THE CANCER LETTER

Vol. 10 No. 45
Nov. 23, 1984

Subscription $150 year North America
$175 year elsewhere

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INTEREST PICKS UP IN SBIR, NCI MAY NOT HAVE TO FACE CHOICE OF GIVING MONEY BACK OR PAYING TO 500 LEVEL

Interest in NCI's share of the Small Business Innovative Research Program has picked up enough to lead Institute executives to feel that this time, they may not be faced with the horrendous choice of (1) turning back money to the U.S. Treasury or (2) funding grants down to

(Continued to page 2)

In Brief

McKENNA NEW ACS PRESIDENT, LEMAISTRE PRESIDENT ELECT; MICHAEL POTTER WINS ALBERT LASKER AWARD

ROBERT MCKENNA, Southern California medical oncologist, is the new president of the American Cancer Society, succeeding Gerald Murphy. The new president elect named at the ACS annual meeting earlier this month is Charles LeMaistre, president of the Univ. of Texas System Cancer Center–M.D. Anderson Hospital. Helene Brown is vice president, Madge Harrison chairman of the Executive Committee, Dakin Ferris treasurer, and Kathleen Horsch secretary. Robert Gadberry is chairman of the board, succeeding Alan Jonas, and Don Heald is vice chairman. Virgil Loeb heads the Medical & Scientific Executive Committee and Harmon Eyre is chairman of the Medical & Scientific Committee.... **MICHAEL POTTER,** whose mouse tumor system developed in the 1950s made possible work that led to development of monoclonal antibodies, has received the 1984 Albert Lakser Award in basic medical research. Potter is chief of the Laboratory of Genetics at NCI's Div. of Cancer Biology & Diagnosis. He will share the award with Cesar Milstein of England and Georges Kohler of Switzerland. Paul Lauterbur, State Univ. of New York (Stony Brook), received the Lasker award in clinical research for his system of creating three dimensional images of the interior of the human body.... **DONALD BUELL,** who was program director for the now completed and highly successful Community Hospital Oncology Program, will leave NCI after 17 years Dec. 3 for a position as reviewing medical officer at the Food & Drug Administration. Buell more recently has been program director for investigational agent development in the Chemoprevention Program of the Div. of Cancer Prevention & Control.... **ABSTRACT DEADLINE** for the Second International Conference on Modulation & Mediation of Cancer by Vitamins & Micronutrients has been extended to Dec. 1. The conference is scheduled for Feb. 109-13 in Tucson, with Frank Meyskens of the Univ. of Arizona and Kedar Prasad of the Univ. of Colorado as cochairmen. The program will include presentations on basic experimental approaches, preclinical chemoprevention, human chemoprevention, prevention trials, and treatment. Contact Mary Humphrey, Conference Coordinator, Cancer Center, Arizona Health Sciences Center, Tucson 85724, phone 602-626-6044.

NCI ENCOURAGES ACADEMIC-BUSINESS PARTNERSHIPS FOR SBIR PROJECTS

(Continued from page 1)

the despised 500 priority score level, as happened in the first round of the program. Vincent Oliverio, who is coordinating SBIR for NCI, said there has been "a tremendous amount of interest, from the phone calls I've received."

SBIR was mandated by Congress, directing federal research agencies to set aside a certain percentage of their budgets to help stimulate technological innovation by bringing small business more into the picture. Goals are to increase private sector commercialization of innovations derived from federal R & D and to encourage participation by minority and disadvantaged persons.

NCI's SBIR set aside was .6 per cent of its budget in FY 1984, or $4.65 million. That funded 58 grants, but NCI had to scramble, picking up some cancer related grants from other NIH institutes, at least one of which had been given the worst score possible in the peer review process, 500 (**The Cancer Letter**, Sept. 28).

Director Vincent DeVita and his staff feel there were some extenuating circumstances in that round—the fact that it was a new program, applicants were unfamiliar with various aspects of grantsmanship, reviewers perhaps not entirely tuned in on what was expected. But they have pulled out all the stops in hyping interest in this year's competition. Appeals have been made to the National Cancer Advisory Board and the divisional boards of scientific counselors, for suggestions on R & D areas of interest which might be passed on to prospective applicants, and for help in talking up the program.

NCI especially has been pushing the suggestion that SBIR permits partnerships between academic institutions and small businesses in competing for the awards. Main consideration is that the small business must maintain control (at least 51 per cent) of the grant. That opens the door for academic investigators with a potentially marketable idea to make a deal with a small (no more than 500 employees) or minority or disadvantaged owned firm, join forces, get some federal R & D money, and attempt to develop the product to the point where it is commercially successful.

Awards may be either grants or contracts. The program is organized into three phases, and all applicants must have had a phase 1 award before they can compete for phase 2 support. Phase 1 is to establish the technical merit and feasiblity of the proposed research and whether they may ultimately lead to commercial products or services. These awards may not exceed $50,0000, for six months.

Phase 2 basically is to implement the R & D effort, and may not exceed $500,000, including direct and indirect costs, for up to two years. Larger grants or longer periods of support may be made in cases where agency needs or research plans so require.

Phase 3 is the part where the small business is supposed to go on its own and take the product out into the marketplace. No federal money is available for that part of the program, except when the product is something the federal government intends to purchase. Support then is negotiable.

This year NCI will have $9.1 million for the program, and Oliverio is optimistic that it will all be used to support good projects. So far, he has received 56 suggested topics for research and development, which will be published by NIH in mid January along with suggestions from other institutes. Most of the ideas have come from NCI program staff.

The next deadline for proposals is March 15.

NCI's "pride and joy," the new Outstanding Investigator Award, generated about 140 letters of intent and more than 100 applications, Barbara Bynum, director of the Div. of Extramural Activities, said at the last meeting of the National Cancer Advisory Board.

OIA is intended to provide long term (seven years), stable support to investigators, based on their track records and not on individual projects. The program utilized a unique review by mail, with 200 scientists as reviewers. The first recommendations will be presented to the NCAB in January.

NCAB member Enrico Mihich asked whether OIA awardees would be able to compete for RO1 grants in areas other than those covered by the award. The program assumes that NCI and awardees will negotiate phasing out much of the existing NIH support the awardee has been receiving, with the new grant providing that support.

Bynum noted that OIA recipients will be required to spend only 75 per cent of their time on that grant, "so there is flexibility there. They can get the rest of their salary from an RO1. The institution must commit itself to assuring the rest of the support, but it could come from an RO1 or another source."

DeVita pointed out that OIA permits supplemental awards "if something happens to warrant it. This is very flexible."

NCAB member Victor Breren praised Elliott Stonehill and his staff "for the tremendous job they did in putting this together." Stonehill is executive secretary of the President's Cancer Panel, which came up with the OIA concept after hearing at a series of meetings that NIH should think more about "supporting people rather than projects."

ONS ADOPTS SCOPE OF ONCOLOGY NURSING PRACTICE DESCRIBING DEPTH, ROLES

The Oncology Nursing Society Board of Directors recently adopted a "Scope of Oncology Nursing Practice." This statement was developed by the Society's Clinical Practice Committee and describes the depth of oncology nursing practice as well as the various roles of registered nurses caring for persons with cancer.

The four ONS Outcome Standards covering practice, nursing education (fundamental level), patient education and public cancer education reflect the Scope of Practice, ONS said, and copies may be obtained by calling the national office, 412-344-3899.

Scope of Oncology Nursing Practice

Nursing is one segment of the health care system. Recognition of cancer as a major health problem has led to the development of oncology nursing as a specialized area of nursing practice. The scope of oncology nursing practice includes clinical practice, education, administration and research and occurs in all care settings. Oncology nursing practice focuses on the optimal function of the individual and family throughout the continuum of the disease process.

The oncology nurse is a professional registered nurse committed to the provision of optimal care to the individual diagnosed with cancer and his/her family. The practice of the oncology nurse is based on: (1) individual professional accountability; (2) in depth knowledge of the interrelatedness of physiologic and psychosocial life processes relative to the dynamic nature of the health illness continuum associated with cancer; (3) collaboration with other members of the health care team; (4) recognition of the individual's wholeness and uniqueness and the significance of social relationships within the framework of living optimally with cancer; (5) advocacy for the individual's self determination, independence and choice in decision making in matters of health; and (6) participation in ongoing continuing education and professional development activities.

The oncology nurse utilizes the nursing process as a framework for practice. In caring for the individual with cancer, the oncology nurse will assess, collect data, and identify the priority of the individual's nursing care needs. The oncology nurse will formulate an appropriate plan of nursing care, implement the plan of care according to the priority of the identified needs, and evaluate the process and outcomes of nursing care. The ONS Outcome Standards—Cancer Nursing Practice, Cancer Patient Education, Public Cancer Education and Cancer Nursing Education (Fundamental Level)—reflect the Scope of Nursing Practice and offer guidance to oncology nurses in providing nursing care to individuals with cancer and their families.

DCE BOARD APPROVES CONCEPTS FOR RECOMPETITION OF DIVISION CONTRACTS

Concept approval for the recompetition of contracts approved by the Board of Scientific Counselors of NCI's Div. of Cancer Etiology are listed below. Those appearing here are a partial list of the recompetitions; the balance will be published in next week's issue of **The Cancer Letter.**

Title: Biological specimen repository for patients at high risk for cancer. Estimated cost, $150,000 a year, five years. This is a recompetition of a contract held by Flow Laboratories. Staff description of the project:

Laboratory studies of persons at high risk for cancer provide opportunities to evaluate the role of host susceptibility and host environmental interaction in cancer etiology. The Family Studies Group of the Environmental Epidemiology Branch and Clinical Epidemiology Branch have pioneered this approach over a 15 year period. Study groups include patients with genetic disorders that might enhance cancer risk, familial clusters of the same or related malignancies, patients with non neoplastic conditions associated with risk for cancer, and patients with prior or current environmental exposures that may increase cancer risk. A repository of 2,733 skin fibroblast and tumor cell strains contributed by members of the EEB and CEB, outside collaborators, and other cell banks represents an invaluable resource for collaborative studies with etiologically oriented laboratory investigators who are collaborating with NCI/EEB or NCI/CEB scientists in testing specific hypotheses, or require cell lines for their own investigations. We retain control over specimen distribution to ensure maximum utilization of the data generated and to ensure the integrity of cell strains bearing our code numbers. For clarification, a "cell strain" is any cell line established from a single sample from a particular individual.

During the current contract, 335 cell strains have been started and 412 selected cell strains have been provided to 40 collaborating investigators. Etiologic leads which have resulted from this work include demonstration of sensitivity to the cytotoxic and mutagenic effects of ultraviolet radiation and ultraviolet radiation mimetic chemicals in melanoma prone individuals and gamma radiation resistance in members of a kindred with multiple types of cancer.

More recently, gram quantities of fibroblasts from selected families have been produced by the contractor. These fibroblasts are being used in experiments to investigate leads concerning the linkage of the dysplastic nevus syndrome to genetic markers on chromosome 1. Advanced restriction enzyme technology is being applied in kindreds with this syndrome to try and identify the exact nature of the

susceptibility locus. Cell strains from other families are also being grown in bulk quantity for investigation of other genetic markers including oncogenes and for cloned probe analysis for human retroviruses in nonlymphoid tissue by several laboratories within NCI as well as in outside institutions. Although the contract was initially targeted for the five years from 12/81-12/86, an increased level of effort was required for the described tasks, necessitating a new procurement at a higher level.

EEB intends to maintain and further develop the repository of skin fibroblast cultures on persons at high risk for cancer. This repository will continue to be a source for irreplaceable cell strains for laboratory investigators studying mechanisms of cancer risk. The contractor will grow the cell strains in large quantities as requested to provide collaborating investigators with gram quantities of cells for molecular biologic studies. The contractor will also develop a repository of epithelioid cell strains on selected study subjects. The contractor, in addition, will propagate and develop a repository of tumor cell lines initiated in other laboratories. In developing these cell lines, the contractor should use the most current laboratory techniques for ensuring the highest viability and cell yield from these cultures. The contractor will not use contract funds for basic research or for the development of new tests. In general, the contractor will engage solely in the application of previously developed techniques that are pertinent to achieving the stated goals for the contract and already in use in their laboratories.

1. Culture of cells. The contractor must demonstrate at least two years experience in the successful establishment of fibroblast and epithelial cell lines. The contractor must also demonstrate success with the culture of established tumor cell lines. The tissue culture techniques must be specified in detail, and data must be provided which document the laboratory's current rate of success in establishing cell lines, cell yield, and cell viability. Cultures will be routinely screened for contamination by PPLO, bacteria and fungi. Outside cultures will be screened to ensure that the cells are of human origin. Normal fibroblast and epithelial cell strains will be established in laboratories where no animal or tumor tissue culture is being performed. Likewise, tumor cell strains will be handled in laboratories where no animal cell culture is performed.

2. Storage of cell strains. All cell strains will be stored under optimum conditions in liquid nitrogen freezers. Specimens at any passage will be stored in at least two separate freezers. Freezers must have a constant central source of liquid nitrogen with emergency backup. Freezers must have automatic filling mechanisms and 24 hour central sound alarm systems, with a guard on duty 24 hours a day, year around, who has explicit directions on the steps to take in case of emergency. Specimens should be frozen in containers impervious to entry of atmospheric CO_2, such as silicon sealed "nunc" type tubes so that they can be shipped on dry ice.

3. Additional responsibilities. The contractor will provide transportation for routine and emergency pickup of specimens, as well as for distribution of coded specimens to collaborating investigators. Media for transport of specimens will be provided by the contractor. In addition, the contractor will keep detailed records of the inventory of cell lines, their locations and number. The laboratory will keep clear documentation of all manipulations on all cell lines and carefully document passage, "crisis events," growth characteristics and types of contamination screening performed on each cell line.

As part of a new study of nevoid basal cell carcinoma syndrome involving 200 individuals, we anticipate starting approximately 100 epithelial cell lines in the next two years. We will continue to seek out additional collaborative studies with other investigators to expand the number and type of etiologic studies possible with this resource. Thus, because of the molecular genetic work involving bulk culture of existing cell strains, the establishment of new epithelial cell lines, and the potential of new studies, we anticipate that we will continue to need support at this present higher level of effort throughout the new contract.

Margaret Tucker is the project officer.

Title: Support services for epidemiologic studies. Estimated first year award, $2.3 million, five years, total estimated cost $12.6 million. This is recompetition of the contract held by Westat Inc.

This contract establishes a mechanism for the provision of all of the support services required to conduct a wide variety of field studies. Included in these activities are development of liaison with organizations and individuals at a local level whose cooperation is needed for the conduct of a study, the design and development of forms required to conduct field investigations (interview forms, record abstracting forms, interviewer manuals, etc.), the hiring, training and supervision of interviewers, record abstractors and persons to collect biological specimens, and the actual collection of the required data. Also included are all of the data reduction activities involved in field investigations including coding, keying, and a variety of data processing activities. Finally, these services include the development of field supervision and quality control mechanisms to ensure the quality of the activities involved as well as the maintenance of control of all aspects of every study by the appropriate EEB investigators.

These support activities have been applied in one of three general ways. In some studies, the contractor is responsible for virtually all of the field activities required to complete a study. This circumstance is most often encountered when the study takes place in areas or with collaborating institutions that have none of these capabilities. A second manner in which the contractor assists is to provide only selected types of support activities that cannot be accomplished by the locally based collaborators. Examples of this include forms development, interviewer training, or random digit

dialing for control selection in areas where such activities are not often conducted. Finally, the contractor may provide one or more of the above mentioned services in conjunction with serving as a coordinating center for multicenter collaborative studies. In these circumstances, in addition to providing these support services, the contractor assists in monitoring and implementing the standardized application of the study design across all areas.

Robert Hoover is the project officer.

Board member William Haenzel supported the concept but had some reservations. The contract supports all field activities of the branch and in addition serves as a coordinating center for multicenter collaborative studies, he noted. "That can only be done with the scientific input of NCI staff." With the pressures caused by the personnel ceiling and resulting understaffing at NCI, "the question is whether the combination of Westat and NCI staff can carry on."

Also, Haenszel continued, "a multicenter activity ought to have an important teaching and training component, and you can't have that with this contract. The coordination of centers should not be handled by this contract, but NCI should compete that task among centers and teaching institutions."

"This contract covers only the support aspects of the coordinating center and does not involve scientific activity," Hoover responded.

"But we have the opportunity to use the coordinating center for the scientific aspects," Haenszel insisted.

Board member Pelayo Correa expressed concern about "one company doing so much." Hoover said that that has not discouraged potential competitors. "This will be a robust competition." He indicated that at least five organizations may fight it out for the award.

Board member Carl Shy suggested that an Epidemiology Committee of the Board be established to oversee implementation of the contract. Board Chairman Barry Pierce and DCE Director Richard Adamson agreed. Pierce appointed Shy, Correa and Haenszel to the committee, with Shy as chairman.

Title: BCB repository for storage and distribution of research resources. Estimated first year cost, $387,000, five years, total estimated cost $2.1 million, much of which may be recouped through a payback system. This is recompetition of a contract held by Microbiological Associates Inc.

The Biological Carcinogenesis Branch is responsible for maintaining a coordinated program of research resources support to meet the needs of extramural investigators funded by the branch. A major component of the resources program is a facility for the centralized storage and distribution of biological reagents. For a number of years, this contract and its predecessors have operated and maintained the BCB repository facility for receipt, storage and distribution of reagents produced by NCI resource contracts. During the three year period since the start of this contract, over 12,000 items of biological materials including viruses and viral proteins, antisera to viruses, viral proteins and immunoglobulins of various species, preimmune animal sera, and human species have been received and stored at the repository. During the past year, 300 shipments totaling more than 7,500 reagents were distributed to domestic and foreign laboratories. These shipments were comprised of the following reagents: 1,000 antisera, 600 virus preparations, 125 preimmune animal sera, 3,500 human sera and 2,200 human tissue specimens. A variety of viral reagents are currently available for distribution including viruses from 65 different virus culture propagation combinations and antisera from over 200 different species-antigen-treatment combinations. Human specimens available include over 25,000 sera and 3,500 tissue samples from donors with malignant and nonmalignant diseases. Some sera are also available from normal individuals. During the last 18 months, investigators have made requests for every type of reagent in the repository.

This project will become part of the branch resources payback system. Resources will be distributed under a cost reimbursement system with recipients paying a reasonable price for items plus shipping costs. Since these materials were previously distributed without charge and include materials acquired or prepared by resource contractors no longer active, we have no past history basis for estimating what portion of the repository contract cost will be borne by recipients. However, based on previous requests, we anticipate that most laboratories now receiving these reagents will continue to utilize the biological reagents from the repository and that a reasonable payback level will accrue to the benefit of the repository contract.

Wilma Varrato is the project officer.

Adamson explained that NCI "puts the money up front the first year," and that paybacks during that year reduce the costs of the second year, and so on. "On one payback program, we were making money, so we reduced the price. Some are completely paying for themselves. Generally it works." He contended that grantees have not been harmed, since they can build those costs into their grants. NIH intramural investigators also pay out of their budgets, which has resulted in requests for lesser quantities and "they don't pass it around to others."

RFPs AVAILABLE

Requests for proposal 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. 20205. 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-CN-55434-50
Title: Formulation, dosage form preparation and packaging of chemopreventive agents
Deadline: Approximately Jan. 1

The government contemplates awarding a series of master agreements for the work described below seeking to establish a pool of qualified sources who will compete for the individual master agreement orders. The required services will be defined by master agreement orders issued during the period of performance. The master agreement period will be five years.

Pursuant to the master agreement orders, the contractor shall be capable of either or both of the following tasks: (1) Furnishing all necessary services, qualified personnel, materials and a fully operational facility including all necessary equipment for all aspects of the manufacture and testing of solid oral dosage forms and/or soft gelatin capsule dosage forms. (2) Furnishing services, qualified personnel, materials, supplies, equipment and facilities for calendar pack daily dose packaging which includes, but is not limited to, (a) developing, packaging and labeling plans to meet the needs of specific clinical trials; (b) manufacturing the required calendar pack preparations; and (c) quality assurance testing of the contents of manufactured batches of calendar packs prior to shipment to the NCI designated facility.
Contract Specialist: David Monk
RCB Blair Bldg Rm 2A07
301-427-8745

RFP NCI-CN-55469-44
Title: Cancer communications system
Deadline: Approximately Jan. 5

The Div. of Cancer Prevention & Control of NCI is soliciting proposals for the operation of regional centers for the dissemination and interpretation of information regarding the cause, prevention, detection and treatment of cancer to cancer patients and their families, the general public, and health professionals. The areas of the United States for which proposals are being requested are Alaska, Arizona, Arkansas, District of Columbia, Idaho, Indiana, Maryland, Mississippi, Montana, Nevada, New Mexico, Rhode Island, South Carolina, Tennessee, Virginia, Wyoming and Puerto Rico.

The goals of the cancer communications system are as follows:

a. To use communication strategies as a cancer control modality to reduce cancer incidence, morbidity and mortality. This will contribute to the overall NCI goal of a 50 per cent reduction in cancer mortality by the year 2000 by making available the latest state of the art information on cancer prevention, screening, treatment and continuing care to cancer patients, their families and friends, the general public at risk to cancer and health professionals.

b. To establish a high quality communications system which can serve as a resource and/or data base for stimulating the development of new research projects in cancer communications, in cooperation with the grantees funded through a separate program entitled "Cancer Communications System Research."

c. To provide regional cancer centers and other major community cancer organizations with a resource to interface and communicate with other information resources and their various publics.

The overall goals will be met by the following objectives:

a. To develop and extend a cadre of cancer communications professionals who can plan, administer, develop and promote support materials for cancer information and education programs which comprise the cancer communications system.

b. To provide the general public and health professionals with access to accurate, current information on cancer. This will be accomplished by establishment, operation and evaluation of a national toll free telephone information system, consisting of regional offices and known as the Cancer Information Service, or CIS. In addition, each office is expected to be an active participant in cancer information/education activities in its area of service.

c. To develop and maintain directories of cancer resources including agencies, organizations and services available to the general public, cancer patients and their families within a designated service area.
Contracting Officer: Dorothy Coleman
RCB Blair Bldg Rm 2A07
301-427-8745

RFP NCI-CM-57694-68
Title: Provision of animal facilities and performance of routine tests
Deadline: Jan. 18

The Developmental Therapeutics Program of NCI's Div. of Cancer Treatment is seeking an organization qualified to provide an equipped animal facility for the maintenance of mice, rats, guinea pigs, rabbits, goats and subhuman primates. To perform this work, the organization should have (a) biocontainment facilities for human virus inoculated subhuman primates conforming to P-2 specifications; (b) Beta scintillation counter; (c) adequate liquid nitrogen facilities; (d) CO2 incubator; (e) laminar flow tissue culture hood; (f) 30 cubic feet-70 degrees and 30 cubic feet of -20 degrees freezer space; (g) well equipped facilities for common laboratory animals and subhuman primates and adequate quarantine and isolation facilities for newly acquired animals and those inoculated with moderate risk viruses; and (h) facilities to perform surgical, pathological and post mortem procedures. The contractor will be responsible for providing veterinary care and technical assistance for performance of routine procedures such as inoculation, of antigens, viruses and cells, and bleeding of animals at appropriate intervals to check for antibody production. It is estimated that 11,000 labor hours will be devoted annually to this

project. The contractor must be capable of inoculating freshly harvested virus and virus infected cells and supplying freshly harvested material on wet ice to NCI in Bethesda within one hour after harvest.

It is anticipated that a cost reimbursement incrementally funded type contract will be awarded as a result of the RFP for a period of 60 months, beginning approximately Sept. 30, 1985. The RFP is a recompetition of the project being performed by Litton Bionetics Inc. of Kensington, Md.

Contract Specialist: Karlene Ruddy
RCB Blair Bldg Rm 212
301-427-8767

RFP NCI-CM-57712-48
Title: Phase 1 clinical trials and pharmacokinetics studies in children
Deadline: Approximately Jan. 25

The Cancer Therapy Evaluation Program of the Div. of Cancer Treatment is seeking organizations with the capabilities and facilities to conduct phase 1 clinical trials and pharmacokinetics studies in children with malignancies on specific investigational new drugs (INDs) in cooperation with NCI on 300 evaluable patients over the five year period of the contract, with no fewer than 60 evaluable patients comprised of 30 leukemia patients and 30 solid tumor patients with noncompromised bone marrow accrued in any one year.

Offerors should be able to perform at least three complete phase 1 studies in two years. A phase 1 study should be considered as requiring an average of 40 patients (20 leukemia and 20 solid tumor) per study in order to identify a suitable dose for phase 2 trials in children. All required IND drugs will be furnished by NCI. Phase 1 clinical studies with drug combinations or bone marrow transplantation may be performed if mutually agreed upon by the contractor and the project officer.

The successful contractor(s) will ensure: (a) the right of NCI to select the agents tested in pediatric patients; (b) an improvement in the quality of pediatric new agents trials in terms of timeliness and quality of data; (c) the ability to obtain pharmacologic information pertinent to the pediatric population. NCI anticipates testing six new agents in children every two years. It is estimated that each successful contractor will test at least three agents every two years. The successful contractor(s) shall define the acute toxicities of new anticancer agents in children with advanced cancer; define the dose of each agent which can be safely given in subsequent phase 2 studies; provide information on the pharmacologic chacteristics (adsorption, distribution, metabolism and elimination) in children of selected tumor agents; and investigate age related differences in these pharmacologic chracteristics. The required product of the studies will be a document consisting of a final report on the results of each study and the NCI designated individual case report form for each patient included in each study. It is anticipated that such documents will be used in support of new drug applications (NDA) to the Food & Drug Administration, by a pharmaceutical company selected by NCI. Specifically, the successful contractor(s) shall:

1. Provide evidence that patients entered into the study have a microscopically confirmed diagnosis of cancer; have disease resistant to conventional therapy; are less than 19 years of age; have given signed informed consent (by themselves or their legal guardians) indicating that they are aware of the investigational nature of the studies involved; have normal liver, renal and bone marrow function unless otherwise indicated by the specifics of the leukemia or pharmacokinetic protocols; and are registered on study.
2. Utilize the toxicity criteria designated by NCI.

The government anticipates that two awards will be made. It is anticipated that resulting contracts will be awarded on an incrementally funded basis for a period of 65 months.

Contract Specialist: Thompkins Weaver
RCB Blair Bldg Rm 228
301-427-8737

RFP NO1-CM-57720-15
Title: Production of hybridomas secreting antibodies reactive specifically with cytokines
Deadline: Feb. 4

The Biological Response Modifiers Program of NCI's Div. of Cancer Treatment seeks a contractor with the expertise necessary to produce monoclonal antibodies reactive with various human, primate and rodent cytokines. It is expected that three to five cytokines will be available annually for development of hybridomas by the contractor, In most cases, the cytokines will be provided by the BRMP and the contractor will provide BRMP with anticytokine secreting hybridomas. In some cases, the contractor may have available cytokines that are of interest to BRMP which will be developed on the contract. In a few instances, the contractor will be required to perform some cytokine purification prior to immunization.

The principal investigator should possess an MD or PhD degree with at least five years experience in immunology and cell biology and must devote at least 25 per cent of his/her time annually to this effort. In addition he/she should have recent experience in the development of monoclonal antibodies to cytokines, radioimmune binding assays and cytokine assays. It would be very desirable if the PI can document recent hands on experience in the production and isolation of both monoclonal antibodies and cytokines.

The qualifications of the overall team should have expertise in rodent handling and experimentation, cell culture (large scale production), biochemistry (protein purification) and immunoassays. The level of effort for this project is estimated at three person years annually.

Contract Specialist: Jeaneen Monk
RCB Blair Bldg Rm 212
301-427-8767

NCI-CM-57716-68
Title: Clincal and preclinical data management
Deadline: Jan. 31

The Clinical Oncology Program of the Div. of Cancer Treatment is seeking an organization qualified to provide computerized data management support for its clinical research program. The workscope includes the development, documentation and maintenance of software necessary to support the various data bases of the COP; provision of data collection and data management capabilities; and response to ad hoc data processing requirements of the COP branches. Prospective offerors should possess the capabilities necessary to: (1) develop, document and maintain software necessary to support COP data bases and clinical trials; (2) maintain existing data base software (developed on the NIH DCRT IBM system written in COBOL and including BDAM and ISAM access techniques) and continue to provide currently specified reports using packages such as SAS; (3) provide operations office and statistical center support for cancer clinical trials; (4) abstract patient related data from computerized data bases and standard medical records; and (5) maintain and update existing data bases and create new data bases as needed.

In addition, the prospective offerors should: (1) be familiar with a variety of computerized data base systems and statistical packages (e.g. BMDP and SAS); (2) have experience with the NIH DCRT or similar computer facility; and (3) be able to respond quickly to requests for nonroutine reports and data processing. Future computing environments will include the DCRT facility (IBM mainframe and DEC 10 computers) and personal computers. Contract staff involved in day to day data abstraction and monitoring will be located full time at NIH in Bethesda. Representative labor categories may include programmers, medical data managers, support staff, and individuals knowledgeable in biostatistics. The data coordinator and data manager abstractor must be registered nurses or have equivalent training and experience of medical procedures and terminology.

It is anticipated that a cost reimbursement incrementally funded type contract will be awarded as a result of the RFP for a period of 60 months, beginning approximately Oct. 1, 1985. This is a recompetition of the project being performed by Orkand Corp., Silver Spring, Md. This proposed contract is a 100 per cent small business set aside.
Contract Specialist: Karlene Ruddy
RCB Blair Bldg Rm 212
301-427-8767

RFP NO1-CM-57718-15
Title: Chemical coupling of cytotoxic agents to tumor reactive monoclonal antibody
Deadline: Feb. 4

The Biological Response Modifiers Program of NCI seeks a contractor with the chemical expertise to conjugate or chemically couple several cytotoxic agents to monoclonal antibodies directed against antigens found on human tumor cells. Examples of cytotoxic agents include the whole toxins ricin and abrin or their A chain subunits, gelonin, pokeweed antiviral protein and diphtheria toxin A chain or fragments or drugs such as chlorambucil, methotrexate, daunomycin, and alpha amanitin, or radioisotopes (alpha and beta as well as gamma emitters). The choice of monoclonal antibodies and cytotoxic agents to be coupled will be made by the NCI project officer or can be proposed by the respondent.

The principal investigator should possess an MD or PhD with extensive experience (a minimum of five years) in immunology, immunochemistry or biochemistry and devote a minimum of 25 per cent of his/her time annually. In addition, he/she should have recent experience in (a) development of methodology related to chemical coupling of a variety of drugs, toxins and radioisotopes to immunoglobulins; (b) experimental immunology including radioimmune assays and in vitro assays to measure antibody activity; and (c) protein purification.

In addition to the PI, an immunologist/immunochemist at the doctoral level should be assigned for a majority of the time to the project and must have recent experience in chemical coupling reactions, cellular immunology, and immunoassays. The qualifications of the support team should have expertise in chemical coupling, in vitro assays, protein purification, radiolabeling of proteins, in vivo animal studies and pharmacokinetics. The level of effort for this project is estimated at 5.5 person years annually.
Contract Specialist: Jeaneen Monk
RCB Blair Bldg Rm 212
301-427-8767

NCI CONTRACT AWARDS

TITLE: Followup study of patients treated for hyperthyroidism
CONTRACTORS: Harvard Univ., $422,080, and Memorial Hospital, New York, $463,080.

TITLE: Investigations of cervical cancer in Latin America
CONTRACTOR: Gorgas Memorial Institute of Tropical and Preventive Medicine, Washington, D.C., $1,102,869.

TITLE: Mortality study of workers exposed to acrylonitrile
CONTRACTOR: Small Business Administration, $1,300,241.

The Cancer Letter _Editor Jerry D. Boyd
Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.