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CCOP RFA On The Street; Addition Of Cancer Control Research Adds New Dimension To Program

The RFA to recompete the Community Clinical Oncology Program finally became available this week, with every indication that the process of renewing the program will be even more competitive, and probably more complicated, than

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In Brief

Potter New AACI President, Sartorelli President Elect; NCI Staffers Get NIH Director's Award

JOHN POTTER, director of the Vincent Lombardi Comprehensive Cancer Center at Georgetown Univ., took over as president of the Assn. of American Cancer Institutes at the organization's recent annual meeting in San Diego. **ALAN SARTORELLI,** director of the Yale Univ. Comprehensive Cancer Center, was elected vice president and president elect. **EDWIN MIRAND,** accociate director of Roswell Park Memorial Institute, was reelected secretary treasurer for the 20th consecutive year. . . . **NIH DIRECTOR'S** awards recently presented to NCI staff members: Richard Masys, chief of the International Cancer Research Data Bank Branch, "for directing initiatives that have increased the ability of NCI to disseminate information on advances in canncer research effectively;" Shirley Dennison, grants technical assistant in DCBD's Cancer Immunology Branch, "in recognition of dedication and highly effective and professional manner of helping other staff and the NCI extramural community;" Roger Esterhay, computer medical specialist at the International Cancer Information Center, "for exceptional achievement in the development of PDQ;" Charles Land, a statistician with the Div. of Cancer Etiology's Radiation Epidemiology Branch, "for applying extraordinary knowledge of statistics and human effects of ioonizing radiation in developing radio-epidemiology tables;" and Stephen Ficca, deputy associate director for administrative management, "in recognition of superb contributions to NIH business operations and specifically for acquisition of a supercomputer and development of a biotechnology fellowship program." Douglas Lowy, chief of DCBD's Laboratory of Cellular Oncology, received an outstanding service medal "in recognition of major contributions to viral oncology with emphasis on the regulation on retroviruses and papilloma viruses and the nature of their oncogenes."

NCI Expects 200 Applicants To Seek 50 Awards In New CCOP Competition

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it was the first time around. The addition of the requirement for cancer control research not only adds a new dimension to the program, with the need for new types of expertise. It also is almost certain to increase the budgets requested in the applications, and since NCI does not intend to add any more to the overall money available, fewer awards will be made.

NCI expects as many as 200 applications for what probably will be no more than 50 awards. Sixty two CCOPs were funded in the first round. Two dropped out voluntarily, and two more were dropped for lack of patient accrual. A few of the remaining 58 have indicated they will not join in the recompetition, but there will be no shortage of organizations hoping to take their place.

The RFA places new requirements on CCOP research bases, particularly in regard to cancer control research. It also modifies patient accrual requirements, basing it on a system of "credits" which varies depending on the complexity of the intervention, the amount of data management required and the duration of followup. For example, each patient accrued to an average phase 2 study will count 0.7 credits; an average phase 3 protocol 1 credit; and a childhood acute leukemia protocol 2 credits.

Deadline Oct. 23

Letters of intent will be due Sept. 2 and applications Oct. 23.

To obtain copies of the RFA and further information, contact Robert Frelick, M.D., Community Oncology & Rehabilitation Branch, Div. of Cancer Prevention & Control, NCI, Blair Bldg Rm 7A05, Bethesda, MD 20892.

The RFA restates the primary goals of the program, which essentially remain the same: providing support for expanding the clinical research effort in the community setting; stimulating quality care in the community through participation in protocol studies; and fostering the growth and development of a scientifically viable community cancer network able to work closely with NCI supported cooperative groups and university cancer centers.

The program has always been funded out of DCPC's line item cancer control appropriation and therefore NCI has been careful to state that expansion of clinical trials in communities is a cancer control effort. Addition of other cancer control research has been justified by a perceived need to more strongly qualify CCOP for cancer control dollars. The new RFA states the goals of additional cancer control requirement:

"This RFA seeks to strengthen the cancer control focus by expanding the program to require that other cancer control research be conducted in addition to treatment clinical research. Thus, the research initiative now includes (1) support for cancer control research in the community; (2) provision of an operational base for the extension of cancer control efforts in early detection, prevention, screening, pretreatment evaluation, treatment, continuing care and rehabilitation; (3) involvement of primary care providers and other specialists in cancer control studies early in the course of clinical treatment; (4) increased involvement of minority and underserved populations in clinical research; and (5) evaluation of CCOP performance and its impact in the community."

Those Who Can And Can't

Eligibility requirements for CCOP applicants have not changed from the first round:

*An applicant may be a hospital, a clinic, a group of practicing physicians, a health maintenance organization, or a consortium of hospitals and/or clinics and/or physicians and/or HMOs, but a single administrative focus is required.

*A university, military, or Veterans Administration hospital may be included in an application as a nondominant member of a consortium led by a community institution. An unfunded nonuniversity clinical trials cooperative group member is eligible to apply.

*Funded Cooperative Group Outreach Program participants are eligible to apply, but should state in the application that CGOP support will be relinquished if a CCOP award is received.

*Institutions not eligible as CCOPs are a comprehensive, consortial, or clinical cancer center holding an NCI cancer center support grant; a university hospital that is the major teaching institution for that university; or a university hospital clinical trials cooperative group member funded by NCI's Div. of Cancer Treatment.

Eligibility of the research bases has been tightened up, and state and local health departments have been added as research bases

for cancer control protocols. To be eligible as a research base, an applicant must be an NCI funded clinical trials cooperative group; an NCI funded clinical, consortial, or comprehensive cancer center; or a state or local health department.

Cooperative groups are expected to participate in both treatment and cancer control research studies; cancer centers may participate in treatment and other cancer control research or cancer control research only; state or local health departments may participate only in nontreatment cancer control research.

Each CCOP may affiliate with up to five eligible research bases, only one of which may be a national multispecialty cooperative group. Those are Cancer & Leukemia Group B, Eastern Cooperative Oncology Group and Southwest Oncology Group.

CCOPs may affiliate with up to five (four if they sign up with one of the national groups) of the disease, modality oriented or regional cooperative groups--Brain Tumor Study Group, Childrens Cancer Study Group, Gynecologic Oncology Group, Lung Cancer Study Group, National Surgical Adjuvant Breast & Bowel Project, North Central Cancer Treatment Group, Pediatric Oncology Group and Radiation Therapy Oncology Group.

Cancer centers and health departments may be included in the total of five.

CCOPs must accrue a minimum of 50 patient credits each year for treatment clinical trials, and 20 credits during the first year for other cancer control researc, 30 the second year and 50 the third year.

Other requirements for CCOPs, which have not changed much, are spelled out in the RFA.

Research bases this time, unlike the first round, must prepare formal applications. They will be peer reviewed and those not approved will not be eligible to serve as research bases. They must show in their applications their ability to:

1. Design and implement multi-institutional treatment clinical trials and/or the potential for multi-institutional studies in other cancer control research. Cooperative groups must have both.

2. Initiate cancer control research. Examples are given in the RFA (and have been published previously in **The Cancer Letter**, May 16).

3. Manage the data from multi-institutional studies.

4. Initiate procedures for training and maintaining the proficiency of personnel from their affiliated CCOPs on techniques for successful management of clinical trials and/or cancer control research.

5. Provide mechanisms for periodic review of the performance of its affiliated CCOPs, including on site monitoring and written procedures and criteria for continued affiliations.

6. Access professionals with the appropriate expertise to design and implement the proposed clinical trials and/or cancer control research.

Further details, including review criteria, are in the 19 page RFA.

Some Misunderstanding

Frelick told **The Cancer Letter** that some community investigators planning to join in the competition have mistakenly gained the impression they will be required to develop their own cancer control research protocols. Actually, research bases will have that responsibility. In fact, one of the prime considerations in review of research bases will be their potential for developing cancer control research studies, Frelick said.

Elm (15 for 17) Has Some Advice For CCOP Hopefuls: Over Prepare

Elm Services Inc., the Rockville, MD, management consulting firm familiar to those involved with cancer centers and community cancer programs, achieved a remarkable degree of success in the 1983 CCOP competition when 15 of the 17 organizations for which the firm helped prepare their proposals were funded.

"We should have had 16," Elm President Lee Mortenson said, referring to one which he felt did not get a fair deal in the review. Considering that only one third of the applicants were funded, Elm's record was stunning. That success led to a deluge of requests for Elm's help this time, and Mortenson had to turn away more than he took on.

Why were Elm's clients so successful? What advice does Mortenson have for any group planning to get into the competition this time?

Mortenson is frank about what was one of the key factors, if not the most important: "We were choosy about who we worked with. We picked those who already had strong programs. Writing the application is the easiest part."

Otherwise, Mortenson said, "the secret to the success of any grant application is over-

preparing. Start early. There are some (CCOP applicants) who started working on this last year.

"People hire us to help them build programs that are fundable. That means getting the organizational structure right, getting your troops in line, developing a track record, getting people to work together in committees. You have to develop a system that works. Then, when it's time to write the application, that's easy.

"We're not cheap," Mortenson continued. "Also, I tell them at the start that they will feel a lot worse working with me than without me. I make them work hard."

Elm has stopped accepting clients for this round, "although if a very good, strong group came in and twisted my arm, we might add one more," Mortenson said. He has 15 groups for the full service and three for which he will only review their applications before they are submitted. Twelve are existing CCOPs "which are extraordinarily good" and the rest are new applicants "that I think are top notch."

A last bit of advice: "Reviewers are looking for top quality throughout in the applications, which should be in great detail. The budget should be solid and strongly justified. Do that and you win."

Three other consulting firms with cancer program management expertise offering their services to CCOP applicants: CDP Inc., with offices in San Diego (phone 619-223-5520); Atlanta (404-391-9872); and Rockville (301-294-9390); W.W. Rice & Associates of Alexandria, VA (703-799-4848); and SHC Health Research Group (a subsidiary of Salick Enterprises), Washington DC (202-857-1800).

TV Film On Cancer Funding Getting Great Reviews, Not Enough Air Time

"Cancer: The Second and Final War," the excellent film produced by Harry Mantel which makes a powerful case for increased funding of the National Cancer Program, has been getting rave reviews everywhere it has been shown on public television. Unfortunately, it has not been shown everywhere.

Mantel says it is too early to know how many stations will use it (it was sent to all public TV stations by satellite feed in May for them to record and use when and if they see fit). He has heard from about 20 stations who have used it or plan to do so.

Convincingly narrated by actor Pernell Roberts, the film uses expertly displayed evidence of progress in cancer research and accurate, powerful comments from a variety of scientists on how tight budgets threaten future progress. Apparently, these arguments are too strongly presented, in the opinion of some timid station and network managers.

Joanne Kaufman, assistant director for public affairs and science programming at PBS: "Unfortunately, while the program deals with a vitally important topic, I am afraid it takes too hortatory an approach to be appropriate for PBS."

(Ed. note: "Hortatory--urging to some conduct or course of action; encouraging"--Random House dictionary.)

Carren Miller, network programming assistant, Nebraska Educational Television Network: "We feel the program both advocates a political position and is out of balance. For these reasons we have decided not to air it."

Ann Engelman, Maryland Public TV: "We will not carry (the film). We feel the program is unbalanced. Not much from the researchers' side."

Anyone who sees the film who has been following the fight for adequate funding of cancer research for the last 15-20 years might feel those comments were somewhat naive. Urging Congress and the Administration to increase the cancer budget is an honorable and acceptable practice; pointing out the consequences of inadequate budgets, even if it is "hortatory," has not been done often enough. And if "political positions" had not been taken by cancer program advocates and their congressional allies, NCI would never have been established.

Does PBS insist that all of its programs be neatly balanced, and that it must avoid anything that looks like controversy? One of the primary reasons for having public, non-advertising supported television and radio was to encourage intellectual and controversial programming. If a program is unbalanced, opposing views can be aired later.

It seems that PBS and some of the public stations are overly concerned about the reaction of the White House and Office of Management & Budget.

Perhaps some pressure from cancer scientists and others around the country on their local public television stations would encourage them to schedule the film. Its message is badly needed to help strengthen the base of support for the cancer program.

--Jerry Boyd

St.Jude Offers Two Fellowships For Advanced Research Training

Two special fellowships are available to investigators with either a PhD or MD at St. Jude Children's Research Hospital--the Karnofsky Fellowship in Cancer Research and the Journey Fellowship in Biomedical Research.

The Karnofsky Fellowship, in memory of David Karnofsky, a pioneer in cancer chemotherapy at Memorial Sloan-Kettering who was a member of the St. Jude Scientific Advisory Board, is available to investigators who are beyond the junior level of accomplishment and would like to gain further expertise in cancer research by collaborating with a member of the St. Jude faculty. Research topics currently under investigation include drug resistance, oncogenes, hematopoietic stem cell differentiation, red cell aging, cancer clinical trials, oncopathology, monoclonal antibodies and experimental bone marrow transplantation. Awards are made for one or two years with an additional year negotiable.

The Journey Fellowship is in memory of Leon Journey, a cell biologist and electron microscopist who served on the St. Jude staff for 10 years. The fellowship is open to junior investigators who seek experience in one of the specialty areas of research available there. Training opportunities are available in biochemistry, immunology, human tumor cell biology, pharmacology, virology and molecular biology, pharmacodynamics, pediatric oncology, hematologic malignancies, and child health sciences. Awards are made for one or two years with an additional year negotiable and are based on merit, recommendations and promise of a productive career in biomedical research.

The application deadline for both fellowships is Sept. 1. Decisions will be made by Nov. 1, with a starting date of July 1. Inquires may be sent to Joseph Simone M.D., Director, St. Jude Children's Research Hospital, PO Box 318, Memphis, TN 38101.

ACS Makes $78.2 Million In Research Awards In FY 1985-86, Highest Ever

The American Cancer Society allocated $78.2 million for support of more than 785 research projects and post doctoral fellowships in the 1985-86 fiscal year, John Laszlo, vice president for research, announced this week.

Those research commitments were in addition to ACS' extensive programs of epidemiological research, its support of an ongoing program to evaluate interferon, and a program of large institutional grants for investigation of cancer cause and prevention. They are the highest in the Society's history.

There were 444 new grants totaling $52.3 million and 341 renewal grants amounting to $25.9 million.

Cancer prevention, by studying environmental agents and lifestyle factors which may contribute to cancer risks, is a major target of research funded by ACS, Laszlo said. In this case, a total of $9.1 million was earmarked for studies in biochemistry and chemical carcinogenesis.

Cell and developmental biology projects were awarded $7 million. Researchers in the rapidly growing field of nucleic acids and protein synthesis received $9.5 million in support.

Awards for clinical investigations in immunology, immunotherapy, chemotherapy, hematology, prevention, diagnosis and therapy added up to $23.3 million.

Grants in psychological and behavioral research in cancer received $702,190.

Microbiology and virology studies received $11 million.

The research program of ACS is second in size only to that of the National Cancer Institute. Applications for ACS grants are screened by teams of scientists in a peer review process. The ACS Board of Directors makes the awards on recommendations of its research and clinical investigation committee which itself is counseled by specialist advisory groups.

NCI CONTRACT AWARDS

Title: Development of dosage forms and delivery systems for new antitumor agents
Contractor: Univ. of Kansas, $471,000

Title: Tracing through other sources for former patients evaluated for infertility
Contractor: Equifax Inc., $34,472

Title: Current cancer research clinical protocol analysis center
Contractor: Informatics General Corp., $781,369

Title: St. George screening and clinical research project
Contractor: Univ. of Utah, $2.3 million

Title: Support for SEER
Contractor:Fred Hutchinson Cancer Center, $438,705

Title: MRI studies data analysis & statistical mgmnt
Contractor: SRA Technologies, $221,710

Blood Donors With Uncertain HTLV-3 Tests Should Be Notified, Panel Says

Potential blood donors whose blood initially tests positive for HTLV-3 infection but is negative by confirmatory testing should be notified of their testing status, a panel of experts convened by the National Institutes of Health has concluded. The panel issued a draft statement at the conclusion of a two and a half day consensus conference on the impact of routine HTLV-3 antibody testing on public health.

Current practice in many centers is to enter the names of those patients whose blood is repeatedly reactive but negative by Western blot into donor deferral lists. "We believe that it is inappropriate to enter a person's identity into such a list without his knowledge and without giving him the personal advantage of sharing that knowledge and its meaning," the panel said.

"It is common practice to allow such individuals to donate again, but to discard their blood without their knowledge," it said. "This practice should not continue; these donors have a right to be advised of their status."

The panel also recommends that all blood banks should adapt a "self deferral" procedure that will allow donors to indicate confidentially that their blood should not be used. It notes that some persons at risk to transmit HIV may feel compelled to donate blood because of "real or perceived social pressures."

The panel refers to the virus as HIV (human immunodeficiency virus), previously referred to as HTLV-3/LAV.

Voluntary blood donors have the right to expect confidentiality of records of blood donation and anonymity with respect to the recipient of their blood, the panel said. They should receive an explanation of tests to be performed, consequences of a positive test, and details of any registry to which their name may be given.

Education is identified as the primary public health measure regarding risky behavior and ways in which such behavior might be modified, including the refraining from donating blood by persons at risk for AIDS.

"It is our belief that punitive and threatening measures against high risk groups are counterproductive; they drive individuals away from responsible behavior and make education almost impossible."

All possible steps should be taken to avoid unnecessary blood transfusion, the panel advised, especially in neonates. Efforts should be made to increase the knowledge of practicing physicians about transfusion medicine and to make consultation readily available to them. Patients should be adequately informed about the risks of transfusion, and effective peer review of transfusion practices should be maintained.

Autologous Donation Endorsed

The panel agreed that autologous blood is the safest form of transfusion therapy. "Blood banks and blood centers should make this option available to qualified patients, simplify the donation process to the extent possible, and inform physicians and patients about the advantages and mechanics of this approach," it advised. During a press conference held at the conclusion of the consensus conference, panel chairman Thomas Chalmers said that blood banks in general are responding to requests from persons who want to give their own blood. Chalmers is a distinguished service professor at the Mount Sinai School of Medicine. Both Chalmers and American Red Cross Associate VP of Medical Operations Gerald Sandler distinguished between autologous donations by persons prior to elective surgery and attempts by healthy people to stockpile their own blood in case it is ever needed.

There was no evidence presented at the conference to show that directed donations from persons known to the prospective recipient are any more or any less safe than donations from the general public.

While maintaining that the nation's blood supply is far safer than before routine HIV testing began, the panel notes that the tests for evidence of infected blood are not yet optimally effective. "There is still room for improved applications of the scientific method to identify methods with increased sensitivity, specificity and predictive value," it said. "Since no test can be totally devoid of error, there must be continuing vigorous efforts to educate the public and facilitate anonymous self deferral at the time of blood donation."

Because of the current ELISA tests' inability to detect antibodies in those persons who have been infected very recently or who have not yet formed antibodies, approximately 120 units of blood from the 12 million donations in the U.S. per year may be contaminated, panel member Lincoln Moses told the press

conference. Moses is a professor of statistics at Stanford Univ. Fellow panel member Richard Aster noted that the chances of contracting AIDS from a blood transfusion are less than 1 in 10,000, "probably several orders of magnitude lower than that" of death from general anesthesia. Aster is president of the Blood Center of Southeastern Wisconsin and a clinical professor or medicine and pathology at the Medical College of Wisconsin.

Noting differences in the various ELISA tests on the market, the panel suggested that "the value of using ELISA tests from different manufacturers on the sample to improve accuracy should be explored."

A report presented the first day of the meeting by National Institute of Allergy & Infectious Diseases researcher Alfred Saah compared the various ELISA tests commercially available. Saah analyzed results of tests conducted during an ongoing prospective study of 4,955 initially healthy, homosexual and bisexual males in four cities. The study, the Multicenter AIDS Cohort Study, is designed to trace the natural history of infection with the virus. Participants are seen every six months, and blood specimens are collected at each visit.

Saah reported that comparison of the data revealed that some blood specimens identified as antibody negative by certain kits were antibody positive when tested with kits from different manufacturers and with Western blots. The Western blots showed that the specimens contained antibodies to core proteins (gag gene products) of HIV and frequently lacked antibodies to envelope proteins, often the first antibodies to develop during early infection with the virus.

Of 30 specimens that were positive for core antibody only, kits from Bionetics identified two, Electronucleonics four, Abbott 13, DuPont 25 and Genetic Systems 25. Tests of subsequent specimens showed increased production of antibodies to both core and envelope proteins, reflecting a true infection with the AIDS virus. The ELISA kits of all the manufacturers identified these later specimens with greater accuracy.

DuPont officials held a press conference in Bethesda the second day of the consensus conference in order to discuss the sensitivity of the firm's ELISA test. Fred Fraser, business manager of blood processing, said DuPont's test "may be two to three times more effective at early detection of antibodies to the AIDS virus than the most widely used tests in the U.S." The test's sensitivity is due to its ability to detect antibodies to both the core and envelope proteins and the firm's process of preparing the viral antigens using psoralen inactivation of the virus and extremely gentle processing steps, he said. The test's sensitivity for detecting antibody to the envelope protein is the same as the other widely used tests, but its ability to measure antibodies to the core proteins p24 and p55 is two to four times more sensitive than the others tested, he said.

The company has made its antigen available as a research product, and is considering supplying it as a raw material for other commercial tests.

Earlier this month, DuPont introduced a radioimmunoassay for the measurement of the 24 kilodalton core protein fragment of the virus. The test is useful for measurement of viral cultures and is currently intended for research use only. The antibody used in the test "is of exquisitely high affinity and, therefore, can achieve up to 200 times greater sensitivity than the reverse transcriptase assay currently used to detect virus in cultures," he said. In addition to the p25 RIA, the firm has just introduced a radiometrically labeled DNA probe for HTLV-3 to allow direct measurement of the viral nucleotide by researchers.

The panel predicts that "the most promising new approaches will be the development of FA techniques for detecting infected T_4 lymphocytes and the development of techniques for detecting viral proteins, based on the one hand on antigen capture and on the other on RT activation and synthesis of HIV DNA, which can then be detected with high sensitivity and specificity."

The development of more sensitive tests to detect low levels of antibody is essential, the panel said. "Highly specific confirmatory tests capable of distinguishing false positive from true positive reactions and that can be performed in a blood center are also required." It adds that since direct detection of virus offers the most specific way of identifying donors who carry HIV, emphasis should be placed on development of improved methods for detecting the HIV genome and virus-specific proteins in blood samples.

AIDS also "presents enormous challenges for psychosocial research," the panel said in its report.

New Publications

"Introduction to Human Immunology," by Teresa Huffer, Dorothy Kanapa and George Stevenson. Self teaching and self paced text designed to help persons without formal training in human immunology to rapidly gain a working knowlege of its basic concepts and terminology. Price $17.50, Jones and Bartlett Publishers, 20 Park Plaza, Boston, MA 02116, 1-800-832-0034.

"Understanding Your Immune System," by Eve Potts and Marion Morra. Explains how to build and protect the body's first line of defense to ensure good health. Price $3.95 U.S./ $4.95 Canada. Avon Books, The Hearst Corporation, 1790 Broadway, New York, NY 10019, phone 212/399-4506.

"Your Breast & You," by David Halbert. Contains sections on breast cancer, cosmetic breast surgery and benign breast conditions, and current information on medical breakthroughs. Price $14.95. Askon Publishing Company, 1025 Cypress, P.O. Box 3156, Abilene, TX 79604, phone 915/672-3640.

"Acute Myelogenous Leukemia," free brochure that briefly explains symptoms, diagnosis, prognosis and treatment of leukemia. It also discusses the causes and risk factors, psychological responses to a confirmed diagnosis and current research. For copies, contact the Leukemia Society of America, 733 Third Ave., New York, NY 10017.

"QuitSmart: A Guide to Freedom from Cigarettes," by Robert Shipley. Stop smoking kit contains 94 page patient manual, self-hypnosis tape and eight page health professional's guide. Three phase approach includes preparing to quit; quitting; and remaining a nonsmoker. $12.95 plus $1.50 shipping, JB Press, P.O. Box 4843-M, Duke Station, Durham, NC 27706.

"Management of Soft Tissue and Bone Sarcomas," European Organization for Research on Treatment of Cancer [EORTC] Monograph Series, Vol. 16. New approahces to diagnosis and therapy of soft tissue and bone sarcomas incorporating recent developments in pathology, radiology, radiotherapy, surgery and chemotherapy. Price $47.50. Raven Press, 1140 Avenue of the Americas, New York City 10036, phone 212/575-0335.

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 Blair building room number shown, National Cancer Institute, NIH, Bethesda MD 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring MD, but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-67910-26

Title: Clinical trials of activated human leukocytes
Deadline: Oct. 20

The Cancer Therapy Evaluation Program of NCI's Div. of Cancer Treatment is seeking organizations which will perform clinical trials using activated human leukocytes in cancer patients. The major objectives of this task shall be to:

1. Determine the antitumor activity of activating agents in combination with activated leukocytes in a variety of human cancers in patients with advanced disease and minimal prior therapy.
2. Define the toxicities of activating agents administered in combination with activated lymphocytes to patients with advanced cancer.
3. Evaluate new methods for activation of leukocytes and to determine the optimum regimen and antitumor activity of activated leukocytes generated using the new methodology.

It is expected that awards will be made to four to six institutions to conduct studies for adult cancer patients and to one institution to conduct studies for pediatric patients. A four year period of performance is expected for this contract. In the duration of this contract, no fewer that 120 (40/year) evaluable patients will be studied at each institution. All patients must be treated at the principal investigator's own institution and directly under the PI's care for initial evaluation, therapy and followup.

A minimum mandatory requirement has been established for this acquisition. The offeror must document the accrual of at least 40 evaluable adult patients to IRB approved Phase 2 studies conducted at the offeror's institution from Jan. 1, 1985, to Dec. 31, 1985. Institutions applying for the pediatric portion of this contract must document the accrual of at least 25 evaluable patients to phase 2 studies at the offeror's institution from Jan. 1, 1985, to Dec. 31, 1985. All patients must have been accrued at a single institution and this institution must be the same as that proposed for studies under this contract.

NCI intends to have a preproposal conference with prospective offerors on Sept. 3, 1986, for the purpose of providing information which may be helpful in the preparation of proposals and to answer any questions which offerors have regarding this solicitation. Complete instructions will be provided in the RFP package.

Contract Specialist: Carolyn Swift
RCB Blair Bldg Rm 228
301-427-8737

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