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THE CANCER LETTER

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NEW CANCER CONTROL APPROACHES MAY INCLUDE CCRU RFA, CENTER COOPERATIVE GROUPS, REGIONAL "ROUNDS"

NCI's "creative approaches" to cancer control funding (*The Cancer Letter*, Feb. 25) include reissuing the RFA for Cancer Control Research Units, revising and reissuing the program announcement for Cancer Control Science Programs, encouragement for individual investigator initiated grants, some possible new help for training programs, and a couple of suggestions for new approaches by cancer centers.

All of those efforts would be supported through various mechanisms by Div. of Resources, Centers & Community Activities cancer control funds. However, NCI staff is remaining firm in the decision not to permit payment for cancer control core activities of centers with cancer control line item money from DRCCA. Those activities may be sup-

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In Brief

TWENTY APPLY FOR ICC DIRECTOR JOB; DEVITA SAYS 30 MORE CENTERS NEEDED; PAP AWARDS TO CLARK, FOX

ILLINOIS CANCER Council's search for a new director started with 20 candidates who responded to the center's call for applicants to replace Jan Steiner. ICC's members hope to have the new director on board by October. Meanwhile, Shirley Lansky is acting director. . . . **NCI HAS STARTED** a search for a chief of the Centers Branch in the Div. of Resources, Centers & Community Activities Centers & Community Oncology Program. Names may be submitted to DRCCA Director Peter Greenwald, Deputy Director Joseph Cullen, or Program Director Jerome Yates. . . . **"WE'RE PROBABLY** shy of the total number of centers we need," NCI Director Vincent DeVita told center directors last week. It will be difficult to increase that number without an increase in the amount of money available for core grants, DeVita said, commenting that he feels "we've done the best we can with the centers program" considering the budget constraints. When more money becomes available, DeVita said "we might want to expand. . . by about 30 centers". . . . **NCI'S DRUG** Development Program has been cut 25 percent since 1978, Div. of Cancer Treatment Director Bruce Chabner pointed out recently. "It's at the point now where we can't cut it any further without dismantling the program". . . . **SENATE HEARING** on NCI's 1984 appropriations has been rescheduled from April 6-7 to April 11-12 before the Labor-HHS Appropriations Subcommittee. . . . **PAPANICOLAOU AWARDS** for 1982 went to **R. LEE CLARK**, president emeritus of the Univ. of Texas M.D. Anderson Hospital & Tumor Institute, and **JACK JAY FOX**, biochemist and researcher with Sloan-Kettering Institute. Clark received the Distinguished Service Award and Fox received the Award for Scientific Achievement, both at the annual Pap Award dinner dance last week in Miami.

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DRCCA DESCRIBES "CREATIVE APPROACHES" TO CANCER CONTROL RESEARCH FUNDING

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ported through the regular center core grant, provided it is approved in peer review.

Those developments emerged from last week's meeting of cancer center directors and administrative officers with NCI staff at NIH. DRCCA Deputy Director Joseph Cullen, who said, "We are looking very hard for new ways to deal with cancer control funding," described the "creative approaches:"

- DRCCA's Board of Scientific Counselors will be asked in May to approve another round of CCRUs. Cullen did not say how much money the Board would be asked to commit in the RFA, nor how many additional CCRUs DRCCA hoped to fund. Review has been completed on the first round, and those grants will go to the National Cancer Advisory Board for approval in May.
- The DRCCA Board also will be asked for concept approval of a new program announcement for CCSPs. "I would speculate that there will be some changes," Cullen said. The new CCSPs would be developed as program projects addressing "critical areas of cancer control science," Cullen said.
- The new R01/R18 guidelines for individual investigator initiated cancer control grants should be published within two months. DRCCA expects those guidelines to help make it easier for cancer control investigators to write applications which will have a better chance of being funded.
- Discretionary funds for training in cancer control may be made available through CCRUs and center core grants.
- A new program is being considered for small grants to predoctoral and medical students who want to do cancer control research.
- Cooperative cancer control activities by groups of centers will be encouraged, sort of "cancer control cooperative groups." DRCCA Director Peter Greenwald said, "We hope to develop this as a major initiative." It would help centers "recruit scientists equal to the best scientists in other fields."
- A "cancer control rounds program" is being considered. That would involve groups of experts being put together to go into a region, assess the cancer control resources, do an epidemiology-geography profile, determine what is needed and what can be done to address a problem or take advantage of the resources available.

Finally, Cullen encouraged the center executives to encourage their investigators to "respond to some of the RFAs we've been putting out" in cancer control.

Although Cullen's list of creative approaches will be welcomed by cancer control scientists who are hoping for more NCI support, the center executives displayed little enthusiasm and did not comment on them. They did comment extensively, however, on the issue of funding core support for control activities.

DRCCA is phasing out the old cancer control core grants for centers engaged in various cancer control programs. Those funds mostly supported staff salaries for the center cancer control directors and core activities related to control. That money came out of DRCCA's line item cancer control appropriations.

The centers have asked for, and NCI has supported, a change in the guidelines for regular core grants to permit payment of control core salaries and other core support through that mechanism. However, the centers want the money for that to come from the cancer control line item, while DRCCA executives insist that it come out of the cancer centers budget. Greenwald and Cullen showed no signs of budging on that issue last week. The question ultimately will be decided by the NCAB.

Stanley Parry, Northern California Cancer Program, commented that the Assn. of American Cancer Institutes has proposed that core support for cancer control be funded from cancer control money.

Jerome Yates, director of DRCCA's Centers & Community Oncology Program, agreed "there's not much argument" that control core activities should be supported in the core grant. "If research in cancer control is in place (through R01s and other mechanisms), then we can justify treating it as part of the core grant."

However, John Durant, Fox Chase Cancer Center, argued that as long as that money comes out of research funds (that is, the regular centers core grant budget), centers are not going to be inclined to ask for control core support. "What you are trying to do is induce us to develop cancer control leadership. You won't induce us if you do not take that money from cancer control. We won't take it away from our laboratory scientists."

Yates noted that the cap on core grant budget requests will be lifted to permit paying for cancer control core support.

"That just takes money away from laboratory scientists at other institutions," Durant argued.

Richard Steckel, UCLA, said, "One of the hypotheses of the new thrust is that we will be able to respond successfully. I hope that is true. If the review results in a number of successful programs, you are vindicated. If not, that could mean that the scientific base does not exist."

Parry asked Cullen what the staff recommendation to the NCAB was going to be on the core grant issue.

Cullen said staff has not yet taken a position. "We do intend to ask for an increase on the cap within a core grant. I know, there's still the question of where the money will come from."

"When you do take a position, what will be your

recommendation," Timothy Talbot, Fox Chase, asked.

"That it not come from cancer control," Cullen said.

"That's a rape," Talbot responded. "An idiotic one."

Ross McIntyre, Norris Cotton Cancer Center and chairman of the Cancer Centers Support Grant Review Committee, opened the discussion of core grant review.

"While no one would deny that some institutions enjoy enviable records of scientific productivity, centers of excellence have developed, flourished, and faded throughout academic history. When functioning best, the center review process should recognize those centers with promising development, reward those which flourish, and let the sun shine on those which are fading."

". . . As a reviewer," McIntyre continued, "I hope I have a system for relating the benefits of the shared animal facility or media preparation facility to the research opportunity for the investigators in a center. I think that a certain amount of experience with such facilities and the type of science underway in that center is necessary for me to make a judgment. My greatest anxiety, however, arises from the possibility that I could miss the point of the presentation: that I would mistake brilliant for ordinary.

". . . Cancer centers, I think we are all agreed, should be centers of creativity, and the guidelines which have been developed appear to me to be based upon the concept that the organization should promote creativity. As such they are imperfect but perhaps helpful guides which if followed may help lead to the correct mix of stability, leadership, intellectual combat, and overall excitement which makes great institutions great. However, we are really no closer to an administrative or organizational formula for creativity in cancer centers than we are to a general formula for creativity in the arts. Although review teams may assess the efficiency with which instruments are shared and glassware is washed, there inevitably creeps into such appraisals an overall feeling for the scientific creativity which the core support is sustaining."

Barbara Bynum, director of the Div. of Extramural Activities, said that NCI has adopted several new procedures to address such issues as the need for consistency of review, qualifications of reviewers, amount of time allotted for presentations tc site visitors, attainment of the proper balance in a review committee, agenda of the site visit, assurances of flexibility, and "the notion of what constitutes a center."

The new procedures include a request for advance copies of presentations to site visitors, to give executive secretaries time to study them; executive secretaries will be directed to work with centers on the agenda, to develop a format that is consistent "and permit an institution to show what it uniquely represents;" center directors and program directors will be asked to submit names of individuals recommended for membership on the site visit teams; site visit teams will be organized farther in advance of the visits than in the past; no significant major changes in the application may be made four to six weeks prior to the site visit; attempts will be made to learn issues of special concern to the center; and executive secretaries will be assured adequate time to thoroughly brief reviewers.

"How best can scientific activity be presented?" Bynum said. "We've asked for it along program lines. At centers, the tendency has been to present individual projects, when the need is to show the overall picture, the influence of the center, the synergism, not a collection of individual projects. Review teams have to be constrained from viewing themselves as re-reviewers of individual projects."

Bynum acknowledged that "it is very difficult to review a center grant without being there. It is also very difficult if not impossible to have the full committee perform the site visit. We have to develop a process of transmitting the message of the site visit team in a uniform manner, and to transmit it accurately. That is the source of the criticism of inconsistency."

Yates described some of the criticism he has heard the centers are not allowed to present their best science because of the need to present "the global picture, shared resources, etc. They can't strut their best stuff. Review looks at bottle washing. Those are the types of comments we hear over and over again."

"The process of serving as a reviewer involves having to look at mechanisms rather than science," Bynum agreed. Questions reviewers of cancer center core grants must look at include, Bynum said, "What does a center mean? What would it be like there if the center did not exist? Centers provide a unified approach. The center has to be something different than a program project or a collection of individual projects."

"Clearly, enough science has to be presented to keep your site visitors interested," McIntyre commented. "My question always is, are those core grant dollars being more effectively spent than they would as supplements to R01s and P01s? The review has to be based on some understanding of the science going on at the center."

"One thing we're trying to do is characterize centers a little better," Yates said.

Steckel, former AACI president, said he appreciated the fact that so many AACI suggestions have been incorporated into the review process. "I'm still apprehensive over the possibility of mistranslation between the site visit teams and the committee." he said. "Center directors sometimes feel compelled

to write letters criticizing or commenting on the site visit. But they feel they may be stigmatized by the fact of writing the letter, that some may feel it was sour grapes. Why not institutionalize it and ask center directors to write a letter each time?"

"The stigma should be removed," McIntyre said. "In some instances, it would help. But please, hold them to one to one and a half pages."

"Ideally, when the site visit team leaves, it should have a good idea what the center is all about," Bynum said. "Rick's suggestion is that the presentation can be augmented with a "Gee, I forgot that' letter. You can do that now. His suggestion is that we provide for it."

"At the end of the site visit, the chairman often does give the director time to present anything left out," Barbara Sanford, Jackson Laboratory, said. "He asks if anything has been left out. Some of these things go on, although not in written form."

Some objections were voiced over making the letter mandatory, and it was left optional, for the present.

Yates discussed the proposed new master agreement for phase 2 cancer control projects which DRCCA is in the process of implementing.

The long lead time required to initiate new work, from conception to funding, through a contract is one year, and through a grant is 18 months. With a master agreement, subsequent task orders can be implemented within three months, Yates noted.

Helen Baldwin, Univ. of Wisconsin, said, "Some of us have had a very disquieting experience with the master agreement for the Biological Response Modifiers Program (in the Div. of Cancer Treatment). That was set up for five years, and now, they are saying, 'allee allee ox in free, we're going to do it again.' That involves a tremendous amount of work."

(DCT decided to recompete the BRMP master agreement in order to make some major modifications in it).

"Despite that, DCT's experience with master agreements in general has been good," Yates said, and Baldwin agreed.

Yates offered an outline of the master agreement mechanism:

I. Prequalification Procedure for Master Agreement Method

As an alternative to conventional procurement procedures, the master agreement prequalification procedure is appropriate only when all of the following conditions are met:

A. Requirements must be fulfilled within time constraints which are so restrictive as to proclude performance either in-house or by contract if normal procurement procedures were employed.

B. The prequalification procedure will serve a legitimate need of the procuring activity and does not reflect mere expediency.

C. The prequalification procedure is expected to assure a pool of competent offerors from whom proposals can be elicited in a short time frame.

II. Goals and Major Objectives

DRCCA proposes to utilize the master agreement for the identification and development of a pool of competent research organizations capable of responding promptly to specific task orders addressed to the mission and programmatic objectives of the division. The goal of this program would be the rapid mobilization of the professional expertise and resources (i.e., patients, facilities) which exist in established cancer research centers and other qualified organizations (e.g., state and local health agencies, universities) for the verification of those emerging concepts in cancer detection, diagnosis, treatment and prevention which can be expected to have a major impact upon public health. Objectives are:

A. To exploit existing knowledge and the expertise and resources of organizations that have the demonstrated capability to undertake specific projects arising from concepts warranting rapid verification which could provide significant benefit to the general population.

B. To develop a mechanism for a quick response (less than three months) for the development of support to cancer centers and other qualified organizations identified by interest and capability in performing specific tasks.

III. Project Description

With the emergence of new leads for cancer control, particularly in areas requiring specific patient resources, research expertise and/or equipment, the ability to confirm or refute pilot results in a timely fashion is presently difficult. The existing grant and contract mechanisms generally require a minimum of one to two years from the time of initial concept generation, approval and funding. This delay may be avoided if a mechanism for rapid involvement of qualified organizations can be employed. The traditional peer review process of the National Institutes of Health will assure performance capability.

DRCCA proposes initially to construct and advertise a master agreement focused upon two phases of cancer control research encompassing three subject areas. Two studies (dysplastic nevi and acquired autoimmune deficiency syndrome) involve phase 2 cancer control studies in identification of high risk popuations. A third study (retinoids) is directed to phase 1 (pharmacological) chemoprevention studies.

A. Acquired autoimmune deficiency syndrome

In the past two years, a relatively unusual cancer in the U.S., Kaposi's sarcoma, emerged initially in the male metropolitan homosexual population. Because of its initial rarity, incident cases have received increasing attention. The resulting expansion of knowledge suggests an increased susceptibility among Haitian migrants to the United States, drug addicts using intravenous heroin, hemophiliacs receiving concentrated blood products, and male homosexuals involved with multiple sex partners. A second equally unusual disease, pneumocystis carinii pneumonia, is most commonly seen in immunosuppressed patients. The emergence of pneumocystis carinii pneumonia and reflection on the occurrence of Kaposi's sarcoma in patients with malignant lymphomas and those undergoing immunosuppression for renal transplants led to the conclusion that an immunological abnormality may explain the increasing incidence of these two diseases. Immunological assessments have demonstrated T-cell abnormalities, and epidemiologic studies have suggested a probable viral type agent causing the immunological abnormalities which appear to be the common denominator in all situations.

Because of the availability of expertise, study population, and public health needs, two administrative supplements to existing cancer center grants were made to facilitate the study of Kaposi's sarcoma. This underlines the need for a more rapid mechanism for providing appropriate research support to develop needed information for rapid public health application. Treatment of both Kaposi's sarcoma and pneumocystis carinii

pneumonia in individuals with immunological abnormalities has not been accomplished without significant mortality. Because the incidence of these afflictions appears to be increasing and may be largely preventable with a better understanding of their etiology, urgent research efforts should have future public health impact.

B. Dysplastic nevi

An unusual mole that may represent a marker of increased risk for melanoma has been identified by scientists at the National Cancer Institute and the Pigmented Lesion Clinic, Hospital of the Univ. of Pennsylvania. These atypical moles may undergo cellular changes which transform them into a skin cancer known as malignant melanoma. Removal of these unusual moles could prevent the progress to malignant lesions in high risk persons.

Occurrence of dysplastic nevi in families with a history of melanoma has led to recognition of the syndrome in the general population as well. Melanoma has been studied in families because of certain patterns observed. First, melanoma seems to occur more frequently in certain families; second, the number of new cases of melanoma each years has been increasing both in the U.S. and internationally; and third, improvements in melanoma survival have resulted from earlier identification of melanoma.

The search for clues to melanoma susceptibility began with an evaluation of a melanoma prone family of 25 members with four known melanoma patients (one deceased) by NCI scientists and their colleagues at the Univ. of Pennsylvania. Of the three surviving melanoma patients, a number of their healthy relatives were found to have a very unusual pattern of moles. Larger and more numerous than ordinary moles, these lesions had irregular outlines and pigmentation and seemed to be found all over the skin including areas where ordinary moles are usually not seen, such as the scalp and buttocks. One family member was discovered to have a previously undiagnosed malignant melanoma. When removed, it was found to be an early melanoma curable by surgical removal; this patient is now alive, well, and free of melanoma five years later (1981). Up to 10 percent of melanoma patients are members of melanoma prone families. An estimated 50 percent of the melanoma prone family members have these distinctive (dysplastic) moles and are thus felt to be the specific family members most likely to develop melanoma.

During 1977-1978, the study was expanded to include six additional families whose members were found to have the same unusual mole pattern as we observed in the first family. Microscopic examination of pigmented moles removed from family members showed that these lesions were distinctively different from ordinary moles: There was disordered, faulty growth (called dysplasia) in the pigment-forming cells (melanocytes) of these unusual moles. Ordinary moles consist of clusters of benign melanocytes, while melanomas consist of malignant melanocytes. The unusual (dysplastic) moles seem to fall someplace in between and to be susceptible to malignant transformation.

Careful monitoring of persons with these unusual moles could lead to a decrease in deaths from melanoma averaging about 5,000 per annum. In addition, the development of melanoma may actually be prevented by removing suspicious changing moles before malignancy occurs and by avoiding excessive sunlight exposure.

C. Phase 1 (pharmacology) clinical trials of chemopreventive agents

Several retinoid analogs are currently in clinical trials as cancer preventive agents, but animal model studies suggest that other analogs may have greater chemopreventive potential. These analogs require phase 1 trials in humans prior to broader scale clinical testing. Suggestions for such a study follow.

Offerors for a project of this nature would formulate a proposal for a phase 1 trial of a retinoid analog. The proposal should include documentation of the availability of a multidisciplinary team, including clinicians, pharmacologists, and nutritional scientists. Since the maximum tolerated dose may differ, based on the patient's baseline nutritional status, an ability to evaluate nutritional parameters, including determination of blood levels of carotenoids, retinoids, and retinol binding protein must be deomonstrated by the offeror. The offerors would also document the availability of a study population which is suitable for administration of a retinoid with therapeutic intent.

The proposal should include a protocol which includes, but is not limited to, the following specifics: criteria for participant selection, a dosage schema, a schema for the study of pharmacokinetics, a description of the possible toxic effects of the drug, a strategy for monitoring participants for evidence of toxic reactions, criteria for adjustment of doses and schedules, a plan for data analysis, and a plan for reporting adverse reactions to the National Cancer Institute, and a written informed consent document. The offerors should document their previous relevant experience and their willingness to collaborate with NCI scientists in the selection of agent(s) and dose.

IV. Mechanism

The mechanism will be the master agreement and master agreement order. The master agreement provides a broad scope within which specific master agreement orders can be implemented. The master agreement is a legal document between the federal government and a resource source or organization setting forth general terms and conditions for performance of immediate or future and unspecified studies in a targeted, identified project area specified in the master agreement.

A. Descriptive elements of the master agreement do not contain performance funding, a specific task, or a specific work scope.

B. The master agreement requires a sense of urgency, the capability of performing specific types of research and development and the ability to perform future specific unidentified types of tasks.

C. The master agreement order is a bilateral contract issued as an operational addendum as part of the master agreement. It provides a scope of work and a time frame for the work, and funding is then negotiated. Competition is limited to holders of the master agreement, and there are dollar thresholds which must be observed.

D. The master agreement and master agreement orders can be simultaneously announced. Master agreement orders can be implemented within as short a period of time as two months.

V. Review Group

The master agreement and master agreement orders would be reviewed by an ad hoc committee. Announcements of master agreements and master agreement orders are reviewed by the NIH Div. of Contracts & Grants and the Office of Extramural Affairs to assure conformity to established guidelines. Applications submitted in response to announcements and solicitations are reviewed by ad hoc peer review groups.

VI. Anticipated Number of Awards

Unknown at this time.

VII. Approximate Annual Budget Per Award

No money to be set aside until tasks are developed.

VIII. Duration

Awards would be made for the projected period necessary, but subject to yearly program scrutiny if multiple year awards are made. The maximum period of award for master agreements is five years.

IX. Justification

Significant patient, professional and research resources re-

side in existing cancer centers and/or other selected research organizations. The average time from concept to grant funding is 18 months and from concept to contract funding is 12 months, making both relatively slow mechanisms for supporting research breakthroughs deserving rapid turnaround.

MURRAY COPELAND MEMORIAL DISPLAY DEDICATED AT ROSWELL PARK INSTITUTE

Youth is not a time of life. It is a state of mind. . . a temper of the will, a quality of imagination, a vigor of emotions; it is a freshness of the deep springs of life. Nobody grows old by merely living a number of years; people grow old by deserting their ideals.

Murray Copeland

Murray Copeland, who died last year at age 80, never grew old, by his standard. A few weeks ago his wife, Jean, and a few friends and colleagues gathered at Roswell Park to dedicate the Dr. Murray M. Copeland Memorial Display, memorabilia from one of the more distinguished careers in the history of oncology.

Copeland became the first professor of oncology in the United States, in 1947 at Georgetown Univ. where he distinguished himself particularly in the fields of bone and breast cancer. His career had started with his MD from Johns Hopkins in 1927. During World War II, he commanded one of the largest Army hospitals in the South Pacific, and his military awards and medals are part of the display.

In 1947, Copeland became professor and chairman of the Dept. of Oncology at Georgetown Univ. Medical School. In 1960, he joined the staff at the Univ. of Texas M.D. Anderson Hospital & Tumor Institute. He was the author of over 170 published scientific articles and was credited with classifying tumors of the bone.

In 1970, Copeland served as secretary general of the Xth International Cancer Congress in Houston. At the age of 70, he was asked by NCI to head the National Large Bowel Cancer Project, which he did until he retired in August, 1981.

Copeland served as national president of the American Cancer Society in 1964-65, vice president of the Society of Surgical Oncology in 1959-60, and was medical director of NCI from 1949-54.

The dedication ceremony included remarks by Copeland's widow, Jean; Gerald Murphy, A. Hamblin Letton, Edward Copeland, R. Lee Clark, and B.L. Aronoff.

ACOS COMMISSION ON CANCER APPROVES 127 HOSPITAL PROGRAMS, TOTAL NOW 994

The American College of Surgeons Commission on Cancer granted 127 three year approvals of hospital cancer programs during the past year, bringing the total number of ACOS approved hospital cancer programs to 994.

Gerald Murphy, presenting the ACOS liaison report to the Assn. of American Cancer Institutes, noted that 15 of the approvals represented new applications, and 19 were one year or provisional approvals.

Other ACOS activities reported by Murphy included:

All approved hospitals are now required to enter the UICC/American Joint Committee TNM classification for breast cancer in their hospital records. Beginning July 1, 1983, similar records for both non-Hodgkin's and Hodgkin's lymphoma will be required. All gynecological tumors—cervical, uterine, and ovarian—will also be similarly required. All institutions must be in compliance when they are reviewed for these issues. The cancer committees at the various institutions are responsible for compliance.

There is a number of new administrative procedures designed to expedite and ease some of the burdens on tumor registrars. These particular rules and regulations will be disseminated following their distribution from the Commission office in Chicago.

The Committee on Patient Care and Research reviewed the 1983 report on breast cancer, prepared on behalf of the Commission at Roswell Park. Over 57,000 cases have been accrued from the 50 states, the District of Columbia, and Puerto Rico. In addition, the report has been mailed out to all participating institutions and further additional analyses will be forthcoming. Approximately 7,000 cases of endometrial cancer, from 754 hospitals, were studied on a prospective, short term study for certain environmental factors. This study is still under a preliminary evaluation and a report is yet due from the Roswell Park investigators in collaboration with the American College of Gynecology & Obstetrics and the Commission on Cancer. Forms have been sent out to institutions for the 1983 study which is already starting on Hodgkin's disease.

There will be a restudy of prostate cancer in 1984, on a national basis, as well as a national survey of soft tissue sarcoma for both long and short term studies. At the present time, the 1985 sites that are being considered include the narrow digestive tract, gastric cancer, and testicular cancer. The Patient Care & Research Committee has discussed a number of items regarding further dissemination of their particular areas of endeavor.

The Committee on Education approved for the spring of 1983 a program entitled: "Recent Progress in the Treatment of Cancer." The fall 1983 postgraduate course to be held at the Atlanta Congress will be on abdominal cancer. In 1983, there will be an additional item on the spring program on breast cancer—symptoms and patterns of care.

The programs for 1984 are presently as follow: The spring program will focus on cancers of the upper alimentary tract and cancers of the thyroid and parathyroid. The fall program will consist of a postgraduate course to evaluate the breast survey

just reported in 1982. The symposium will concern the melanoma results obtained by the Commission on Cancer and include matters addressed to that particular area.

The Board of Regents has approved a Cancer Management Course in principle and the College will provide funds for this. Preliminary plans for documents, course materials, and the like will begin on a pilot basis at the present time and continue up through July of 1983. At that time, pilot courses for evaluation of impact and reevaluation afterwards will be held in different regions in the U.S. If this program is successful, it will result in a national program in which cancer courses are held for general surgeons; these will not be cancer courses for new innovations, but rather for routine principles in management.

The Committee on Field Liaison reported that it currently has 1,659 members. All state chairmen of of all states and the District of Columbia and Puerto Rico now have printouts of the hospitals, the hospital size, the name of the field liaison person, whether the program is approved or nonapproved. There is a six year limit on the terms of state chairmen, and as a result in the past year 20 state chairmen retired and 20 additional individuals were appointed. Dr. Ronald Jones has completed his period of time as chairman of the Committee on Field Liaison and will be replaced by Dr. LaMar McGinnis. The Executive Committee chairman, Dr. Robert Schmitz, completed his term and has been succeeded by Jones.

The National Tumor Registrars Assn. has recently held its first national qualification exams with a goal towards having national certification for all participants.

DUGAN HEADS ACCC, YARBRO NAMED PRESIDENT ELECT; AMOS HONORED

William Dugan, Indianapolis medical oncologist, assumed the presidency of the Assn. of Community Cancer Centers at the organization's annual meeting last weekend in Washington. John Yarbro, professor of oncology at the Univ. of Missouri, was elected president elect.

Other officers are Edward Moorhead, Grand Rapids, reelected to a second term as secretary; and Ann Welch, Cincinnati, treasurer.

Harold Amos, member of the President's Cancer Panel, former member of the National Cancer Advisory Board, and professor of microbiology at Harvard, received the organization's annual Outstanding Achievement Award.

David Johnson, outgoing president, presented special awards to Donna Minnick for her work as chairman of the Communications Committee; and Robert Clerke, retiring treasurer of the organization.

NCI CONTRACT AWARDS

Title: Programming and data entry services in support of the NCI/CMS

Contractor: Sigma Data Services Corp., Rockville, Md., $70,774.

PERIOD FOR INDIVIDUAL NRSA FELLOWSHIP ACTIVATION REDUCED

A recent policy decision by the Public Health Service has reduced the maximum period of time for activation of fellowship awards from 12 months to six months. The activation period is that time from the initial award of an individual NRSA fellowship to the actiaul initiation of the fellowship experience. Previously, fellows have been permitted up to a maximum of 12 months following award to begin their fellowships.

Effective for new fellowship awards issued in the government's fiscal year 1983 (Oct. 1, 1982–Sept. 30, 1983), the maximum activation period is six months. Extensions of the activation period may be granted for good reason. Recipients of NRSA fellowship awards are encouraged to keep the awarding units of NIH, Alcohol, Drug Abuse & Mental Health Administration, and the Health Resources & Services Administration Div. of Nursing, well informed of their activation plans.

This notice revises and updates information published in the PHS Grants Policy Statement dated Dec. 1, 1982.

Questions on this issue may be addressed to staff of the awarding unit as identified on the Notice of Fellowship Award.

AVAILABILITY OF CONGENIC MOUSE STRAINS NATIONAL CANCER INSTITUTE

This announcement is being issued to inform investigators of the availability of strains of congenic mice representing discriminative alleles of genes of special interest in viral leukemogenesis.

The Biological Carcinogenesis Branch, Div. of Cancer Cause & Prevention, supports a congenic mouse production facility at Sloan-Kettering Institute for Cancer Research under NCI contract. At present there are 14 strains of congenic mice in various stages of development and 2 Gix-gp70 mutant strains. The gene substitutions involved include Akvp, Fv-1, Gv-1, Gv-2, H-2, Pca-1 and T1a. In several cases, reciprocal substitutions of alleles have been effected between inbred strains that differ categorically in one or more characteristics pertaining to leukemia or leukemia virus providing a quartet of inbred strains, two standard and two congenic with switched alleles, for each gene system.

There is a charge for the animals and the shipping costs are the responsiblity of the recipient. For further information, contact: Dr. Edward A. Boyse,

Sloan-Kettering Institute for Cancer Research, 1275 York Ave., New York, N.Y. 10021, phone 212-794-7500.

NOTICE

NATIONAL CANCER INSTITUTE

NCI will resume accepting new and competing renewal applications for the clinical cancer education program grants (R25). Next receipt date will be June 1, 1983. For copies of the new guidelines contact Dr. Olga G. Joly, Program Director, CCEP, DRCCA, NCI, Blair Bldg. Rm 722, 8300 Colesville Rd., Silver Spring, Md. 20910, phone 301-427-8855.

SITE VISITS TO ANIMAL CARE FACILITIES

NATIONAL INSTITUTES OF HEALTH

NIH is embarking on a series of site visits to randomly selected awardee institutions to assess the adequacy of the current process for promoting proper care and use of animals in the biomedical research which NIH funds.

In particular, the visits are intended to determine whether or not the facilities, systems, and practices for the care and use of laboratory animals are consonant with the statements of assurance now on file with NIH.

The information gathered will be valuable for addressing three overriding questions: Is the present assurance system adequate? Even if adequate, how can it be improved? If inadequate, what other approaches should be explored?

As a part of its overall mission to fund high quality biomedical research and research training, NIH has an obligation to promote the appropriate care and use of laboratory animals. Since 1971, NIH has required awardee institutions which conduct experiments with laboratory animals to submit written statements of assurance committing themselves to follow the principles set forth in the NIH *Guide for the Care and Use of Laboratory Animals* as well as all federal, state and local statutes relating to laboratory animals. In addition, many institutions have sought and received accreditation by the American Assn. for Accreditation of Laboratory Animal Care.

As a matter of policy, NIH negotiates these assurance statements carefully but has made no systematic effort to assess compliance unless concerns are raised by: (a) peer reviewers and/or staff during the normal processes of evaluating applications, proposals, and progress reports, (b) individuals or groups who submit evaluable allegations, and/or (c) authorized inspection, such as performed by the U.S. Dept. of Agriculture under the Animal Welfare Act of 1966.

In recent years, critics of NIH policies have questioned the adequacy of the assurance process both in concept and in relation to a few specific instances of actual or apparent failure by awardees to ensure appropriate practices. Because of the need to maintain public confidence in science and in the officials who administer federal funds, NIH has decided to examine its assurance system.

The effort is being conducted under the leadership of the Office of Extramural Research and Training. NIH staff and advisors have developed a protocol for conducting the site visits. The first group of institutions will be visited during the period March through September 1983. Visits will be made to a stratified, random sample of 10 institutions which operate under approved assurances but which do not have accreditation from the AAALAC. The institutions will be selected according to the following plan: (a) one institution will be chosen from each of the 10 Dept. of Health & Human Services geographic regions, and (b) three or four institutions will be taken from each of three categories of total annual NIH support of more than $10 million, $5-10 million, and less than $5 million.

Each site visit team will be composed of several members (usually three to five), comprising NIH employees and nonfederal consultants. A member of the NIH staff will notify the appropriate institutional representatives about one month before the scheduled visit.

Additional information concerning this notice may be obtained from Dr. Louis R. Sibal, Office of Extramural Research & Training, NIH, Shannon Bldg. Rm. 314, Bethesda, Md. 20205; phone 301-496-4716.

NOTICE OF AVAILABILITY – RFA

COOPERATIVE AGREEMENTS FOR ORPHAN DRUGS AND MEDICAL DEVICES RESEARCH

FOOD AND DRUG ADMINISTRATION

FDA will soon announce the availability of funds for fiscal year 1983, for the award of cooperative agreements ot support clinical trials on the safety and effectiveness of orphan drugs and medical devices.

Approximately 20 to 80 awards will be made in the range of $20,000 to $100,000 each. Applications must be submitted on form PHS 398, Public Health Service Research Grant Application.

For further information, contact: Office of Orphan Products Development, Parklawn Bldg. Rm. 12-11, 5600 Fishers Ln., Rockville, Md. 20857; phone 301-443-4903.

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