pay caps of senior biomedical researchers in the Public Health Service. It is intended as a demonstration project to run for five years to determine the effectiveness of pay raises in retaining and recruiting senior scientists.

The bill stipulates that the base pay shall not exceed the rate provided for individuals who are paid at Level 4 of Executive Schedule. About $10,000 will be provided in supplemental pay for those whose duties include significant administrative responsibilities, and $25,000 in case of persons who render distinguished scientific accomplishments. There also would be a physicians comparability allowance for those who are physician scientists.

The bill is designed to provide 75 percent of the average of what biomedical investigators are paid in comparable university positions.

The bill is expected to provide pay raises to about 750 scientists in PHS.

The bill also provides $5 million in FY 1990 to establish a National Center for Medical Rehabilitation Research, and a $25 million per year discretionary fund for the NIH director.

Assurances On Methods For Dealing With Scientific Misconduct Required

The Public Health Service has issued a notice reminding institutions about its new procedures for dealing with possible scientific misconduct.

Following is the text of the announcement:

As soon as possible after Nov. 8, 1989, but no

later than Jan. 1, 1990, each institution that applies for or receives assistance under the PHS Act, for any project or program which involves the conduct of biomedical or behavioral research, research training or related research activities, must complete and submit to the Office of Scientific Integrity an assurance regarding procedures for dealing with and reporting possible misconduct in science.

OSI has mailed an Initial Assurance Form and Instructions to the president or director of each institution that has received PHS research support in fiscal year 1988 or later, or had an application for support under consideration at the time the form was mailed. This form must be used to comply with the Final Rule published in the "Federal Register" on Aug. 8. The rule requires each institution to certify that is has 1) established policies and procedures for investigating and reporting instances of alleged or apparent scientific misconduct, and 2) will comply with its own administrative process and the requirements of the rule.

Only one assurance is to be submitted for each organization or institution. Where major components (e.g., college of life sciences, school of medicine, department of pathology, research institute, etc.) have their own uniquely tailored scientific misconduct policies, the overall institutional or organizational assurance certifies that all the various policies are in compliance with the Final Rule.

Institutions or components that have not received a form should check with the central administration of their institution to determine if they are covered under an already submitted assurance. If not, a form may be requested from the Assurance Processing Section, Office of Scientific Integrity, PHS, NIH, Building 31, Mailroom, Bethesda, MD 20892.

Requests for assistance, copies of the Final Rule, or help with any questions should be directed to the address above, or call 301/496-7948.

RFAs Available

RFA 90-CA-03
Title: DCT small grants to stimulate correlative laboratory studies and innovative clinical trials
Application receipt date: Feb. 9, 1990
Letter of intent receipt date: Jan. 8, 1990

NCI's Div. of Cancer Treatment invites grant applications for tightly focused innovative laboratory studies which are related to clinical trials or for innovative clinical trials which take advantage of new developments in the laboratory.

NCI supports an extensive network of clinical and laboratory research studies related to cancer therapy through contracts, grants, and cooperative agreements. It has been difficult for investigators to obtain complementary funding through either the traditional basic research grant (RO1) mechanism or through the cooperative agreement (U10) mechanism for either (1) innovative pilot clinical trials that take advantage of new developments in the laboratory, or (2) correlative laboratory studies to existing clinical trials.

The Cancer Therapy Evaluation Program of DCT has targeted the use of the small grants mechanism (RO3) to support single or multiple institutions (individual institutions, consortia, cancer centers, etc.) to perform innovative pilot clinical trials or correlative studies of relevance to clinical trials. Some examples of categorical areas for RO3 studies include (1) oncogenes and growth factors, (2) antigen express on tumor cells, (3) biochemical modulation, (4) biological response modifiers, and (5) pharmacology and cell kinetic studies.

The aims of this initiative are twofold: to provide a mechanism for accelerated review and funding of innovative correlative studies relevant to clinical trials; and to stimulate pilot clinical studies with novel laboratory correlations so as to foster the development of interactions between basic science laboratories and clinicians performing clinical trials.

Studies should be proposed for a tightly focused, integrated research program at the interface of laboratory experimentation and concurrent clinical trials. The laboratory studies must have been demonstrated to be applicable to tissue samples and/or body fluids, etc. from patients entered onto clinical trials. Evidence of statistical support should be included to ensure proper correlation of assay parameters with clinical outcome. Some examples of support that would qualify under this RFA would be (1) salary for an additional technician, (2) funds for additional supplies or small equipment required for the project, (3) salary support for data management, data entry, or coordination of sample procurement, and (4) funds for the collection and shipment of specimens.

Approximately $750,000 in first year total costs will be committed to specifically fund applications submitted in response to this RFA. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. NCI plans to make multiple awards for project periods up to two years. The total direct costs per year must not exceed $48,000.

The earliest feasible start date for the initial award will be June 1, 1990. Although this program is provided for in the financial plans of NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

Domestic nonprofit and for profit institutions are eligible to apply. Foreign institutions are not eligible. Although NCI funded cooperative groups are ineligible to be the principal investigator, individual institutions or consortia which may or may not be members of cooperative groups may apply.

Awards will be made only to institutions with either a funded clinical or laboratory component of the proposed study. These awards are to complement a previously existing source of support. These pre-existing resources need not be at a single institution, but may exist within a consortium. The sources of funding must be documented in the application. Applications without this documentation will be returned to the applicants without further review.

NCI encourages applicants to recruit women and minorities into their study populations. Applicants should address the study population issue in their applications.

Copies of the complete RFA may be obtained from, letters of intent directed to, and written or telephone inquiries made to Dr. Roy Wu, Health Scientist Administrator, CTEP, DCT, NCI, Executive Plaza North Room 734, Bethesda, MD 20892, phone 301/496-8866; FAX, 301/496-9384.