THE CANCER NEWSLETTER

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COMMUNITY CANCER CENTER GROUP FORMED TO DEAL WITH "TOAD-LIKE PACE OF NCI," OTHER PROBLEMS

The "toad-like pace of NCI in accomplishing any given thing" has prompted several small cancer centers to organize "The Association of Community Cancer Centers," headed by James F. Donovan of the Kern Radiation Oncology Center in Bakersfield, Calif.

The organization came out of a meeting in Denver of physicians and planners to discuss problems they are encountering in the development of cancer care programs at the community level. All "voiced remarkably similar frustrations giving every indication that commonalty of purpose could and should be achieved," according to the news release announcing the association's existence.

Donovan told *The Cancer Newsletter* about the frustrations:

"First, there's the toad-like pace of NCI in accomplishing any given thing. We're practicing community physicians, trying to organize the multidisciplinary approach we need to get the best care possible to cancer patients. We're not grantsmen, we can't take our time and

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In Brief

NO INTENTION OF CUTTING BACK ON CANCER, HEART RESEARCH, WEINBERGER SPOKESMAN INSISTS

WEINBERGER'S OFFICE denies the HEW secretary has any intention of trying to "scale down" cancer and heart research, as intimated in a *Wall Street Journal* item last week. The Journal said Weinberger is pushing for appointment of a Presidential panel to reassess the federal role in biomedical research. Among the results, the Journal said, is "scaling down special heart and cancer projects; switching more work to the private sector. Nixon may buy the idea despite researchers' misgivings." The report came out of a luncheon meeting Weinberger had with reporters, one of whom was WSJ's Jonathan Spivak. Weinberger mentioned that he had replied to a letter from OMB Director Roy Ash asking cabinet heads for their suggestions for future projects. The panel to take a look at research was one of the suggestions, Weinberger said. But a spokesman for the secretary denied that the suggestions included any thought of cutting back on cancer and heart research. "That was purely Spivak's own conjecture, or perhaps he came up with it from somewhere else." Neither Weinberger nor Nixon need at this time the kind of flak that would be generated by attempts to reduce two of the programs most in favor with Congress and the public, the spokesman agreed . . . . **CANCER BILL** conference to work out differences between Senate and House versions was scheduled for Wednesday, June 5, after *The Cancer Newsletter* went to press. Conferees are Sens. Kennedy, Williams, Nelson, Eagleton, Cranston, Hughes, Pell, Mondale, Hathaway, Schweiker, Javits, Dominick, Beall, Taft and Stafford; Reps. Staggers, Rogers, Satterfield, Kyros, Preyer, Symington, Roy, Devine, Nelsen, Carter, Hastings, Heinz and Hudnut . . . .

NEW COMMUNITY CENTER GROUP TO TACKLE COMMUNICATIONS, OTHER PROBLEMS

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money to prepare grant applications and to do everything else required in dealing with NCI.

"The other major frustration is encountered in our own communities, and that is getting our colleagues to recognize and put into practice the latest and best expertise in cancer care.

"We were all of one mind about these problems. It's the first time I've ever seen 20 physicians agree on anything."

The group concluded that an organization composed of community level institutional members could:

– Investigate requirements for development of multidisciplinary programs at the community level.

– Develop guidelines and assist community groups in their efforts to establish cancer programs which complement NCI cancer control efforts and comprehensive center outreach programs.

– Provide a communications link for dissemination of information between community cancer centers.

– Act as a focal point for cooperative clinical efforts.

Donovan said he envisions the organization as a clearinghouse for information and to provide consulting services to members. Exactly how these services will be delivered has yet to be worked out. The association bylaws are still in the process of being developed, and will be presented to the group at another meeting, probably in September.

Both Cancer Control and the Div. of Research Resources & Centers have been interested in the community centers. DRR&C executives have commented favorably on the arrangement worked out between the Fred Hutchinson comprehensive cancer center in Seattle and the Mountain States Tumor Institute in Boise. They see this as a prototype for implementation of the outreach programs required of comprehensive centers as well as a logical means to carry out cancer control demonstration projects.

Most of the community centers are involved in clinical research, through the clinical cooperative groups, through use of investigational new drugs, with a few even doing some basic research. It is not, however, the kind of sophisticated research supported by the centers program; therefore, the best chance for funding of community centers will be through the Cancer Control Program.

Donovan claims that the NCI mandate to comprehensive centers on cooperating with and assisting community centers is not being carried out. He has established a working relationship with the USC center in Los Angeles. "How this special arrangement will work is not clear. It certainly has not moved ahead vigorously."

Donovan said he knew of only two examples so far of successful comprehensive center-community center relationships -- Mountain States-Hutchinson and the El Paso Cancer Center arrangement with M. D. Anderson.

"We need the supportive services the comprehensive services can give us," Donovan said. "Educational and consultive backup, exchange of personnel, cancer biology -- the sophisticated expertise we don't have on the community level. Fifteen or even 30 university-based comprehensive centers are not going to deliver the patient care that the cancer program requires. The community centers are the key to an efficient and effective cancer control mechanism."

Donovan is president of the association. James K. Luce of the Mountain States Tumor Institute is vice president, and Simeon Cantril of the West Coast Cancer Foundation in San Francisco is secretary-treasurer.

HUMAN SUBJECT RULES NOW HAVE FORCE OF LAW; MOST ALREADY CONFORMING

New regulations adopted by HEW last week dealing with the protection of human subjects probably will not affect most NIH grantees and contractors.

The regulations, published in the May 30 *Federal Register*, for the most part merely write into law policies HEW had been requiring of institutions and investigators who conduct research involving human subjects.

The fact that the rules now have the force of law should not be taken lightly: This gives HEW considerably more clout in enforcing them. Institutions and principal investigators can now be taken to court over failure to comply. There are no criminal penalties, but HEW is in a stronger position to terminate grants and contracts or to withhold awarding grants and contracts explicitly on the basis of not meeting the human subject requirements.

"This takes a policy and converts it to law." said Donald Chalkley, NIH institutional relations branch chief. "It is subject to interpretation by the courts; NIH is accountable to the courts; and institutions and principal investigators are accountable to the courts."

Three provisions that have not been requirements will affect those institutions which have not already adopted them:

– The initial review of contract and grant applications must be completed by the institution prior to submission to NIH. Chalkley said about half of the institutions already follow this policy, with the rest delaying their review until just before the NIH review begins. The new policy insures that nothing

will reach the NIH review stage until it has institutional approval.

– Adverse drug reactions must be reported immediately to HEW. The requirement has been only that they be reported to the sponsor.

– Institutional review committees must include outside members not associated with the institution. Most NIH grantees and contractors already comply. This provision also specifies that review groups not consist entirely of members of one profession. "Surprisingly, this is not aimed at medical review bodies but at the psychology and sociology groups," Chalkley said. Most medical groups have been careful about bringing in other disciplines.

The regulations make it a matter of law that NIH review boards, such as the National Cancer Advisory Board, may disapprove applications on grounds other than scientific merit, specifically, lack of concern for human subjects.

Contract Awards

SOUTHERN SCREENING CONTRACT NOW AT $2 MIL. YEAR FOR FIVE YEARS

Some of NCI's bigger contracts were renewed last week with the biggest so far -- behind Litton Bionetics Frederick contract and Tracor Jitco's bioassay prime contract – going to Southern Research Institute.

Southern has been working on a contract for primary and secondary screening and methodology, at a level exceeding $1 million a year. NCI decided the renewal would consist of a five-year commitment and put it out for competition. Southern's proposal was accepted over four others.

Southern will receive $11 million over the five years. Although the $2 million plus per year represents an increase over the existing contract, NCI said most of the additional amount is accounted for by inflation – there is no increase in the total number of man years.

Two other million dollar contracts were awarded: To Stanford Research Institute for analysis of chemicals and pharmaceutical formulations, a continuation, for $1,351,551; and to Litton Bionetics, for new prognostic and therapeutic modalities, a continuation, for $1,374,120.

Mayo Foundation received a contract for $247,070 to study the incidence and natural history of genital tract anomalies and cancer in offspring exposed in utero to synthetic estrogens.

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. Some listings will show the phone number of the Contract Specialist, who will respond to questions about the RFP. Contract Sections for the Cause & Prevention and Biology and Diagnosis Divisions are located at: NCI, Landow Bldg. NIH, Bethesda, Md. 20014; for the Treatment and Control Divisions at NCI, Blair Bldg., 8300 Colesville Rd., Silver Spring, Md. 20910. All requests for copies of RFPs should cite the RFP number. The deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CM-53752-18

Title: *Therapy of patients with brain tumors*
Deadline: *July 8, 1974*

(A brief summary of this RFP appeared in the May 24 issue of *The Cancer Newsletter*)

The Baltimore Cancer Research Center, Div. of Cancer Treatment desires to expand its studies of intensive multidisciplinary therapy of patients with malignant gliomas and other types of intracranial tumors, and to determine the efficacy of a number of therapeutic approaches. Possible intrarelationships to morphologic type, extent and clinical stage of the disease, changes in roentgenographic findings, alterations in nuclear imaging, and pharmacotoxicology of selected agents in certain cases, may be explored within the framework of these therapeutic investigations.

Each contractor must demonstrate a high level of cooperation between the neurosurgical service and the neuropathology and radiation therapy departments of his institution. Additionally, an effective working relationship between the afore-mentioned groups and the neurology, oncology, hematology and clinical chemistry departments of that institution should exist. Since more than one institution is expected to be selected for these studies, each institution must be willing to cooperate with the project officer and staff of NCI, other contractors, and the members of the Brain Tumor Study Group (BTSG) participating in these trials and the development of the protocols for such investigations. A minimum total of 35 newly operated on and evaluable patients, having a microscopically confirmed diagnosis of malignant glioma shall be required each year.

The primary objectives of these studies are to:

– (1) Determine the efficacy of various modes of therapy in prospective, controlled clinical trials by randomizing patients with intracranial tumors to selected treatments in both Phase II and Phase III type studies;

– (2) Assess the toxicity related to such modes of therapy.

– (3) A third objective, which will not be pursued in all contracts awarded, will be to conduct ancillary clinically relevant and related research to develop and

determine the accuracy of evaluating, staging and following patients with brain tumors, develop techniques for the prediction of tumor recurrence, and develop and evaluate brain tumor model systems to be used in the testing of combined modality therapy.

Specifically, the contractor shall assure that patients randomized to the various modes of therapy will:

– (a) Receive appropriate diagnostic, surgical and pathologic evaluation;

– (b) Receive designated clinical and laboratory tests as required in each protocol study to provide baseline information. These will include such evaluations as CBC, platelet count, clinical chemistries, studies of hepatic and renal function, and other special or newly devised tests as indicated;

– (c) Receive follow-up CBC, blood chemistry determinations and other appropriate tests at the intervals specified in the protocol;

– (d) Be treated with one of the following modes of therapy, 3 to 4 weeks following surgery, according to the Phase III protocol of the study currently in progress.

1. BCNU (80 mg/m2/d on 3 successive days every 6 - 8 wks) and megavoltage therapy (6,000 rads over 6 wks)
2. Methyl CCNU (200 mg/m2 orally once every 6 - 8 wks) and X-ray therapy (6,000 rads megavoltage over 6 wks)
3. Methyl CCNU (220 mg/m2 orally once every 6 - 8 wks)
4. X-ray therapy (6,000 rads megavoltage therapy over 6 wks)

The contractor shall perform special studies into measurements of tumor biology, marker systems, roentgenologic and radionucleotide imaging, neuropharmacological evaluations and biochemistry of tumor samples. These studies may be performed for the entire BTSG.

Offerors are advised that all relevant ancillary studies shall be given consideration. It is recognized that the studies proposed may vary from fully developed and verified routines which are currently being used, to unproven studies that may require full BTSG support in order to provide the input necessary to validate the concept.

Contract Specialist: Michael M. Del-Colle
301-427-7466
Cancer Treatment

RFP N01-CP-55613-68

Title: *Transplacental carcinogenesis in Erythrocebus patas*

Deadline: *July 8, 1974*

(A brief summary of this RFP appeared in the May 24 issue of *The Cancer Newsletter*)

NCI is interested in establishing a contract for a research project involving the Old World monkey Erythrocebus patas. A breeding facility for these animals will be established and a chemical carcinogen to be furnished by the NCI will be administered to pregnant animals at specifically defined times during gestation in order to observe the effect upon the offspring exposed to this chemical agent during fetal life. Non-pregnant animals will also receive the compound.

Animals will be mated, pregnancy diagnosed, and pregnant and specified non-pregnant monkeys injected intravenously with the carcinogen 1-ethyl-1-nitrosourea (ENU, furnished in injectable form by the project officer) in accordance with specified protocols for each individual animal. These protocols will be developed jointly by the project officer and the project director.

Blood or other tissue samples will be obtained by the contractor as required by the protocol agreed upon. Animals will be furnished to other research laboratories at the request of the project officer. All dead animals will be refrigerated at 4 degrees C immediately after death and prior to necropsy. All histopathology required for these studies will be performed by the government.

Specifically, the contractor shall provide housing and care for approximately 120 adult and juvenile E. patas monkeys:

– Twenty-four animals in individual cages held in a separate room (quarantine) for 3 months.

– Another room should be available to hold 10 double isolation chambers (NIH Drawing 6010) in which 20 animals on test can be housed.

– Two additional rooms should be furnished to hold the remaining 60 - 75 animals in individual (double stacked) open cages.

– A surgical and prep-treatment suite consisting of two rooms at least 12 ft. x 12 ft. will be furnished. Necessary bench space and cabinets in this area will be furnished by the contractor. The government will furnish an operating table and surgical explosion proof light.

– The total space requirements will be contained in the same building, preferably in contiguous areas.

– The facility should be equipped with emergency power in event of electrical failure. Air handling equipment in animal rooms and surgical and prep-treatment suite lighting should be connected to this emergency power source.

– Facilities should have an automatic cage washer that operates on 180 degrees wash cycle.

– The availability of space for possible eventual expansion of the primate population to a maximum of 200 adult and juvenile animals.

All caging will be furnished by the government. All cage repair will be done by governmental personnel at NIH at government expense. Cage transfer to and from the contract facility for repair will be by con-

tractor, and these costs should be included in the proposal. Cages to be furnished are in good operating condition.

The government will furnish approximately 45 adult conditioned E. patas monkeys as a nucleus for this colony. Upon initiation of the contract, these will be picked up in Rockville, Md., at contractor expense. Contractor will purchase additional 15 adult male and 60 adult female monkeys and quarantine them for 3 months prior to introduction into the colony. These newly purchased animals must be negative by immuno-preciptin test to Simian Hemorrhagic Fever antigen. Details of this test will be furnished by NCI.

All animals will be observed daily seven days per week for signs of ill health by qualified personnel. Individual records will be maintained for each animal regarding its health status, any treatments, and the results of periodic weighing. Monthly tuberculosis tests will be done on each newly acquired animal for 6 months thereafter.

All equipment rooms and personnel (technicians and animal caretakers) utilized on this contract will be restricted to work on this project to prevent cross-contamination with other projects the contractor may have in progress. A professional veterinarian who will serve as project director will need to inspect animals. Since this individual will devote only part of his time to this activity, the proposal should specifically speak to the issue of preventing cross-contamination with other projects with which the project director may be associated.

The contractor will comply with public law 89-544, Title 9, Chapter 1, Laboratory Animal Welfare of the code of Federal Regulations and Specifications of the Contract.

Contract Specialist: S. W. Ranta
301-496-1781
Cause & Prevention

RFP N01-CM-53771

Title: *Cancer Therapy Abstracts*
Deadline: *July 15, 1974*

NCI is interested in organizations qualified to prepare the Cancer Therapy Abstracts, Volumes 16 and 17, covering pertinent literature appearing from Dec. 1, 1974, through Nov. 30, 1976.

Each volume will consist of 12 monthly issues and shall contain approx. the following: (a) 4,700 concise and informative abstracts (b) 650 brief annotations (c) 650 citations (d) Subject and author indexes to be contained in each monthly issue. The final cumulative index for each volume shall be provided in the last monthly issue. This will be a fixed price contract.

Contract Specialist: Dan Longen
301-427-7460
Cancer Treatment

RFP NCI-53778

Title: *Operation of an animal disease diagnostic laboratory*
Deadline: *July 3, 1974*

The scope of effort will consist of a major service phase. This phase will be concerned with the operation of a salmonella spp. and pseudomonas spp. diagnostic effort for monitoring all rodent strains, stocks, and species maintained by the Div. of Cancer Treatment animal resources. It is estimated that these diagnostic services will require processing 8,000-10,000 fecal specimens per year.

The research phase of the project will require studies in support of the Div. of Cancer Treatment screening program. These studies will be directed towards improvement of diagnostic methods and techniques and into the source and nature of materials produced by aerobacter cloacae that inhibit the growth of salmonella.

Contract Specialist: J. Kerner
301-427-7470
Cancer Treatment

RFP NCI-CM-53775

Title: *Maintenance and operation of rodent production centers*
Deadline: *July 3, 1974*

NCI plans to award contracts for the purpose of producing and supplying various inbred, hybrids of inbred and outbred rodents as progenitors for large-scale production colonies and for laboratory investigations sponsored by NCI.

To be considered respondents must meet the following animal criteria.

– 1. Contractor(s) must be accredited breeders with the DR&D, DCT, NCI and must have an existing barrier type facility with, as a minimum, an absolute filtration system, mechanical cage washing machines, auxiliary power sources, autoclaves (steam sterilizers) with sufficient capacity for large numbers of caging equipment, and large volumes of animal food and bedding.

– 2. Contractor(s) must have a minimum of two years experience in the production of inbred and/or hybrid and/or outbred laboratory rodents. This experience shall be based upon the production and provision of a minimum of 1,500 rodents per week.

Respondents will have the option of responding on four different cage levels (3,000; 4,500; 6,000 and 7,000 cages) and it is anticipated that multiple awards will be made as a result of this RFP. Request for Proposal will be available o/a 28 May 74. Requests for RFP must cite the number.

Contract Specialist: J. Kerner
301-427-7470
Cancer Treatment

MEETINGS

NCI advisory group meetings frequently are closed, usually for review of contract and grant applications. Times scheduled as open will be shown with each listing, but these sometimes are changed.

Childrens Cancer Study Group, Toronto, June 10-12.

Committe on Cancer Immunodiagnosis, Williamsburg, Va., June 10-11, open June 10 8-8:30 a.m., June 11 2-2:30 p.m.

Cancer Control Advisory Committee, NIH Bldg 31 conference room 8, June 11 open 9 a.m.-2 p.m.

First European Congress on Thermography, Amsterdam, June 12-14.

Endocrine Society, Atlanta, June 12-14.

Virus Cancer Program Scientific Review Committee, NIH Bldg 37 room 1B04, June 13-14, open June 13 9-9:30 a.m.

Fourteenth National American Cancer Society Medicinal Chemistry Symposium, Univ. of New Hampshire, June 16-20.

National Cancer Advisory Board Subcommittee on Carcinogenesis & Prevention, NIH Bldg 31 conference room 8 June 15, open 4-4:30 p.m.

NCAB Subcommittee on Diagnosis & Treatment, NIH Bldg. 31 conference room 7, June 15, open 4-4:30 p.m.

National Cancer Advisory Board, NIH Bldg 31 conference room 6, June 17-18, open 9-5, June 17, 2-4 June 18.

Breast Cancer Treatment Committee, Landow Bldg, room C-418, June 17, open 9:15 - 10:30 a.m.

Committee on Cancer Immunobiology, NIH Bldg 10 room 4B17, June 19, open 12 - 12:30.

Committee B, Virus Cancer Program Scientific Review Committee, NIH Bldg 31 conference room 3, June 19, open 8:30 - 9 a.m.

Diagnostic Radiology Committee, NIH Bldg 31 conference room 3, June 20, open 9 - 12.

Committee on Cancer Immunotherapy, Landow Bldg room C-418, June 20-21, open June 21 8:30 - 2

Southeast Cancer Study Group, Atlanta, June 20 - 21.

American Assn. for Study of Neoplastic Diseases, Chicago, June 22-27.

American Medical Assn. annual meeting, Chicago, June 22-27.

Eastern Cooperative Oncology Group, Jasper Park, Alberta, Canada, June 23-25.

Board of Scientific Counselors for the National Cancer Institute, NIH Bldg 31, conference room 9, June 23-25, open June 24 9 - 5.

8th Miles International Symposium, Role of Immunotherapy, London, June 24-25.

Gynecologic Oncology Group, Denver, June 27-29.

National Prostatic Cancer Project Workshop, Buffalo, June 28-29.

European Organization for Research on Treatment of Cancer Plenary Session, Paris, June 29.

SOLE SOURCE

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

Title: Cancer surveillance system
Contractor: Fred Hutchinson Cancer Research Center, Seattle

Title: In vitro tests for tumor specific antigens, antibodies and immune cells with animal and human serum cells.
Contractor: Litton Bionetics Inc.

Title: Mechanisms of the immune response to cutaneous neoplasms in relation to the detection of oncogenic viruses
Contractor: SUNY Research Foundation

Title: Evaluation of carcinogenic risk of chemicals to man
Contractor: International Agency for Research on Cancer, Lyon, France

Title: Preparation of bulk chemicals and drugs
Contractor: Dow Chemical Co.

Title: Preparation of bulk chemicals and drugs
Contractor: Parke, Davis & Co.

Title: Studies of biochemical aspects of cancer chemotherapy
Contractor: Southern Research Institute

Title: Studies on the role of hormonal factors on the induction of breast tumors
Contractor: Mason Research Institute

Title: Studies on role of prostaglandins in mammary gland neoplasia

Title: Studies on the role of cyclic adenosine monphosphate and related enzyme systems in mammary gland neoplasia

Title: Development of methods for the isolation of mammary epithelial cell-membranes

Title: Study of breast cancer and estriol dynamics

Title: Continue research involving intracellular membrane biogenesis in hormonemediated differentiation of mouse mammary epithelium in vitro

Contractor: (For all five above) Worcester Foundation for Experimental Biology Inc., Shrewsbury, Mass.

The Cancer Newsletter—*Editor* JERRY D. BOYD

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