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CCOP Recompetition Approved, "Institutionalized;" Board Okays Concept For Eight Minority CCOPs

The Community Clinical Oncology Program, born in controversy and accepted with great apprehension by many of those involved, which quickly became indispensable to the country's clinical cancer research effort, is now "institutionalized" as an ongoing extramural NCI program.

The Div. of Cancer Prevention & Control Board of Scientific Counselors last week approved recompetition of

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In Brief

Greenwald Reorganizing DCPC, Elevates Surveillance To Program Status, Moves Branches

REORGANIZATION of NCI's Div. of Cancer Prevention & Control is under way, Director Peter Greenwald told the division's Board of Scientific Counselors last week. DCPC presently is grouped in three programs--Centers & Community Oncology, Cancer Prevention, and Cancer Control Sciences. The Prevention Program will remain in place. Centers & Community Oncology wll become the Centers & Resources Program, which will include the Centers, Facilities and Cancer Training branches; the former Surveillance Branch has been elevated to program status, probably to be named the Cancer Control Science & Surveillance Program, and will include the Special Population Studies and Early Detection branches; the Cancer Control Science Program will be renamed the Health Promotion & Community Research Program. It will include the Community Oncology & Rehabilitation Branch and the three other branches which will be merged into two--Smoking, Tobacco & Cancer, Health Promotion Sciences and Cancer Control Applications. DCPC will be searching for new associate directors and branch chiefs to fill existing vacancies. . . . **NEW MEMBERS** of the DCPC Board of Scientific Counselors are Mary Madonna Ashton, Minnesota health commissioner; Rumaldo Juarez, sociology professor at Pan American Univ.; and Alfred Haynes, director of the Drew Meharry Morehouse Consortium Cancer Center. . . . **ROSWELL PARK** Memorial Institute is sponsoring a conference on Quality of Life and Ethical Issues, Feb. 24, in Buffalo, NY. Contact the Cancer Control Office, Elm and Carlton Sts., Buffalo, NY 14263 phone 716/845-4406. . . . **ROBERT BEAZLEY**, professor of surgery at Louisiana State Univ., has been named chief of the section of surgical oncology at Boston Univ. Medical Center. He replaces Peter Mozden, who has retired.

CCOPs To Include 5-year Awards, Minority Category; Diffusion Seen

(Continued from page 1)

CCOP, which will result in the third round of awards, with some major changes and additions:

* A separate competition will be held for minority CCOPs, with the intention of funding eight in the first round.

* In the regular CCOP competition, the top one third (approximately) in priority scores of the existing CCOPs will receive five year awards; the next one third, four years; and the rest of those funded, three years. New CCOPs will be limited to three years.

* The number of funded CCOPs will be increased next year to 60 from the present 52, in addition to the minority CCOPs, provided sufficient money is added to the program. An effort will be made to locate the new CCOPs in geographic areas not presently served by any NCI supported clinical trials program.

The cancer control clinical trials aspect of the program, started with CCOP 2, will be strengthened and expanded, with the intention of making it equal to the treatment effort.

The evaluation of CCOP 1, the still incomplete evaluation of CCOP 2, and the successful accrual record experienced by the cooperative group research bases from their CCOP affiliates all point to one conclusion, according to Leslie Ford, chief of the Community Oncology & Rehabilitation Branch: "CCOP works."

At its outset, CCOP had two major goals: bring more community patients into clinical trials, and make new treatment available, faster and more effectively, to all cancer patients being treated in community settings.

The latter became known as the "diffusion hypothesis," under the theory that physicians who place some of their patients on trials testing new treatment would offer that treatment to other patients when appropriate. Evaluation of the first round of CCOPs (CCOP 1) failed to find much evidence that the diffusion hypothesis was working. But the ongoing evaluation of CCOP 2 is finding that "in communities where protocols are available, earlier and more effective adoption of new technology is taking place," Ford said. "That is especially true with the National Surgical Adjuvant Breast & Bowel Project and the segmental surgery trial."

The proposal to shift at least some of the CCOP cooperative agreements to five year awards will add stability to the program and participants, and will ease the review burden on NCI's Div. of Extramural Activities. The next recompetition will involve only about a third of the CCOPs, and from then on, about one third will be recompeted every year.

The new awards will begin June 1, 1990. To further ease the burden of initial review, all research bases (cooperative groups and cancer centers, now numbering 17) will be administratively extended one year to June 1991. Beginning at that time, successful research base applicants will be funded for up to five years.

"Successful applicants previously supported under this program will be funded for three, four or five years, depending upon priority score, review committee recommendations, and programmatic considerations," the CCOP concept statement said. "Successful new applicants will be funded for three years. If funds are available, new applications will be solicited annually."

What about those in CCOP 1 which were not funded in CCOP 2? Will they be limited to three year awards?

Not necessarily, Ford and Program Director Carrie Hunter agreed. If they have been carrying on successfully without NCI support, and if they score in the top third, they may qualify for five years.

The plan to fund a total of 60 regular CCOPs depends on getting more money into the program. The President's budget for FY 1990 includes only $11.5 million, the amount that is funding 52 CCOPs and 17 research bases. It will take $15 million to fund 60 CCOPs.

It would seem that Congress would not have any problem adding $3.5 million, assuming

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Appropriations Committee members are properly informed. Failing that, NCI could probably squeeze that much out of other areas. DCPC Director Peter Greenwald is adamant that there is not enough in the 1990 budget elsewhere in cancer control to do the job.

The Board in approving the concept okayed the five year projection for the program's growth, reaching 80 CCOPs by FY 1992. The estimated budgets would be $17 million in FY 1991, $19 million in FY 1992, $19.5 million in FT 1993 and $20 million in FY 1994, which presumably would be enough to fund 80 awards.

The average annual budget estimated for the CCOPs would be $170,000; for research bases, $300,000.

The minority based CCOP is aimed at bringing both academic and community based oncologists with large minority populations into the clinical trials program. This program will differ from the other CCOPs in that it will accept applications from university hospitals of major teaching institutions if they serve large minority populations with greater than 50 percent of new cancer patients.

Although the second CCOP RFA encouraged wider minority involvement, any university hospital that was part of a major teaching institution was excluded from applying. However, a large segment of minority populations which are available for clinical trials are found in urban and university settings. A cadre of university trained oncologists is involved in treating minority cancer patients in these locations.

The estimated budget for minority CCOPs is $1.2 million for FY 1990, increasing to $1.3 million in 1992.

RFAs for both the regular and minority competitions are expected to be released by early May.

Presentations on the two concepts included the following:

Community Clinical Oncology Program.

The proposed initiative seeks to build on the strength and demonstrated success of the Community Clinical Oncology Program over the past five years by (1) continuing the program as a vehicle for supporting community participation in treatment and cancer control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI); (2) expanding and strengthening the cancer control research effort to equal that of cancer treatment; (3) utilizing the CCOP network for conducting cancer control research sponsored by DCPC; and (4) establishing the CCOP as an ongoing, institutionalized program of NCI.

Utilizing the national resource of highly trained oncologists in community practice, CCOP (1) provides support for expanding the clinical research effort in the community setting; (2) stimulates quality care in the community through participation in protocol studies; (3) fosters the growth and development of a scientifically viable community cancer network able to work closely with NCI supported clinical cooperative groups and cancer centers, and public health departments; (4) supports development of and community participation in cancer control intervention research, including prevention, early detection, patient management, and continuing care; and (5) involves primary care providers and other specialists in cancer control studies. Combining the expertise of community physicians and other health care professionals with NCI approved treatment and cancer control research protocols lprovides the opportunity for the transfer of the latest research findings to the community level.

Over 80 percent of patients with cancer are treated in the community. Through CCOP participation, physicians have access to the latest anticancer agents and protocol information regarding treatment, followup, and overall patient management. Although many cancer patients will not be eligible for protocol research, knowledge gained from protocol participation is applied to the treatment of patients not on protocol.

In the first three years of CCOP, community programs in 34 states were funded. During this time approximately 14,000 patients were entered onto NCI approved treatment clinical trials through CCOP. The data from CCOP participants met or exceeded all the quality control standards of the cooperative groups. The CCOP evaluation indicated that patients on protocol and patients treated by CCOP participating physicians received more appropriate patterns of care than patients seen by physicians who never used protocols. The CCOPs also had an increase in the number of physicians using protocols, the number of protocols used, and the number of patient registrations. It was further documented that CCOPs with higher accruals were often associated with more appropriate patterns of care. All of these factors contribute to establishing a framework that is critical to the diffusion process and the widespread dissemination of state of the art practices.

CCOPs were very effective in accruing patients to treatment clinical trials. The second RFA, issued in 1986, expanded the focus to include cancer control research, based on the rationale that the multi-institutional clinical trials model essential for testing new treatment regimens, is also required for conducting large scale cancer prevention and early detection trials. CCOPs are a vital resource for conducting NCI cancer control research because they provide access to a national network for cancer control studies which require large sample sizes for completion; geographic areas which include cross sections of the population, providing mixes of patients not always available in university or urban settings; large clinics or health maintenance organizations which can provide the opportunity for population based studies in screening and early detection; and cancer patients' family members and others who may be at high risk of developing cancer and thus be candidates for prevention and detection studies. The requirement for CCOPs to participate in cancer control research also further expands the network of community physicians, increasing the potential for diffusion of state of the art cancer control practices.

As a result of the second RFA, 52 community programs in 30 states received three year awards in June, 1987, with approximately 240 hospitals participating. More than 900 physicians were entering patients on protocols, and an additional 900 were actively supporting the CCOP effort. The following year, more than 4,200 patients were entered onto treatment clinical trials through CCOP. Sixty five percent of the entries were to phase 3 studies, which

accounts for approximately 30 percent of the phase 3 accrual to the NCI clinical trials program. An additional 2,000 subjects were enrolled in cancer control studies.

The development of cancer control research in the CCOP network has been increasing steadily since funding was begun in 1987. Most research bases have formed active cancer control committees and a process for protocol development and review is in place. To date, 120 concepts have been reviewed by DCPC staff; 39 protocols have been reviewed by the Cancer Control Protocol Review Committee, and 19 have been approved. These cover the full spectrum of cancer control research including chemoprevention and marker studies for future prevention intervention; screening and early detection; and pain control and other supportive care interventions aimed at reducing cancer morbidity. Two exciting studies testing new approaches for the early detection of colon and urinary tract cancers currently are under way and have the potential for making a major impact on the mortality from these diseases. These and other cancer control protocols are accruing well and have demonstrated the ability of CCOPs to attract physician participants, such as urologists and gastroenterologists, who were not previously part of the clinical trials network.

The establishment of an annual receipt date will strengthen the program and provide greater flexibility for program development by allowing new applicants to apply each year, unfunded applicants to reapply after one year, the flexibility to reallocate funds annually including the addition of new CCOPs, and program expansion to occur in a systematic fashion.

An individual CCOP may be a group of physicans, a clinic, a hospital, an HMO, or a consortium of physicians and/or clinics and/or hospitals and/or HMOs that agree to work together with a principal investigator and a single administrative focus. A university, military or Veterans Administration hospital may participate as a nondominant member of a consortium led by a community institution. An unfunded, nonuniversity, clinical trials cooperative group member or outreach affiliate may apply.

Participating CCOP physicians will be required to enter a minimum number of patients onto NCI approved treatment and cancer control research protocols through one or more NCI funded research bases. CCOPs may affiliate with a research base for treatment or cancer control research, or a combination of both. CCOP investigators are expected to form a collaborative relationship with the research bases.

Applicants will be expected to have (1) demonstrated ability to participate in treatment and cancer control clinical trials; (2) access to a sufficient number of cancer patients to satisfy the requirements for accrual to treatment protocols; (3) sufficient physician and patient resources for cancer control research (4) data management support and patient followup capability; (5) mechanisms for quality control of data; (6) access to a tumor registry; (7) multidisciplinary input from committed health care professionals, including oncology nurses and social workers; (8) institutional support services; and (9) adequate facilities for participation in cancer treatment and cancer control research.

Minority based Community Clinical Oncology Program. This program is designed to utilize as a national resource physicians involved in the care of minority cancer patients who are available for treatment and cancer control clinical trials research. The linkage of minority cancer patients to the current clinical trials network will facilitate the transfer of new technology in treatment and cancer control practices to minority communities and their physicians.

In general, there is limited participation in clinical trials research by minority patients. Seven percent of CCOP patients are minorities, compared to 13 percent in the SEER registry and 20 percent minorities in the general U.S. population. This is probably reflective of the patient populations available to the current CCOPs. When access to clinical trials through CCOPs is provided, the proportion of Black patients with protocols available who are judged to be clinically eligible and entered on protocol is similar in experience to that of white patients. That suggests that a major factor in influencing participating in clinical trials by minority patients is access to the system.

Greater involvement in clinical trials research by Black, Hispanic, Asian-American, American Indian and other minority patients is needed if the advances in clinical research are to be extended to all ethnic groups, and the results of clinical trials are to be generalizable to the entire population.

In addition to providing advancements in diagnosis, treatment and cancer control to minority patients, the involvement of minority populations and their physicians in treatment and cancer control research provides opportunities for studies in selected high risk populations which may lead to a better understanding of cancer etiology and its control. Areas of research where additional population resources are needed include cancer control intervention strategies to improve screening and early detection practices; studies of barriers to screening and treatment applications; and methodological research on ways to increase the educational awareness of individuals at risk for cancer.

Participating physicians will be required to enter patients onto NCI approved protocols through one or more NCI funded research bases (cooperative groups or cancer centers). Applicants to this RFA must have access to a large minority cancer population (e.g., greater than 50 percent of new cancer patients) and a demonstrated potential to participate in NCI approved clinical trials and cancer control activities. The applicant may be a clinic, a group of physicians, a hospital, a HMO, a consortium of physicians and/or hospitals and/or HMOs that agree to work together with a principal investigator. Primary teaching hospitals of medical schools with large minority populations may apply. A Veterans Administration hospital may participate as a nondominant member of a consortium led by a minority based institution. The applicant must have adequate facilities, a potential to conduct clinical research and an interest in participating in cancer control research. University hospitals participating as Div. of Cancer Treatment funded cooperative group members will not be eligible. Unfunded, nonuniversity group members will be eligible. Multiple awards will be made.

Applicants must have access to a sufficient number of minority cancer patients to satisfy the requirement for accrual, access to a tumor registry, patient resources for cancer control, especially for early detection, multidisciplinary input from other committed health care professionals, including nurse oncologists and social workers, institutional support services and cancer control activities.

In addition, applicants must provide a plan for data management support, patient follow up capability and quality control procedures. A description of the organizational plan, relationship of the organizational leadership to the fiscal agency and other consortial components, line of responsibility of key support personnel to the organizational leadership and procedures for monitoring and evaluating the progress of the program in meeting its accrual goals should be described. Cancer control activities including educational programs, tumor boards, supportive care services, outreach programs, home care, etc., should be described.

The research bases will be responsible for protocol development in treatment and cancer control research, and for data analysis and monitoring of quality control. A collaborative relationship will the CCOP investigators is expected.

Rumaldo Juarez, new member of the board who is associate professor of sociology at Pan American Univ., suggested that the evaluation of CCOP could be used to stimulate minority participation. "I don't believe the minority initiative will adequately address the problem. There is already a rich potential for improvements in minority participation (in the existing CCOPs). If you don't incorporate a minority point in the evaluation, CCOPs won't see that as something they had better address."

Board member William Darity supported that position, but Ford responded that "CCOP hospitals, for the most part, are not hospitals that minorities go to. That is why, in the minority CCOP concept, we are opening it to hospitals who do have large populations of minority patients."

Edward Sondik, DCPC acting associate director, said, "I get disturbed bringing this into evaluation. Evaluation is to evaluate, not to drive policy. I would rather see the policy come first, and then let the evaluation follow that."

Board member Robert McKenna noted that the average number of patients entered annually onto trials by CCOPs was 60 to 70, "roughly 10 percent of the patients they have. Do you have any idea why that is so low, and how could it be increased?"

Ford said that the 60 to 90 patients "is only the tip of the iceberg. Those physicians with private practices treat 10 times the number that are randomized to clinical trials. Our information is that those other patients are getting the same level of care as those on trials. The problem is getting more physicians to participate."

McKenna said that "a lot of patients are not eligible for protocols." He suggested that a study be done on those patients and that protocols be devised for them.

Board member Lloyd Everson recalled that the evaluation of CCOP I found "the bulk of patients were eliminated at the start. The protocol design didn't fit. The second biggest cut was the physicians' decisions. One of the main reasons this is an issue is that most CCOPs don't have capable, institutionalized systems to take that decision out of the physicians' hands."

Board member Shirley Lansky said that CCOP "is a terribly underfunded program."

Board member Donald Hayes said that "I spend a large part of my time with industry and health care payers who are interested in containing costs. One way is that they don't pay for experimental treatment. Another is to hire people on a part time basis so that they do not have to provide them with health insurance."

"That problem will get worse before it gets better," Ford said.

Board member Edward Bresnick asked if it is "realistic to expect to get eight new minority CCOPs the first year?" He suggested that the program be phased in, with a goal of five the first year. He also asked about the expected funding level of $150,000, compared with $170,000 for the regular CCOPs.

Program Director Carrie Hunter said she felt there would be at leaast "eight good applicants." Ford said that the lower average cost for minority CCOPs is based on the fact that they would be in their start up phase, with fewer patients entered the first three years.

"You can give us the authority to re-release the RFA after the first year if there are problems in the first competition in getting enough funded," DCPC Director Peter Greenwald said. That point was included in the board's approval of the concept.

Scientific, Funding Challenges Test NCI Prevention Efforts, Broder Says

NCI faces unprecedented scientific and administrative challenges in the years ahead, NCI Director Samuel Broder told the Div. of Cancer Prevention & Control Board of Scientific Counselors last week.

In his first address as NCI director to a Board of Scientific Counselors, Broder listed several topics he is concerned about and asked for the board's help in dealing with them.

Broder said the major challenges include the high incidence of smoking among minorities and women, the need to develop an intramural program of prevention research, protecting the Cancer Centers Program from budget cuts and placing more emphasis on reducing the disproportionately high rate of cancer among minorities.

Before listing those concerns, however, Broder praised the division and noted some of its accomplishments.

"A patient who comes to a physician requiring therapy for cancer represents a failure of prevention," Broder said. "Therefore, DCPC is arguably the most important division in our institute."

Saying that the most important resource of NCI is "the brain power of the people who work with us," Broder singled out several people involved with DCPC:

--Edward Sondik, director of the Surveillance, Epidemiology and End Results program. The program "has become a major statistical scientific tool that allows us to formulate goals and implement technologies to reduce mortality from cancer on a nationwide basis," Broder said.

--Joseph Cullen, who, Broder said, "has developed the strongest smoking prevention program in the federal government."

--Daniel Nixon, whose work in nutrition and chemoprevention research "has brought us to important chemoprevention trials."

--Charles Smart, who got NCI, major medical organizations and the American Cancer Society to reach a consensus on guidelines for early detection.

--Leslie Boss and Larry Bergner, who have worked with state health agencies to improve cancer control efforts.

Broder said he considered HHS Secretary designate Louis Sullivan a member of the division's "brain power trust" since he was a member of the Board of Scientific Counselors from October 1985 to May 1986. Sullivan worked with Claudia Baquet of the DCPC staff to develop cancer control projects for black populations, Broder said.

Broder also singled out board members William Darity and Alfred Haynes for making "substantial contributions to this effort." He also mentioned Elva Ruiz, on Baquet's staff, who is developing a cancer control program for Hispanics.

Despite the progress in some areas, DCPC faces "unprecedented challenges from a scientific and administrative point of view in order to meet the realities of the budget process," Broder said. Those challenges are:

--The high rate of smoking among women and minorities. These "ominous developments could undo much of the good work already accomplished" in antismoking efforts, Broder said.

--The need to build a strong intramural program of prevention research. "We foresee the possibility of developing top flight molecular and biochemical research collaborations within existing intramural programs throughout the institute targeted toward cancer prevention," Broder said. "We would like to explore the establishment of an expanded intramural program which can collaborate with centers in the U.S. and around the world."

--The division should consider the feasibility of adopting certain cancer therapies for treatment of individuals with a high risk of cancer. Broder asked the board to consider the possibility of studies using tamoxifen in women who are at risk of developing breast cancer, but who are in a precancerous state. "Could placebo controlled trials help us find a new use for this hormonal therapy?"

In response to a question from board member Robert McKenna noting that the Food & Drug Administration at one point was not willing to consider such a trial, Broder said, "The ball is in (the board's) court. I am framing a hypothesis here, which you have the expertise to advise us on. Is this a good idea or a bad idea?"

--The need to protect and expand the Cancer Centers Program. Broder said he is waiting to hear from the National Cancer Advisory Board Committee's review of the centers program and the Institute of Medicine study. "We are eager to hear their suggestions about the evolving needs and new perspective for centers in a time of restricted resources."

--Renewal of the Community Clinical Oncology Programs. "This is an exceedingly important mechanism for ensuring an effective transfer of the newest technologies to patients who need them."

--The need to address the disproportionate incidence of cancer in minorties. "I do not wish the next director of NCI to be faced with the set of statistics that show the disproportionate death rate in blacks compared to other populations," Broder said.

"We need to have a broad approach to the specific issues related to nutrition, smoking and patterns of care as they affect cancer in blacks, Hispanics and Native Americans.

"I would hope that we give special emphasis to those types of tumors that can be prevented or reduced by an application of available knowledge, but I would also hope that we would do more to focus some of the elegant tools of the new molecular biology in this direction," Broder said.

Board member Edward Bresnick asked Broder about the prospect of getting some construction money, which was not included in President Reagan's fiscal 1990 budget.

"In a public forum of this type I defend the President's budget," Broder replied. "Whether that is something that the board wants to comment on, that is in your capacity."

Advances In Cancer Control Meeting Is Set For March 22 Following ASPO

The date for the Advances in Cancer Control meeting has been set for March 22, at the Guest Quarters Suite Hotel in Bethesda, MD, directly following the ASPO meeting March 20-21 at the same location.

Panel discussions will include papers on smoking cessation research, moderated by Tracy Orleans; research in cancer screening, moderated by Paul Engstrom; chemoprevention and nutrition, moderated by W.K. Hong; and an adherence workshop, moderated by Barbara Rimer.

Marshall Becker will give the keynote address. Other speakers include Henry Lynch, discussing prevention and screening intervention in people with familiar risk factors; Rodger Winn on the role of physicians in chemoprevention trials; and Dennis Turk on enhancing patient participation and adherence.

All ASPO attendees are invited. The registration fee of $50 covers the cost of the buffet lunch and coffee breaks. Payment must be made by March 20. Checks may be made payable to Advances in Cancer Control and mailed to Linda Morgan, Div. of Cancer Control, Fox Chase Cancer Center, 7701 Burholme Ave., Philadelphia, PA 19111, phone 215/728-2986.

RFAs Available

RFA 89-CA-08
Title: New approaches to studying Epstein-Barr virus oncogenesis
Letter of intent date: June 3
Application receipt date: Aug. 3

Recent evidence appears to link Epstein-Barr virus with parotid gland tumors and B-cell lymphomas in immunosuppressed individuals. In vivo studies of EBV oncogenesis are complicated by the long interval between primary infection and the occurrence of neoplasia; and by the high prevalence of EBV infection in geographic areas where a high frequency of EBV associated neoplasias occurs: e.g., in the malaria belt in Africa in the case of Burkitt's lymphoma, and in the Far East in the case of nasopharyngeal carcinoma.

In vitro studies of EBV have been hampered by the lack of a lytic infection system. Studies have focused on lymphocytes whch have been immortalized or transformed by EBV infection and in which a limited set of viral gene products are expressed. The application of recombinant DNA technology to this system has led to progress in elucidating the structure of the viral genome, further definition of viralgene products, and identification of several regulatory regions of the viral genome.

However, the viral and host factors determining the disease manifestations and clinical outcomes for EBV infections are as yet undefined. Additionally, both B-cells and epithelial cells appear to be sites of viral latency and replication. While a number of investigators are studying specific aspects of EBV replication and tumorigenesis, delineation of viral and host factors which may determine the outcome of individual EBV infections has been difficult to approach directly.

The overall thrust of this RFA is to stimulate research on the mechanism of EBV oncogenesis by developing and using new methodological approaches to overcome the difficulties inherent in EBV research. Examples of research objectives would include the following: (1) use of novel methods and probes to define RNA transcripts unique to or with clinical significance for different EBV neoplasias; (2) use of new approaches to alter the viral genome followed by the study of the effect of altered genes on viral oncogenesis; (3) use of cell lines expressing individual EBV gene products (both structural and regulatory) to define viral genes and assess their role in the neoplastic process; (4) use of specific reagents such as monoclonal antibodies to viral gene products to determine the role of regulatory and structural EBV proteins in the neoplastic process; (5) measurement of host response to individual viral proteins with the goa of delineating differences in the host response in specific EBV associated neoplasias; (6) delineation of differences in cell mediated responses in individuals with different EBV neoplasias; and (7) exploitation of EBV's unique pathologic aspects such as the use of the CR-2 receptor and the activation of B-cells during the infectious process, to develop approaches to alter these unique aspects of EBV pathogenesis with the ultimate aim of preventing or reversing neoplastic conversion.

Where appropriate, collaborative arrangements to facilitate the achievement of research goals should be considered.

Applications should contain as goals both methodological development and application to a specific area of EBV oncogenesis; basic and/or clinical issues are considered as appropriate subjects for this RFA.

Furthermore, in studies involving differences between various EBV associated neoplasias, investigators should consider not only the classical EBV associated neoplasias, such as Burkitt's lymphoma and naso-pharyngeal carcinoma, but also give some emphasis to newer EBV related neoplasias such as EBV lymphomas in immunocompromised individuals, EBV tumors in other areas of the oropharynx such as the parotid gland, and other new EBV associated diseases such as hairy leukoplakia.

Approximately $850,000 in total costs per year for five years will be committed to specifically fund applications which are submitted in response to this RFA. It is anticipated that four to five awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications should not exceed five years. The earliest feasible start date for the initial awards will be April 1. Although this program is provided for in the financial plans of NCI, award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose. Nonprofit and for profit institutions are eligible to apply. Foreign and domestic institutions are eligible.

A copy of the complete RFA, the review criteria and the method of applying can be obtained by contacting Dr. Susan Spring, Program Director, DNA Virus Studies I, Biological Carcinogenesis Branch, Div. of Cancer Etiology, NCI, Executive Plaza North, Rm 540, Bethesda, MD 20892, phone 301/496-4533.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number,

to the individual named, the Executive Plaza room number shown, National Cancer Institute, NIH, Bethesda, MD 20892. Proposals may be hand delivered to the Executive Plaza, 6130 Executive Blvd., Rockville, MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CO-94390-63
Title: Office of Cancer Communications support contract
Deadline: Approximately March 20

NCI Office of Cancer Communications is interested in a master agreement on projects to support the planning, development and implementation of public information projects which require application at the regional or local level.

Contract Specialist: Tina Huyck
RCB EPS Rm 635G
301/496-8603

RFP NCI-CM-07301-74
Title: Clinical trials of anticancer agents (phase 1)
Deadline: April 22

The Cancer Therapy Evaluation Program of NCI's Div. of Cancer Treatment is seeking organizations with the capabilities and facilities to provide phase 1 and clinical pharmacokinetic evaluation of investigational new drugs which are developed through the DCT drug development program and are sponsored to the Food & Drug Administration under an investigational new drug application held by DCT.

Specifically, the organizations shall perform studies to define the acute toxicities ofnew anticancer agents in patients with advanced cancer; redefine the acute toxicities and pharmacokinetics of anticancer agents administered in combination with agents to modulate toxicity or antitumor effort; provide information on the pharmacokinetic characteristics (absorption, distribution, metabolism and elimination) and pharmacodynamics of selected antitumor agents; and determine a treatment regimen suitable for evaluation of antitumor activity in phase 2 trials.

All patients for these studies must be treated at the offeror's own institution. Offerors who propose must demonstrate an adequate patient accrual rate within the offeror's institution to provide at least 50 fully evaluable patients per year. It is estimated that the contractor shall perform at least three phase 1 trials per year. The contractor shall perform at least two pharmacokinetic studies per year on the compounds evaluated in the phase 1 trials.

The proposed acquisition is a recompetition of six existing contracts currently held by Memorial Sloan Kettering, Mayo Foundation, Univ. of Maryland, Univ. of Wisconsin, Ohio State Univ., Univ. of Texas (San Antonio), Johns Hopkins Univ., Univ. of Texas M.D. Anderson.

It is anticipated that eight awards will be made and that the resulting contracts will be awarded on an incrementally funded basis for a period of 66 months.

Contract Specialist: Odessa Henderson
TCS EPS Rm 603
301/496-8620

RFP NCI-CM-07309-74
Title: Clinical trials of anticancer agents (phase 2)
Deadline: April 22

The Cancer Therapy Evaluation Program of NCI's Div. of Cancer Treatment is seeking organizations with the capabilities and facilities to provide a resource for the conduct of early and high priority phase 2 trials. Specifically, the organizations shall (1) test new agents which have just completed phase 1 trials to confirm that the dose and schedule chosen can be safely gien in subsequent phase 2 trials; (2) determine the antitumor activity of existing antitumor agents which can be administered in significantly higher doses when used with colony stimulating factors or other factors which modulate toxicity or antitumor activity; (3) determine the antitumor activity of combinations of antitumor agents and modalities; (4) evaluate laboratory parameters which may correlate with or predict for response; and (5) determine the spectrum of antitumor activity for new agents in selected human cancers.

While the contract will permit occasional phase 3 trials, major emphasis shall be on early phase 2 studies which are pivotal for drug development and require rapid initiation, completion and data reporting.

All patients for these studies must be treated at the offeror's own institution. Offerors who propose must demonstrate the institution's ability to accrue at least 200 fully evaluable patients per year and complete, on average over the length of the contract, at least seven phase 2 trials a year. The minimum requirements for each tumor typle shall be dictated by the particular protocols which are approved for each contractor. For any proposed trial, the contractor shall be required to document the institution's ability to accrue the required number of patients within a reasonable time period.

The proposed acquisition is a recompetition of four existing contracts currently held by Memorial Sloan Kettering, Mayo Foundation, Univ. of Maryland and Univ. of Texas M.D. Anderson.

It is anticipated that four awards will be made and that the resulting contracts will be awarded on an incrementally funded basis for a period of 84 months.

Contract Specialist: Odessa Henderson
TCS EPS Rm 603
301/496-8620

RFP NCI-CO-94388-63
Title: Cancer Information Service, NCI
Deadline: Approximately March 15

NCI's Office of Cancer Communications is soliciting recompeting the Cancer Information Service. Goals of CIS are as follows:

1. To use communication strategies to reduce cancer incidence, morbidity and mortality. CIS is an important element in NCI's plan to meet the year 2000 goal of reducing the cancer mortality rate by 50 percent by making available state of the art information on cancer prevention, screening, diagnosis, treatment and continuing care to cancer patients, their families and friends, the general public and health professionals.

2. To provide regional cancer centers and other major community cancer organizations with a resource for communicating with their various audiences.

3. To establish a high quality system that can serve as a resource and a database for stimulating the development and implementation of new research projects in cancer communications, in cooperation with NCI grantees funded through a separate program entitled Cancer Communications Systems Research.

The overall goals will be met by the following objectives:

1. To support a network of regional CIS offices throughout the country that will serve as local resources for NCI to disseminate cancer information to communities.

2. To operate a toll free telephone service in the regional offices to provide cancer patients and their families, health professionals and the general public with rapid access to information on cancer prevention, detection, diagnosis, treatment and rehabilitation.

3. To support cancer information and education programs at the regional level that promote NCI's priorities.

4. To establish reliable data collection strategies to facilitate research on the role of information dissemination in cancer control.

Contract Specialist: Tina Huyck
RCB EPS Rm 635
301/496-8603