

THE

CANCER

RESEARCH
EDUCATION
CONTROL

LETTER

P.O. BOX 2370 RESTON, VIRGINIA TELEPHONE 703-620-4646

Vol. 3 No. 44

Nov. 4, 1977

Subscription \$100 per year

NEW TREATMENT PROJECTS GET GO-AHEAD; GROUPS COMPETITION TO BE INCREASED, VA STUDIES FACE CUT

NCI's Div. of Cancer Treatment revealed last week to the division's Board of Scientific Counselors how the staff determined it wants to spend DCT's 1978 fiscal year money. The Board concurred for the most part, letting stand some major cuts for some programs and approving \$1.5 million in new projects.

The Board also went along with a policy that will increase the competitiveness of Cooperative Group grants, and approved a proposal to phase out DCT's support of two Veterans Administration clinical research programs unless they conform to NCI review requirements.

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In Brief

NEWELL DENIES REPORT HE'S LEAVING FOR JOB ON WEST COAST, SAYS HE IS A "FREE AGENT"

GUY NEWELL, who has been deputy director of NCI since 1972 except for nine months during the past year when he was acting director, denied rumors that he will leave NCI for a job on the West Coast. "I have received no offer better than the job I have. I consider myself a free agent," he said. . . . **JOINT IRAN-International Agency for Cancer Research Study Group** has concluded that the exceptionally high risk for esophageal cancer in northeast Iran probably arises from the severely limited and irritant nature of the diet, along with exposure to a carcinogenic agent derived either from opium tars or wheat contaminants. The report appears in the October *Journal of NCI*. . . . **ASSOCIATIONS OF CANCER** site and type with occupation and industry were studied in data from the Third National Cancer Survey and reported in the same issue. Roger Williams, Univ. of Utah; Nancy Stegens, NCI; and John Goldsmith, California State Dept. of Public Health, came up with these findings: Lung cancer patients were found more often than expected among several categories, including trucking, air transportation, wholesaling, painting, building construction, building maintenance, and manufacturing (furniture, transportation equipment and food products). Controlling for cigarette smoking did not change these associations. Leukemia and multiple myeloma were associated with sales personnel of both sexes; lymphomas and Hodgkin's disease were excessive among women in the medical industry. Other associations—rectal cancer and retail industries; prostate cancer with ministers, farmers, plumbers, and coal miners; malignant melanoma with school teachers; invasive cervical cancer with women working in hotels and restaurants; breast cancer with teachers and other professionals even after controlling for education. The authors pointed out weaknesses in the survey, said some "spurious associations" might be expected, and suggested their findings should be used only as a research resource to follow up leads.

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DCT MAKES MAJOR CUTS IN NUTRITION, PANCREATIC RESEARCH; CREGS GO UP

(Continued from page 1)

DCT will get \$132.9 million in fiscal 1978, when and if Congress gets around to breaking the deadlock on the abortion issue and passes the appropriation bill. This is \$5.6 million more than the division received in FY 1977.

Of that increase, \$500,000 is a transfer from the Div. of Cancer Biology & Diagnosis for treatment contracts awarded and funded through the Breast Cancer Task Force. DCBD has administered the task force in the past and will continue to do so, except for the treatment contracts. DCT will issue any new treatment RFPs the task force generates in the future, and will conduct the review of proposals and awarding of contracts.

Other features of the 1978 budget include major reductions in nutrition and pancreatic carcinoma research; a cut of about \$3 million in drug development; and a reallocation from contracts of \$1.2 million to Cancer Research Emphasis Grants.

DCT Director Vincent DeVita explained some of the background for the budget changes in a statement sent to Board members before the meeting:

"In 1974, we opted to expand the capacity of the Cooperative Groups to allow more combined modality work. We elected to utilize some funds from the Drug Development Program. We did this by forward funding and readjusting the workload of some of the screening contracts. At that point in my young career, the exact site for any future reduction of effort in the Drug Development Program was not clear. The redistribution of the workload allowed us time to review and reorganize the program prior to reducing the funding. This year, if we had received greater amounts of additional monies, the magnitude of the cuts in the Drug Development Program might have been minimized. With a limited budget, we asked Dr. (Vincent) Oliverio (director of the Developmental Therapeutics Program which includes drug development) to absorb the entire redistribution of the workload in the 1978 budget for developmental therapeutics, and he has responded well, with minimal impact on a very busy and important program.

"The Baltimore Cancer Research Center has been reorganized and until such time as a decision has been made about the final organization, the budget has been held flat with one exception—funding to the PROMIS system. This system was reviewed and approved by the Board two meetings ago at the \$900,000 level. We held it up for budgeting reasons, and now our staff has approved it at the \$350,000 level for FY 1978.

"The Clinical Oncology Program was reorganized a year ago (this is DCT's intramural clinical program). It incurred heavy equipment costs at the time of the reorganization, and as a result does not require many

dollars for equipment in the coming year. It will operate on essentially a flat budget, with one exception. With the building of a new radiotherapy unit and the acquisition of a new radiotherapy branch chief, we need a new linear accelerator and have allocated funds for this.

"Cancer Therapy Evaluation Program. As you know from previous meetings, we tried as much as possible to divert dollars from the preclinical Drug Development Program into the clinical trials area to take advantage of some of the therapeutic opportunities presented to us. From 1975 until the present time, we increased the Cooperative Group Program by some \$8 million, as well as clinical trials supported under contract. A peculiarity of the Cooperative Group Program in the past has been that all approved new and re-competing renewal grants have been funded. Thus no attention was paid to priority scores given each grantee, and little attention was paid to giving these priority scores by the study section involved (CCIRC).

"A year ago," DeVita's statement continued, "I asked for CCIRC members to begin to use priority scores to rate the quality of researchers within each Clinical Cooperative Group, so funding decisions could be based on priority of work within each group. We feel, with the current shortage of funds, and the increases to the groups in the last few years, we should begin to use the priority score to assure these dollars flow to the highest priority researchers. Thus this year it is our proposal that a priority score should be set below which approved group grants will not be funded. Also, competing renewals and new grant applications will receive priority for funding on an equal basis. In the past, competing renewals received priority if there was any distinction made between the two. This will have the effect of allowing new investigators to compete equally with old investigators.

"Funding for the Cooperative Groups in the early part of the year is based on our predictions of the rate and level of approval by review bodies before it actually happens. Two major Cooperative Groups have been reviewed, or are coming up for review this year—the Southwest Oncology Group and the Eastern Oncology Group (SWOG has already been reviewed). We anticipate the review bodies will recommend as much as a 30-40% increase in funding based on the limited experience we already have. Obviously, with the division receiving a total increase of 4½%, it will be difficult to follow this advice. Using the priority scores in conjunction with a cost of living increase, we feel we can fund the majority of good competing renewals and new grant applications. We feel this is a fair approach for the coming year, but recognize there may be some disagreement.

"As a result of the Board review of the lung program two years ago, we re-competed the entire Working Party for Lung Cancer and a new set of contracts

is now operational. The old Working Party has been disbanded. The Board comments about the VA Lung Group during that review led us to make further reductions in the VA Lung Group this year as well."

APPROVED NEW PROJECTS

The Board approved the staff's suggestions for funding nine new projects this year, totaling \$1.467 million in estimated cost. The projects are:

- Synthesis of radiosensitizing agents. Estimated FY 1978 cost, \$185,000.
- Maintenance of frozen bank of human tumor cells, \$30,000.
- Fermentation and/or tissue culture of plant and animal cells, \$100,000.
- Hormone receptors in endometrial carcinoma, \$400,000.
- Norton-Simon model for predicting tumor response, development and application, \$60,000.
- Clinical trial for treatment of spontaneous canine neoplasms using hyperthermia, \$62,000.
- Pharmacology and clinical trials—Chester Beatty Research Institute, \$30,000.
- Computerized problem-oriented medical information system (PROMIS), hardware only, \$350,000.
- Treatment of pediatric brain tumors, \$250,000.

Most, and perhaps all, of the above new projects will be funded through contracts, some of them sole source.

Additionally, two contracts will be recompleted—post-surgical adjuvant therapy for osteogenic sarcoma, supplement to phase II-III contract with the Mayo Foundation, \$180,000; and drug distribution and protocol monitoring system, Value Engineering Co., \$125,000.

Previously approved new projects which will be funded with FY 1978 money were adjuvant chemotherapy trials in head and neck squamous cell carcinoma, \$1 million; registry of radiation therapy complications, \$148,000; and clinical trials monitoring services, \$500,000.

DCT was at first reluctant to reveal the cost estimates. Release of such information prior to submission of contract proposals or grant applications in the past has sometimes tended to distort the proposals, some staff members feel. DeVita announced the figures, however, after Board members indicated they needed the information to determine the scope of each project.

Prospective proposers and grantees should keep in mind that the figures are only estimates and they should not tailor their proposals to fit them.

Board member James Holland is chairman of a cooperative group and has argued for more support for the groups at previous Board meetings. He continued along that line, asking DeVita for justification for the Mayo osteogenic sarcoma contract "in view of the level funds for cooperative groups" which are involved in clinical studies of that disease.

"This is the only group willing to test the concept

that we aren't making as much progress as we thought," DeVita answered. The Mayo study is designed to randomize 60 patients a year, half receiving high dose methotrexate following surgery and half receiving no further treatment unless they recur. Any who do recur will be treated aggressively with methotrexate or methotrexate plus adriamycin.

"Randomizing is hard to get through institutional review," noted Joseph Burchenal, chairman of the Clinical Trials Committee, one of DCT's contract technical review committees.

"But \$180,000 for that is incredible, considering the size of the study," Holland said.

"It's a little amount of money to ask the question, what is contributing to advances in osteogenic sarcoma," said Franco Muggia, director of DCT's Cancer Therapy Evaluation Program. Mayo was the only institution receptive to the study, Muggia said.

"I would strongly endorse the study," said Board member Samuel Hellman. "There is a large body of people that think it (adjuvant treatment) is overstated. It is very important to have good stopping rules."

Board member Henry Kaplan agreed that "if the group at Mayo is prepared to do an objective assessment, it may be one of the few not over committed." He pointed out that the studies at Sidney Farber Cancer Institute, where some of the first adjuvant studies with the disease were conducted, are reporting 80% five year survival.

"Unfortunately, at our institution (NCI's intramural program) the data is not holding up," DeVita said.

"The study asks a lot of questions about the natural history of the disease, and the team (at Mayo) is high caliber," Muggia said.

EXISTING PROJECTS—Pancreatic Carcinoma, Nutrition Research Cut Back; Increases for Bowel, Lung Projects

Here is DCT's analysis of 12 ongoing contracts, with 1978 funding estimates:

Brain Tumor Study Group—\$1.168 million. This group consisting of 15 contracts, has been transferred from the Baltimore Cancer Research Center to the Cancer Therapy Evaluation Program. All 15 contracts will be incrementally funded in FY 1978 and the funds have been transferred from the BCRC budget.

Breast Cancer—\$974,000, up \$560,000 over FY 1977, with the increase representing the amount transferred from DCBD. Two existing contracts DCT supported with its own funds in 1977, totaling \$414,000, are scheduled to terminate in 1978. The two either will be recompleted or the money will be reprogrammed to the Cooperative Groups for breast research.

Gastric carcinoma—\$595,000, up \$39,000 over 1977. There are six contracts, and the 7% increase is the estimated cost of living increase.

Large bowel—\$1.782 million, up \$247,000 over

1977. There are 11 contracts, with incremental funding planned in FY 1978. The 16% increase appears large because of artificially low 1977 obligations. This is a result of low patient accrual during the past year, DCT said. However, in anticipation of accrual rates increasing, the funds budgeted for 1978 are above the cost of living increase.

Lung—\$1.23 million, up \$122,000 over 1977. There are seven contracts in this group which began their first year of a three year project period in 1977. The increase of 11% is to cover cost of living increments and to full fund immunologic and marker studies which were not started until late in 1977 but require a full year funding in 1978.

Nutrition—\$219,000, down \$187,000 from 1977. DCT funded six contracts in 1977 of which five were administered through the Div. of Cancer Cause & Prevention for pediatric patients. DCT intends to terminate those five contracts one year early. The remaining nutrition work will be at Goergetown Univ.

Ovarian cancer—\$817,000, up \$270,000 over 1977. This consists of six contracts which suffered from low patient accrual during 1977. This resulted in a large carryover of funds and subsequently an unusually low amount of 1977 funds were obligated. However, because indications are now that the patient accrual will increase to the levels expected in the project plans, DCT has budgeted the full amount negotiated for 1978, including the cost of living increase.

Pancreatic carcinoma—\$202,000, down \$344,000 from 1977. "The performance of the six active pancreatic contracts has been somewhat disappointing with poor patient accrual," DCT said. Because of the limited budget, DCT intends to terminate all pancreatic contracts except for the one with the Mayo Foundation. Mayo has been the most successful in accruing patients.

Phase I—\$641,000, down \$142,000 from 1977. Support for this group of seven contracts will decrease for two reasons: The project period is to terminate Sept. 31, 1978, with recompetition and new awards scheduled for Oct. 1978, with FY 1979 money, thus requiring only nine months funding. Also, DCT was unable to provide a cost of living increment for the nine month period.

Phase II/III—\$2 million, down \$799,000 from 1977. In conjunction with the phase I recompetition, DCT intends to add early phase II clinical trials to those phase I contracts (at least to those for which the contractors agree). As a result, early phase II support will be deleted from the phase II/III group of six contractors beginning Oct. 1, 1978. Because those contracts cycle on June 30 of each year, this represents a considerable savings in FY 1978 dollars. Also, DCT said, because of budgetary restrictions, it is forced to terminate the hyperalimentation study (nutrition work) under the M.D. Anderson contract

as well as allow no cost of living increase for the other contracts.

Interagency agreements—\$1.294 million, down \$176,000 from 1977. The Cancer Therapy Evaluation Program had three interagency agreements in 1977—the National Naval Medical Center, \$31,600; Walter Reed Army Medical Center, \$62,099; and Veterans Administration, \$1.376 million. DCT intends to maintain the Navy and Walter Reed agreements at roughly the same levels as last year and to reduce the VA agreement by \$176,000, with the cut coming out of the VA Lung Group.

Foreign contracts—\$256,000, down \$27,000 from 1977. There are three foreign contracts. One is a one-year protocol study which will terminate next year, accounting for the decrease.

Miscellaneous—\$650,000, an increase of \$21,000 over 1977. This includes four support contracts for various CTEP activities.

Two clinical trials support contracts will be re-competed in 1978.

Board members were concerned about the problem of obtaining sufficient numbers of patients to carry out clinical trials with certain diseases.

"Has any thought been given to finding new solutions to recruiting patients for high priority studies?" Kaplan asked. "We need to take a fresh look at the problem."

"All new studies have those problems," DeVita said. "It always takes a while to build up. Perhaps we don't say enough about it. But when NCI suggests to physicians that they refer their patients, we get a heavy mail response that says 'Keep your hands off the practice of medicine'."

"Those of us in the forefront of clinical trials just have to take the heat," commented Board member Bernard Fisher. "We have to keep pounding away despite the opposition of organized medicine."

DEVELOPMENTAL THERAPEUTICS: Contracts Down, CREGs Up, New Drug Development Cut Back

The Developmental Therapeutics Program will drop from \$48.9 million in 1977 to \$45.9 million in the current fiscal year. Most of the cuts will be made in drug development contracts: Natural products, \$4.8 million, down from \$5 million in 1977; screening, \$10.4 million, down from \$11.3 million; preparation of bulk drugs, formulated products and chemicals, \$5.4 million, down from \$5.7 million; and drug synthesis, \$2.6 million, down from \$4.2 million.

Other cuts will be made in virus and leukemia research, \$2.4 million, down from \$2.9 million; pharmacology and biochemistry, \$3.8 million, down from \$4.7 million; toxicology, \$2.7 million, down from \$3 million; and immunology, \$662,000, down from \$697,000.

The \$898,000 reduction in pharmacology and biochemistry contracts represents contracts that will either be re-competed this year or transferred to CREGs.

The drug development cutbacks came mostly out of analog development. DeVita said that pharmaceutical companies were doing enough in that area at the moment to permit NCI's reduction without damaging the program. The toxicology cuts were possible "because when you cut the flow (of new drugs) you cut other expenses," DeVita said. And the virus and leukemia cut came out of support for research conducted by Robert Gallo, chief of DCT's Laboratory of Tumor Cell Biology. "I'm very impressed with his contribution," DeVita commented.

The \$4.8 million cut in DTP contracts was partially offset by an increase of \$1.2 million in CREGs and a jump in intramural costs, mostly pay raises.

COOPERATIVE GROUPS: More Competition For The Same Amount Of Money

Money to fund grants to the Clinical Cooperative Groups will be the same as in 1977—\$27.1 million. This will include \$16.4 million for noncompeting continuations (115 applications), \$10.2 million for new and competing renewals, and \$500,000 for administrative costs and competing supplementals.

Renewal applications have been asking for 30-40% increases, as DeVita pointed out. But he said a decision has been made to limit them to a maximum of 7% increase over their 1977 funding.

With that 7% increase coming out of the same total money that was available in 1977, funds obviously will be spent before they reach everyone who was funded this year. Muggia told *The Cancer Letter* that applicants with priority scores over 250 probably will not be funded.

The \$27.1 million does not include any amounts Cooperative Groups would get if they land any DCT contracts. Six groups are competing for the head and neck cancer contracts out of 23 proposals DCT has received from that RFP.

Holland continued his effort to wangle more money for the groups, without much success. "Can't you take a sharper knife to the contracts?" he asked DeVita. "If you can cut 60% out of pancreatic cancer, you can probably cut the rest. The leads are precious few." DeVita agreed that suggestion "is not entirely bad. . . . Out of 18,000 cases, we have 18,000 deaths."

Referring to the ovarian cancer contract, Holland said, "You have the Gynecological Oncology Group (one of the Cooperative Groups). I would like to hear the reason why instead of expanding the contract, you don't say to GOG, here, take this money and take a look at it."

"GOG did take part in protocol development," DeVita said. "They said at that time they were not able to do this. George Lewis (GOG chairman) agreed that it was appropriate to do it this way."

"Is it your premise that no clinical project can be done without first offering it to the Cooperative Groups?" Hellman asked Holland.

"No," Holland said. "I'm just saying that in place of an expensive new program, we present it to the groups, that have developed this far."

"I'm answered in the affirmative," Hellman said. "I don't think we should discriminate for or against the groups. I don't think it is reasonable that everything should first be offered to the groups."

"When you have a mechanism, one with a proven record, that is starved for money, you should use it,"

"Our policy is to attack the gaps," DeVita said. "If the mechanism exists, use it. If not, go some other way. The problem comes in determining if a mechanism can do it. If we offer something to the Cooperative Groups, they always say they can do it. We don't always agree."

Holland complained that the 7% increase for competing renewals without increasing the total amount would force the groups "to eat their own innards."

DeVita told the Board that he was planning to put on a "full dress review" of all DCT supported clinical trials, including the Cooperative Groups, in the spring of 1979. He mentioned that the objective of moving the groups into DCT from the Div. of Cancer Research Resources & Centers two years ago was to coordinate contract programs with the efforts of the groups. "The review process was tightened, some groups did not pass, others are on probation, we have intergroup protocols, information is exchanged, the chairmen meet regularly, funds were increased from \$19 million to \$27 million. We need now to determine if all this is appropriate."

The review will include an updating on each disease, how it is treated, and the changes being made in treatment, DeVita said. Also, "There is a strong feeling that therapeutic researchers in centers have no mechanism for competing for funds for clinical research without their walls. Clinical research is not reviewed adequately by study sections, except for the CCIRC, and the CCIRC is overworked now just with the groups. One answer that could come out of the review might be that centers people would compete for funds as members of the groups."

Kaplan said he would be more interested in seeing evidence of "original, new ideas coming out of the groups and the centers. It would be difficult to assess, but could be valuable."

"We will try to look at progress," DeVita agreed. "But what we will be asking is, are we organized now, for the next 20-30 years, to do what we want to do?"

"An attempt should be made to pay attention to quality," said Board member Enrico Mihich. What Dr. Kaplan is saying is that we need a definition of parameter criteria by which a group or a center should be reviewed. Has enough thought been given to define parameters?"

Hellman said it would be a mistake to talk about the Cooperative Groups without including all other clinical research. DeVita said it had been the original intention to review only the Cooperative Group Pro-

gram, "but we realized we need to look at the entire package."

"I'm sitting in several of these camps," Holland said. "I think you've left out a fourth factor—cancer control. There is a great under emphasis on cancer therapy in cancer control. I think we should bring what cancer control is doing in transferring the value of therapeutic research to patients."

DeVita agreed that "there is ample evidence that excessive duplication exists in some areas. I think we've limited a lot of it. We need to make sure that mechanisms do not get in the way of therapeutic research."

"It is axiomatic that at the present time, clinical research is underfunded," Holland said. "Surgery is underfunded, radiotherapy is underfunded, even chemotherapy and immunotherapy are underfunded."

"It is axiomatic to others that clinical research is overfunded," commented Board member Charles Heidelberger.

VA GROUPS: Improve Review Or Else

DCT has two major programs in collaboration with the Veterans Administration. One is the NCI-VA Medical Oncology Branch at the VA hospital in Washington, D.C. It will cost about \$4.4 million this year, and functions almost as part of NCI's intramural program. There is no problem here with the VA-NCI relationship.

The other program functions essentially as two cooperative groups, with NCI support at \$1.2 million for FY 1978, down from \$1.37 million in 1977. One is the VA Surgical Adjuvant Group chaired by George Higgins in Washington and includes surgeons at 26 other VA hospitals. "They have been a major resource for adjuvant chemotherapy and radiotherapy trials in colorectal and lung cancer and occasionally other GI malignancies," DCT said in a statement describing the program.

The other group is the VA Lung Group, chaired by Julius Wolf, with 20 hospitals participating. Studies have concentrated on advanced lung cancer both by chemotherapy and radiotherapy. Staging and statistics from these studies have formed the basis for many subsequent group studies. Ancillary research on pathologic classification by Raymond Yesner and on ectopic hormones by recent Nobel Prize winner Rosalyn Yalow have been ongoing efforts.

The problem is not with the performance of the two groups—"We're getting a lot for our money," Muggia said—but with the review, or lack of it. NCI support is accomplished by an interagency transfer, not with grants as other cooperative groups are funded, so the CCIRC has no opportunity to review.

"We have very little understanding of how the money is spent," DeVita said.

"We ought to cut it off entirely," said Board member Harris Busch, "until the review is as thorough as

it is for other work we support."

"This is a high year of achievement for VA employees," Holland said. "They happen to do good work."

Higgins later told *The Cancer Letter*, "If there's ever been any problem about review, it is news to me. Anytime DCT wished to review, we've been reviewed, usually by a special group."

He said that Thomas Newcomb, who recently assumed the job of coordinating VA activities with NCI and is a member of the National Cancer Advisory Board, is attempting to set up a review panel. "The information I had was that the group would be partly NCI, partly VA people, and some from the outside," Higgins said. "There may have been some high level sparring around in the past. But there is no reluctance on our part to submit to review."

ACCC ANNUAL MEETING TO FEATURE ONCOLOGY UNIT AND ITS COMPONENTS

The Assn. of Community Cancer Centers has scheduled its fourth annual meeting for Jan. 27-29 at the Twin Bridges Marriott Hotel in Washington.

The meeting will focus on the oncology unit and its components, with emphasis given to:

- Development of the Oncology unit.
- Administrative planning and staffing.
- Patient/family/staff education.
- Psychosocial considerations for staff and patients.

—Hospice and continuing care.

—Research and the oncology unit.

The Jan. 28 luncheon keynote speaker will be NCI Director Arthur Upton.

The meeting is open to physicians, hospital administrators, nurses, rehabilitation specialists, and others interested in community cancer programs. Advance registration is recommended. Registration fees are \$100 to ACCC members and \$150 for non-members.

Further information may be obtained by writing ACCC 1978 Conference, 6000 Executive Blvd., Suite 508, Rockville, Md. 20852.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses, all followed by NIH, Bethesda, Md. 20014, are:

Biology & Diagnosis Section — Landow Building

Viral Oncology & Field Studies Section — Landow Building

Control & Rehabilitation Section — Blair Building

Carcinogenesis Section — Blair Building

Treatment Section — Blair Building

Office of the Director Section — Blair Building

Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NO1-CP-85600-56**Title:** *Synthesis of chemical carcinogens***Deadline:** *Dec. 30*

The Carcinogenesis Program has assumed the responsibility of providing well-characterized reference compounds to carcinogenesis researchers. This project has two functions. One is to provide compounds that are unavailable from commercial sources and the other is to provide well characterized chemicals to researchers, in order to eliminate variability in experimental results due to the use of unanalyzed chemicals from a variety of sources.

An important benefit from this program has been the assurance of safe preparation and distribution from carefully monitored facilities. All facilities devoted to this project must comply with the OSHA regulations for handling carcinogenic materials.

It is estimated that approximately 20-30 labeled or non-labeled chemicals will be prepared per year and that the procedures will vary in complexity: some of the compounds may be commercially available and therefore would only need purification and analysis. Most of the compounds will be representatives of the various classes of carcinogens such as N-nitroso compounds, amino azo dyes, aromatic amines, alkylating agents, poly nuclear compounds and miscellaneous substances.

The quantities will depend upon the availability of raw materials and difficulty of preparation and will range from one gram to one kilogram. Analytical support facilities are required for performing complete chemical characterization studies on each compound. Each compound is to be characterized by elemental analysis, melting or boiling point, UV, IR, NMR, TLC and/or SPLC and GC/MS when needed.

It is anticipated that a two year contract will be awarded. During the course of NCI's collaborative research program, specific tasks will be identified for performance under this requirement.

Contract Specialist: M. Hamilton
Carcinogenesis
301-427-7574

RFP NCI-CM-87185**Title:** *Pharmacologic studies of antitumor agents***Deadline:** *Approximately Jan. 3*

The Developmental Therapeutics Program, Div. of Cancer Treatment, is seeking a contractor to establish and operate a research unit for studies on pharmacology and physiological disposition of new antitumor agents in the BDF₁ mouse, Sprague-Dawley rats, Rhesus monkeys and beagles or foxhound dogs.

Such animal studies shall be coordinated and integrated with ongoing phase I and II clinical trials within the same or a closely affiliated institution. Two to four new antitumor agents will be studied per year requiring approximately 10 technical man-

years per year. The objective of this project is the generation of pharmacological information of immediate practical usefulness to the physician conducting phase I and II studies with new antitumor agents.

It is anticipated that one award will be made for a three year period.

Contracting Officer: S.R. Gane
Cancer Treatment
301-427-8125

RFP NCI-CM-87178-22**Title:** *Statistical support for a Cooperative Group engaged in intensive studies and investigations on patients with gastrointestinal carcinomas***Deadline:** *Dec. 15*

This notice supercedes that appearing in *The Cancer Letter* Sept. 23, under the title "Statistical Support for Cooperative Groups Engaged in Intensive Studies and Investigations on Cancer Patients."

Provide statistical support and analysis for a cooperative group (11 institutions) accruing approximately 700 patients annually. Interested sources should have available to direct and perform the work a senior biostatistician and trained computer personnel who are experienced in (a) sophisticated study designs for multidisciplinary therapeutic treatment programs on patients with gastrointestinal carcinomas, (b) setting-up effective multifaceted computerized programs for clinical data retrieval and interim and final evaluation of such data, (c) participating in the writing of protocols and publications and (d) dealing effectively with physicians participating in group research studies.

Contracting Officer: J. Thiessen
Cancer Treatment
301-427-8125

SOURCES SOUGHT**RFP NCI-CM-87191****Title:** *Studies concerning the role of hormone receptors in endometrial carcinoma***Deadline:** *Nov. 30*

Only one source is known which can perform the above. That source is the Gynecologic Oncology Group. Specifically, the work required involves the correlation of hormone receptors and the response of the same patients to hormone manipulation. The source must be able to accrue 180 patients per year and be able to demonstrate such a capability over the previous three year period. Any subcontractor must be able to accrue not less than 30 patients per year and demonstrate such a capability over the previous three year period.

Patients must not have had prior therapy with any progestational agent and at least 30% of the patients must have either advanced primary or recurrent disease such that they are qualified for entry onto a

therapeutic regimen to determine the usefulness of the receptor assay in the therapy of this disease.

The work requires access to early stage endometrial carcinoma which dictates the involvement of gynecologists. Also, the source must have the necessary personnel and facilities for the performance of hormone assays. If any organization feels that it has the demonstrated technical capabilities and patient accrual required for the aforementioned work, the submission of complete, concise resumes is invited. Such resumes must clearly demonstrate the respondent's ability to accrue the required patients and capabilities of proposed professional employees and the ability of assignment of these employees to this project. Any responding organization must clearly identify the proposed gynecologists and steroid biochemists giving complete details of their training and experience.

Information submitted must be pertinent and specific in the technical area under consideration. Unnecessarily elaborate brochures are neither required nor desired. This synopsis is not a request for proposals nor does it obligate the government in any manner. Resumes must be submitted in 25 copies.

Contracting Officer: J. Thiessen
Cancer Treatment
301-427-8125

RFP CANCELLED

Title: *Establishment of rodent quality control and diagnostic laboratory*

This procurement, RFP NO1 CM-87179, has been cancelled. Due to a redirection of needs the requirements will be readvertised as two separate procurements, NCI said.

RFP NIH-NIAID-OSRF-78-4

Title: *Recombinant DNA testing laboratory*
Deadline: *Feb. 1*

Establish a laboratory for testing the characteristics of vector-host systems in sewage and during sewage treatment. The contractor will be required to develop procedures for monitoring E. coli and its plasmid and bacteriophage cloning vectors and to test six to eight vector-host systems per year that have been constructed by other laboratories.

The basic objectives of the contract are to:

- 1.) Determine the survival and multiplication of the host and vector components of selected EK1 systems in commonly used sewage treatment processes to obtain baseline information and reference points for new and potentially safer EK2 systems.
- 2.) Determine the survival of the host and vector

components of a variety of EK2 systems in commonly used sewage treatment processes in order to assess whether they meet the criteria specified in the NIH guidelines for EK3 status. 3.) Determine the capacity of vectors from the EK1 and EK2 systems to be transmitted to secondary bacterial hosts. It is unlikely that a single laboratory will be staffed by individuals with the appropriate experience to conduct this work. Therefore, the submission of a proposal based on collaboration between laboratories with experience in sewage treatment, sewage microbiology and microbial genetics is permissible.

Contract Management Branch
National Institute of Allergy and Infectious Diseases

NIH
Westwood Bldg Room 707
Bethesda, Md. 20014

CONTRACT AWARDS

Title: Screening, abstracting, and indexing of cancer-related literature for input to the ICRDB program data base, modification.

Contractor: Franklin Institute, \$60,628.

Title: Support activities of the U.S.A. National Committee for the International Union Against Cancer (UICC), modification

Contractor: National Academy of Sciences, \$464,340.

Title: Preparation of bulk chemicals and drugs, three-year incrementally funded

Contractors: Aldrich Chemical Co., Milwaukee, \$952,630; Pharm-Eco Laboratories Inc., Simi Valley, Calif., \$844,093; Warner-Lambert/-Parke-Davis, \$1,140,753; and Starks Associates Inc., Buffalo, \$1,407,588.

Title: Prototype comprehensive network demonstration project in head and neck cancer, renewal

Contractor: Illinois Cancer Council, \$677,529.

SOLE SOURCE NEGOTIATIONS

Proposals are listed here for information purposes only. RFPs are not available.

Title: Breast Cancer Detection Demonstration Project, continuation

Contractors: Duke Univ., College of Medicine and Dentistry of New Jersey, and St. Joseph Hospital.

Title: Demonstration of cancer rehabilitation facilities and/or departments, renewal

Contractor: Emanuel Hospital, Portland, Ore.

—Editor JERRY D. BOYD

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