THE CANCER LETTER

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SHORTFALL IN CENTERS BUDGET THREATENS GRANTS OF HALF OF THE 17 COMPETING FOR RENEWAL IN 1980

As many as eight or nine of the 17 centers which are competing for core grant renewals in the current (1980) fiscal year could end up in the "approved but unfunded" category due to the level Centers Program budget, the National Cancer Advisory Board was told last week.

The Centers Program budget is $63.5 million, almost identical to the FY 1979 budget, despite the fact that total NCI spending will increase

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In Brief

GAO PROBE OF CANCER CONTROL PROGRAM NEARS END; RENEWAL BILL MARK UP NOT BEFORE OCT. 22

GENERAL ACCOUNTING Office's investigation of the NCI Cancer Control Program "is in its terminal stages," acting Div. of Cancer Control & Rehabilitation director William Terry told the National Cancer Advisory Board. The probe probably will be wrapped up by the end of the year, with the report coming out sometime in 1980. . . . **SENATE HEALTH** Subcommittee mark up on S. 988, renewal of the National Cancer Act and other biomedical research authorities, probably will not be held before Oct. 22. Sen. Edward Kennedy is pushing to get the bill ready for the full committee this month. House Health Subcommittee Chairman Henry Waxman's staff is in the process of drawing up similar legislation and plans to introduce a bill before Congress adjourns at the end of this year. . . . **GERALD WOGAN**, professor of toxicology at MIT's Dept. of Nutrition & Food Science and a member of the National Cancer Advisory Board, is the new chairman of NCAB's Subcommittee on Environmental Carcinogenesis. He replaces Henry Pitot, now chairman of the entire Board. . . . **EMIL FREIREICH**, chief of developmental therapeutics at M.D. Anderson, will receive the Leukemia Society of America's 1979 de Villiers Award. . . . **ONLY TWO** organizations—Assn. of Community Cancer Centers and the American Society of Hematology—have formally joined the Coalition for Cancer Issues. ***The Cancer Letter*** (Sept. 21) listed several other organizations as members; in fact, the others mentioned were represented at meetings of the proposed coalition but have not yet committed themselves to membership. . . . **KATHY KOWALCZYK**, administrative officer of the Field Studies & Statistics Program in NCI's Div. of Cancer Cause & Prevention, died last month of cancer. She was 35. . . . **BIOLOGICAL SAFETY** Conference, sponsored by NCI's Office of Research Safety, will be held Oct. 15-17 at NIH, Wilson Hall. Topics include medical surveillance and emergency care, hazard assessment studies, current guidelines for recombinant DNA research, etiologic agent classification, HEW guidelines for safe use of chemical carcinogens, and FDA's good laboratory practices. Contact Manuel Barbeito, conference chairman, 301-496-1862. Preregistration is required.

NCI FACED WITH REDUCING ALL CENTERS GRANTS OR LEAVING 8-9 WITHOUT FUNDS

(Continued from page 1)

from $937 million in 1979 to $1 billion in 1980. All of the increase was earmarked for other programs.

Acting Centers Program Director William Terry said that "if we pay all noncompeting grants at the peer review recommended levels and all competing renewals at levels likely to be recommended, we will be $8-9 million short. We could fund only about half of the 17 competing renewals." The average core support grant is between $800,000 and $900,000 a year.

Included among the 17 centers whose grants are being recompeted this year are six comprehensive centers. The NCAB previously had adopted a policy which requires that if a comprehensive center loses its core grant and is unable to obtain a new one within two years, it will have to be reviewed to determine whether its recognition as comprehensive should be withdrawn.

That policy would apply both when a center's application for renewal of a core grant is disapproved and when it is approved but at too low a priority to obtain funding.

Terry pointed out at a meeting of the NCAB Subcommittee on Centers last week that the program would be faced with choosing one of two alternatives: Cut funding across the board for all core grants to provide enough money to support all approved competing renewals; or fund by priority scores as long as the money holds out.

When the program was faced with a similar shortfall three years ago, NCI decided to cut them all and fund all approved renewals. The result was havoc everywhere. Center directors have since favored the other option, even if it meant that some of them would lose their core support.

The Assn. of American Cancer Institutes has urged NCI to fund center core grants at their full peer review recommended levels, and if funding is not available to fund them all, phase out the less competitive ones. AACI also has taken the stand that new applicants should be permitted, as Terry said, "to compete head to head with competing renewals."

William Shingleton, chairman of the Subcommittee on Centers, asked in reporting to the Board on the budget problems if NCI Director Arthur Upton "has any ideas on how to make up the deficit." Upton's response: Any extra money for centers would have to come out of other NCI programs. He made no promises, but agreed to closely scrutinize them all to see what might be squeezed out.

NCAB DELAYS APPROVAL OF GUIDELINES FOR COMPREHENSIVE CENTER RECOGNITION

The National Cancer Advisory Board first approved a new set of "Guidelines for Recognition of a Cancer Center as Comprehensive" which would supercede the original 10 "characteristics" that have been applied to such recognition since 1972, and then withdrew that approval until the Board's meeting in November.

The Board had previously discussed various proposed new characteristics or guidelines. NCI staff and the Board's Subcommittee on Centers, in consultation with representatives of the Assn. of American Cancer Institutes and others, had developed the guidelines which Subcommittee Chairman William Shingleton presented to the Board last week.

Board member Harold Amos suggested that members should have more time to consider them, with a final decision delayed until the November meeting. His motion to that effect did not get a second, and the Board unanimously approved the new guidelines.

Later, however, Kash Mostofi, ex officio member representing the Dept. of Defense, said he had had second thoughts. "I think we should reconsider, study this in more detail, so we don't get accused of rubber stamping the subcommittee's report."

Amos' motion to rescind the approval and delay final action until November was approved by a 4-2 vote, with Shingleton and Board member Frederick Seitz opposed. Shingleton agreed the delay would not create any problems, since there are no pending applications for comprehensive recognition;

The new guidelines add the requirement that a center have a funded core grant to be considered for recognition as comprehensive. The rationale for this requirement is that it demonstrates a center has been subjected to and has passed a broad and intensive peer review. Sixty-three institutions have funded core grants; 21 of them are comprehensive centers, although the grant to the Colorado Comprehensive Cancer Center is in the process of being phased out. Colorado will be the first to be reviewed as the result of losing its core grant and stands a good chance of being the first to lose its comprehensive recognition.

The new guidelines make it clear that comprehensive centers are not expected to do everything, a sore point with some center directors who felt they were unfairly downgraded in the NCAB review for comprehensiveness. The guidelines also provide more flexibility in the administrative makeup of centers, and in the general application of all aspects of the guidelines. They specifically, for the first time, allow leeway in administration required by consortia centers.

The new complete guidelines, as recommended by the Subcommittee on Centers:

These guidelines describe the qualities and characteristics that the National Cancer Advisory Board (NCAB) considers essential for recognition of a cancer center as comprehensive. They will be used by reviewers to evaluate centers that are seeking recognition as new comprehensive centers and also to

evaluate established centers to determine the advisability of continued recognition.

In establishing these guidelines, the NCAB does not intend that any institution participate in all possible activities relevant to cancer. For example, although one of the requirements for recognition as comprehensive is the existence of high quality research activities, there is no requirement that *all* research areas (for example, virology, cell biology, immunology, biochemistry, pharmacology, etc.) be pursued at a given center. Rather, there is the requirement that there be high quality activity in *some* aspects of clinical research, *some* aspects of laboratory research, *some* aspects of cancer control, and *some* aspects of training, education, and information dissemination. The term comprehensive is intended to convey that the cancer center has high quality activities in each of these major areas, but that within any given area, the center may choose to pursue particular topics and not others.

1. National and Local Support

The cancer center must have a funded Cancer Center Support (Core) Grant, indicating that center activities are of sufficient quality to achieve funding from the National Cancer Program. In addition, there must be evidence of material support for center activities from the parent institution(s) and the local community.

2. Research Activities

The cancer center should support laboratory, clinical, epidemiologic, and evaluative research efforts of the highest quality and should create an environment which fosters cancer-related information exchange, cooperation, and collaboration between laboratory scientists of multiple disciplines and between laboratory scientists, clinical scientists, and epidemiologists. Centers should maintain their own clinical investigative activities. In addition, they should also engage in regional and/or national clinical trials and should have available the personnel and facilities to carry out high quality diagnostic, therapeutic, and rehabilitative procedures in the interdisciplinary setting most suited to the cancers being studied. The center should make a commitment to participate in uniform clinical data acquisition and reporting through the Centralized Cancer Patient Data System (CCPDS).

3. Cancer Control Activities

The cancer center should serve as a primary focal point for local and regional programs designed to control cancer through research and demonstration activities in areas such as prevention, detection, diagnosis, treatment, and rehabilitation. The center should seek the active participation of all sectors of the professional and lay community in control activities.

4. Training, Education, and Information Dissemination

The cancer center should serve as a primary focal point for local and regional information dissemination, as well as for professional and lay education programs. Programs to assess which methods of information dissemination and education effectively modify professional and lay behavior patterns are desirable. Centers should also be involved in training of professional and support personnel for all pertinent research.

5. Administration

The cancer center (or in the case of consortia, the constituent institutions) should have a formal commitment of support from the parent institution(s), manifested by the center director having the following: (a) primary control of space and equipment, (b) necessary control over professional and staff appointments to enable the center director to effectively direct the center and assure accomplishment of its mission, (c) control of grouped beds and ambulatory facilities for cancer research, and (d) responsibility for program planning, evaluation, and execution, preparation of budgets and control of expenditures. In addition, the center must have an administrative structure that will assure long term viability, efficiency of operation, and sound financial practice.

6. Geographic Impact

Scientific excellence of any center is a primary consideration. The geographic location of the cancer center, however, should increase the national capability to carry out regional clinical trials, regional cancer control programs and regional training, education and information dissemination activities. The location of other comprehensive centers and the size of the regional population with access to the center are additional factors bearing on recognition.

Not included as a formal part of the guidelines but still a matter of Board policy is its action adopted last year regarding the procedure to be followed in the event a comprehensive center loses its core grant.

That action, in the form of a motion which was approved by a vote of 8-3, was:

"If a comprehensive cancer center loses its core grant and chooses to continue to be recognized as comprehensive, the center can reapply for a core grant within two years. If the center fails to obtain a funded core grant within this period, or the center decides not to reapply for a core grant within two years, the center shall be re-reviewed at that time in order to determine whether it shall continue to be recognized as a comprehensive cancer center by the director of NCI."

William Terry, acting director of the Centers Program, asked the subcommittee if the 're-review trigger" would be applied to a consortia center which includes two or more institutions each with core grants if just one of those institutions were to lose its core grant.

"It would have to be," said Board member Maureen Henderson, "or that would suggest that one

is more important than the other."

"It would be logical to say that if one of two institutions making up a comprehensive center loses its core grant, the center would have to be looked at for re-review," Shingleton agreed.

Centers Program staff member Ray Morrison pointed out another possible complication. At least one and possibly two comprehensive centers have more than one core grant (not including the cancer control core grants, which 15 comprehensive centers have). Would losing only one of the two grants trigger the re-review?

Terry said that Roswell Park Memorial Institute has two—the primary core support grant with Director Gerald Murphy as principal investigator, and another which evolved out of a program project grant, with Enrico Mihich as the PI. The Wisconsin Comprehensive Cancer Center has a similar situation.

Morrison called attention to the fact that the Illinois Cancer Council, a consortium comprehensive center, has a core grant to the center and that two members of the consortia—Northwestern Univ. and Univ. of Chicago—each have core grants.

"Wouldn't you view the loss of even one as serious and would merit re-review?" asked David Joftes, chief of NCI's Review & Referral Branch.

Subcommittee members agreed that if a center with two core grants loses one, or if a member of a consortium loses its core grant, the re-review process for comprehensive recognition would be triggered.

In hammering out the final makeup of the guidelines, the subcommittee had brought in as consultants three center directors—Murphy, representing the free standing comprehensive centers; Albert Owens, director of the Johns Hopkins Univ. Cancer Research Center, representing the university based centers; and Jan Steiner, director of the Illinois Cancer Council, representing the consortium centers. Murphy is the current AACI president and presented the views of that organization.

Murphy listed as "areas of concern" expressed by AACI members:

—The emphasis on the core grant as a requirement for comprehensive recognition; requiring participation in national and regional clinical trials when some centers feel local trials can be unique and contribute greatly; overemphasis on "final authority" in center administration; the requirement that comprehensive centers use the Centralized Cancer Patient Data System, when some members prefer to use their own systems.

The subcommittee remained firm on core grants and CCPDS but added local trials to the requirement for participating in national and regional clinical trials. The subcommittee also relaxed the requirement that center directors control beds, space and staff appointments to "primary control" of space and equipment and "necessary control" over staff appointments.

"This seems to be a workable set of rules," Owens said. "The addition of core grants as a characteristic, as I understand it, is as an administrative tag to identify a center. If one reviews a core grant, that is not reviewing the center. Perhaps the center should be reviewed periodically as a center."

"That is only one step, not a definitive requirement," Shingleton said.

"The Board's motion was concerned only with the major core grant (not the cancer control core grants)," NCAB Chairman Henry Pitot said.

"I would agree that a failing core grant is a sign of major trouble," Owens said.

Steiner was concerned with the requirement that the director of the comprehensive center control beds. That is not possible with consortium centers, he said.

The discussion moved on to the question of whether cancer control core grants should be considered as important as the support core grants in retaining comprehensive status.

"If a center loses its support core grant but retains the cancer control core, does that trigger a review?" Terry asked.

"Turn it around," Steiner said. "If you lose a cancer control core but keep the support core, does that trigger a review? In my opinion, a cancer control core grant is as important as the other."

Shingleton suggested that the two types of core grants might be combined. "There was a storm of opposition to that idea when I brought it up at the AACI meeting," Terry said.

"If you have type A support core and it fails, that is alarming," Owens said. "That is reason for review. If you have type B, cancer control core, and it fails, that is equally alarming."

Murphy noted that six comprehensive centers do not have cancer control core grants, although some of them have cancer control activities that are not federally supported. "These places have already been designated as comprehensive. Why solve one problem and create another for six centers?"

Shingleton insisted that the Board's motion dealt with the support, or research, core grants, and Murphy agreed.

After a discussion on whether a comprehensive center must have its own clinical investigations (in addition to participation in national and/or regional trials), Terry asked, "Would it knock them out if they don't?"

"Yes," Owens answered, and no one argued with him. Henderson said that "national and regional trials are more important. Be sure they do not use that rather than participate in national or regional studies."

On the uniform data system issue, Murphy said that R. Lee Clark, president emeritus of the Univ. of Texas System Cancer Center (which includes M.D.

Anderson Hospital) and others "feel strongly that there are uniform data systems and that it should be shared, but they take umbrage at the requirement for a specific system (CCPDS)."

"Every comprehensive center is participating in CCPDS," Terry said. "M.D. Anderson has a CCPDS grant but is not submitting data to it. USC has no grant but is submitting data. We have 18 working together, submitting data. We have to determine if it is useful in epidemiology and other studies. Because one institution is strongly opposed, I wonder if we should back off from requiring this system?"

"That may be a concern of others, not just one," Murphy said. "There is a feeling by some that this is making the system more important, rather than the principle of data exchange."

"Uniformity is essential. I don't see how it can be if we do not all use the same system," Shingleton said.

"The minimum data set in CCPDS is not doing the job required," Steiner said. "It is limited. There is a need for a research data base. But I agree it has been a tremendous achievement to get it going."

"I do not want to erode the investment in CCPDS," Terry said. He pointed out that the wording of the particular requirement had already been changed from "must" to "should . . . I wonder if backing off further is necessary?"

"Why drop 'must'?" Pitot asked. "It's a minimal thing from the old characteristic 8. Why not leave it in?"

"In the past, there was a concern that data were utilized inappropriately," Murphy said.

"Was that concern expressed by a small voice or a large one?" Shingleton asked.

"Make the change and you'll hear it yourself," Murphy said.

"What if an applicant says he won't participate?" Henderson asked.

"I would say not recognize him," Steiner answered.

In discussion of guideline No. 5, administration, as it had first been written, Steiner said, "Adoption of items b and c or anything like it would be de facto derecognition of consortia centers." He asked that a more general requirement of a "commitment of these resources" to the center be included specifically for consortia centers.

"Consortia centers have already been recognized as comprehensive without that exception," Murphy said. "Staff and site visitors can make the correct interpretation. If we try to clarify the guidelines for one group, others would want other clarifications."

"The peer review system needs to be reinforced," Steiner said. "Site visitors are permissive, but we have five years of experience which we should take note of."

"We may need a separate discussion of consortium centers," Terry said. "We could have general characteristics explicitly for consortia centers, and point out that administrative requirements for them are different."

"I like the statement like it is," Owens said. "Is there a likelihood of more consortia centers?"

"The first center to be reviewed under these guidelines will be a consortium center," Terry answered. He explained that in the review of existing comprehensive centers by the NCAB on how well they were living up to the characteristics, site visitors at Colorado called for another review in the spring of 1980. Colorado's problem with a core grant also would require review.

"The NCAB has accepted diversity," Steiner said. "There are university based, free standing, and consortia centers. There are two comprehensive centers in Los Angeles. Maybe the Illinois model is better for the National Cancer Program than the Los Angeles model (of two comprehensive centers in a city rather than a consortium)."

Steiner argued for a general statement which would say, "None of these guidelines need be strictly applied."

"That would invalidate the guidelines," Terry said. "If a center is not up to snuff, it could say, 'Well, you say we don't have to be.' "

Terry commented that control over appointments is necessary "to effectively direct the center."

"I don't have personal control," Steiner said. "The deans make the appointments."

"We have shared control at our center," Shingleton said.

David Goldenberg, executive director of the Kentucky Cancer Control Network who is on a sabbatical to work at NCI, was an observer at the subcommittee meeting. "These guidelines are important for institutions aspiring for comprehensive recognition," Goldenberg said. "We use them to obtain concessions from participating institutions and departments. This document will be used beyond the review process. I urge you not to relax it."

Steiner eventually agreed with the others that by inserting the word "necessary" before "control over professional and staff appointments," the guidelines would be acceptable to him.

Steiner and Pitot argued over the emphasis on "science" in the guidelines. "Science is not everything we do," Steiner said and pointed out that most comprehensive centers participate in the Cancer Information System.

"That's information science," Pitot said. "It doesn't have to be research to be science."

"The conduct of education programs is not research," Steiner said.

"You equate science with research," Pitot said. "I disagree. Knowledge is science. NIH is in the business of supporting excellence in science, not excellence as a whole."

"I don't disagree with a thing you said, but in re-

ality, some things are going on which I have difficulty calling scientific."

"Which?" board member Mary Lasker asked.

"I better keep my mouth shut," Steiner said.

UPTON SAYS NCI TO PROCEED WITH ONE NEW DIVISION, DROP PLANS FOR ANOTHER

Director Arthur Upton wrapped up the reorganization of NCI last week, completing the process he started soon after he came to the job, when he outlined to the National Cancer Advisory Board the components of one new division and announced he was dropping a proposal to create another.

There were no surprises. The new division will include all components of the Div. of Cancer Control & Rehabilitation plus the other programs left without a home when Upton decided in January, 1978, to remove the program elements from the Div. of Cancer Research Resources & Centers, make it into a grant and contract review division, and permit the remaining program divisions to administer grants along with their contract and intramural programs.

Upton also dropped his proposal to establish a new Div. of Cancer Prevention, for a number of reasons.

The new division will be named (unless someone can come up with a better one), the Div. of Cancer Control, Centers, Community Activities & Resources. Moving into it with the control and rehabilitation activities will be the Centers, Construction, Education and Training, and Organ Site Programs. The latter includes the Urinary/Bladder, Large Bowel, Prostate and Pancreas Cancer Programs.

Upton told the Board that a search committee chaired by Thomas King is "actively seeking and evaluating candidates for the permanent director position" for the new division. William Terry, who has been acting DCCR director, will head DCCCCAR in the interim. Terry also will continue as acting head of the Centers Program until the new division director (who very well could be Terry) is on the job, and he/she will choose someone to run the Centers Program.

Upton said Terry has been asked to prepare a detailed plan for organizing the new division and for integration of control, centers, demonstration, outreach and education activities and for collaboration and coordination with other divisions and the Office of Cancer Communications.

This plan will determine where the various components will fit in the division. For instance, the Centers Program probably will be at the "program" level, one step below the director's level and one step above branch status. It would be headed by an associate director for centers and probably something else.

Reorganization at the division level must be approved by the HEW secretary and will have to go through the NIH director and assistant secretary for health. NCI executives would like to see it approved by the end of the year, but in view of HEW's normally glacial pace that is not very realistic.

Upton said he had decided against a new prevention division because of:

"1. The existence of the National Toxicology Program and its promise as an effective mechanism to facilitate NCI's liaison with and support to the Secretary and regulatory agencies in the area of carcinogenesis testing and risk evaluation.

"2. Creation of the new DCCCCAR, which now provides the basis for integrating control activities in prevention with the relevant activities in education, training, centers and organ site programs.

"3. The crucial importance of research activities in the Div. of Cancer Cause & Prevention, and to a lesser extent in both the Div. of Cancer Biology & Diagnosis and Div. of Cancer Treatment, to effective control programs in cancer prevention and screening."

Under this arrangement, Upton said, DCCP will bear major responsibility for identification of risk factors—inherited, acquired, environmental; elucidation of mechanisms of action; development of measures for eliminating, blocking, inhibiting, or reversing carcinogenic process; and laboratory and field studies to accomplish these goals.

DCBD will be responsible for basic and applied research in cancer biology and measures for detection, diagnosis, staging, characterization of tumors and for monitoring their course; and development of understanding of biology of cancer, critical to all approaches toward prevention and detection of cancer.

DCT will be responsible for development of measures for arresting or reversing the further development or recurrence of clinically detectable cancers or precancerous lesions; and evaluation of efficacy of such measures.

The new division will expedite the application of new knowledge in practical measures for the prevention and early detection of cancer; and will require:

a. Continual surveillance of status of all relevant knowledge, and vigorous exploitation of developing leads through assistance to, or collaboration with, other divisions at NCI or investigators in the scientific community at large.

b. Systematic evaluation, in advance, of prospective intervention, through appropriate laboratory or field studies, as needed to insure the timeliness and scientific validity of such intervention.

c. Ongoing evaluation of effectiveness of interventions, with a view toward continuing refinement of strategies providing maximum benefit to greatest number in population with least risk and cost.

d. Development of close liaison with cancer centers, public and professional educational organizations, public health groups and agencies, labor unions, trade and professional associations, and regu-

latory agencies, to foster communication, exchange of information and cooperation.

e. Close collaboration with all other divisions at NCI, the NTP, OCC, other NIH institutes, and other national and international research institutions.

Upton described briefly the National Toxicology Program, of which NCI's Carcinogenesis Testing Program is a major part. Its functions include actual performance of large scale testing procedures; development, refinement, and calibration of test methods; and assistance to the Secretary and regulatory agencies in evaluation of test data, for purposes of risk assessment, in general.

Administrative responsibility for the NCI component of NTP is no longer in DCCP,

The reorganization package will include changing the name of DCRRC to the Div. of Extramural Activities, as previously reported. Upton said that King would continue as director of that division.

"These proposals complete the process of reorganizing the institute initiated last year," Upton said. "Pending reports from each division on its prevention related activities and plans, no further organizational changes are foreseen at this time. I extend my sincere thanks to all members of the institute staff for their patience, understanding, advice and cooperation during this difficult and lengthy period. I am confident that upon full implementation of these important changes and with the continued cooperation of a truly excellent staff, the National Cancer Institute will be organized to fully meet the challenges of the 1980s which we are about to face."

FOX CHASE-U.PA. RADIATION THERAPY DEPARTMENT HAS NCI NEUTRON CONTRACT

Reports in ***The Cancer Letter*** on the award of the neutron radiotherapy contracts by NCI have created some confusion about the institutional arrangements in Philadelphia, where one of the three facilities will be developed.

The Fox Chase Cancer Center and the Univ. of Pennsylvania collaborate in the operation of the NCI recognized Fox Chase-Univ. of Pa. Comprehensive Cancer Center. There is one Dept. of Radiation Therapy for both institutions. Robert Goodman is chairman of the department and is principal investigator for the neutron radiotherapy contract. Professional staff of the department is 100% employed by the university, and technical staff of the department at Fox Chase are employed by Fox Chase.

The Fox Chase-Univ. of Pa. neutron facility will utilize a DT generator developed with an NCI grant to U. Pa. James Brennan was principal investigator for that grant. He is now emeritus professor of radiation therapy and is a consultant on the neutron contract. Peter Bloch, co-PI with Brennan on the grant, is co-PI with Goodman on the contract.

The DT generator was developed with the cooperation of the Cyclotron Corp. of Berkeley, Calif.

REQUEST FOR APPLICATION

RFA NIH-NCI-DCBD-DB-79-1

Title: *Identification and evaluation of biophysical probes suitable for distinguishing malignant cells in automated instrument (cytology automation)*

Deadline: *Nov. 15*

The Div. of Cancer Biology & Diagnosis of NCI is inviting grant applications to identify probes for nuclear, cytoplasmic and/or membrane structure and fluidity applicable to automated instrument sensing for differentiating normal and malignant cells.

DCBD has major responsibility in the Diagnosis Branch for research in early diagnosis of cancer. The widely used practice of routine cytological screening of exfoliated cervical and vaginal cells has been followed by a decrease in the mortality rate of cancer of the uterine cervix.

Development of automated instrumentation capable of screening large populations should result in a larger number of early malignant lesions being detected.

DCBD is currently supporting a Cytology Automation Program with the ultimate goal of perfecting automated screening of gynecologic samples to determine the presence or absence of premalignant and malignant cells.

Automated systems currently undergoing development and testing include both flow and static high resolution systems. The program has supported development and evaluation of new markers applicable to gynecologic specimens. Several cytochemical markers have been studied. The program effort has emphasized the application of optical techniques such as fluorochrome and absorption dye staining of macromolecules; light scattering techniques have also been studied.

Technology and instrumentation now exist for the study of physical properties of cells such as nuclear, cytoplasmic and membrane structure and fluidity, and degree of chromatin condensation. These techniques include fluorescense depolarization and inter- and intramolecular energy transfer. New probes are desirable since they may reveal distinctive information concerning normal, premalignant, and malignant cells.

It is the intent of this RFA to stimulate research in identification and evaluation of new biophysical probes for existing instrumentation in flow and static cell analysis systems. It is hoped that this research will lead to innovative approaches to automated system(s) that can be employed to screen normal and abnormal cells.

The proposed study may employ model cell systems; however, if possible, the applicant should test developing methodology on gynecologic specimens.

The support mechanism for this program will be the traditional NIH grant-in-aid. Successful applicants will plan and execute their own programs. It is an-

ticipated that at least three awards will be made by NCI and the proposal should not exceed three years. The total approximate level of support for year 1 is $300,000; $350,000 for year 2; and $400,000 for year 3. July 1980 starting dates are anticipated.

Upon receipt, applications will be reviewed by the NIH Div. of Research Grants and the NCI staff for responsiveness to this announcement. If the application is judged unresponsive, the applicant will be given an option to withdraw the application or to submit it for consideration in the traditional grant program of NIH.

Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group in Feb. 1980. The recommendations of the peer review group will be considered by the National Cancer Advisory Board in May 1980.

The factors considered in evaluating each application will be:

1. The scientific merit of the proposed approach. Technical merit includes adequacy and innovation of methodological approach, research design, and statistical analysis.
2. The expertise and qualifications of the principal investigator and proposed staff including pathology support.
3. Documentation of the adequacy of the facilities and appropriate collaboration for clinical specimens.
4. Evaluation plan and timetable for completion of each proposed task.
5. Provision for human subjects protection and copies of informed consent forms as necessary if human derived cells are proposed to be used.
6. Documentation of proper animal welfare provisions if it is proposed to use animals.

Application should be submitted on form PHS 398. The conventional presentation for grant applications should be utilized and the points identified above must be fulfilled. The words "Identification and evaluation of biophysical probes suitable for distinguishing malignant cells in automated instrument (cytology automation)" must be typed in bold letters across the top of the face page of the application.

The present RFA announcement is open to all interested investigators. Applications must be received no later than Nov. 15, 1979. Applications received after this date will be returned. The original and six copies of the application should be sent or delivered to:

Application Receipt
Div. of Research Grants
National Institutes of Health
Room 240, Westwood Bldg.
Bethesda, Md. 20205

A brief covering letter should accompany the application indicating that it is in response to this RFA. A copy of the covering letter should be sent to:

K. Robert McIntire, M.D.
Director for Diagnosis Program
Chief, Diagnosis Branch
Div. of Cancer Biology & Diagnosis
Room 10A10, Westwood Bldg.
Bethesda, Md. 20205

Questions concerning this announcement may be directed to McIntire. His phone number is 301-496-1591.

NCI CONTRACT AWARDS

Title: Professional education in cytology related to bladder, lung, colorectal and cervical cancer
Contractors: Univ. of Washington, $387,203; and St. Louis Univ., $222,007.

Title: Data management support for the "hospice" demonstration project, 15-month renewal
Contractor: Information Management Services Inc., Bethesda, Md. $99,564.

Title: Cancer control program for clinical cooperative groups—Children's Cancer Study Group, six-month extension
Contractor: Univ. of Southern California, $357,455.

Title: Cancer control program for clinical cooperative groups—Southwest Oncology Group, six-month extension
Contractor: Univ. of Kansas, $499,289.

Title: Development of a course on prevention, focusing on cancer, for undergraduate medical students and/or residents, 3-year contracts
Contractors: Univ. of Wisconsin, $197,184; Michigan State Univ., $281,021; Wayne State Univ., $937,714; State Univ. of New York, Buffalo, $166,927; Maryland Cancer Program, $559,134; Baylor College of Medicine, $305,901, and UCLA Medical Center, $263,330.

Title: Development of a model post-master's fellowship program in oncology nursing education
Contractors: Univ. of Alabama, $646,048, and San Jose State Univ., $908,012.

Title: Studies and investigations on therapy of patients with stage II and stage III carcinoma of the breast, continuation
Contractor: Case Western Reserve Univ., $99,500.

Title: Studies of the distribution, disposition and metabolism of antineoplastic agents
Contractor: Ohio State Univ., $294,833.

The Cancer Letter _Editor Jerry D. Boyd

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ticipated that at least three awards will be made by NCI and the proposal should not exceed three years. The total approximate level of support for year 1 is $300,000; $350,000 for year 2; and $400,000 for year 3. July 1980 starting dates are anticipated.

Upon receipt, applications will be reviewed by the NIH Div. of Research Grants and the NCI staff for responsiveness to this announcement. If the application is judged unresponsive, the applicant will be given an option to withdraw the application or to submit it for consideration in the traditional grant program of NIH.

Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group in Feb. 1980. The recommendations of the peer review group will be considered by the National Cancer Advisory Board in May 1980.

The factors considered in evaluating each application will be:

1. The scientific merit of the proposed approach. Technical merit includes adequacy and innovation of methodological approach, research design, and statistical analysis.
2. The expertise and qualifications of the principal investigator and proposed staff including pathology support.
3. Documentation of the adequacy of the facilities and appropriate collaboration for clinical specimens.
4. Evaluation plan and timetable for completion of each proposed task.
5. Provision for human subjects protection and copies of informed consent forms as necessary if human derived cells are proposed to be used.
6. Documentation of proper animal welfare provisions if it is proposed to use animals.

Application should be submitted on form PHS 398. The conventional presentation for grant applications should be utilized and the points identified above must be fulfilled. The words "Identification and evaluation of biophysical probes suitable for distinguishing malignant cells in automated instrument (cytology automation)" must be typed in bold letters across the top of the face page of the application.

The present RFA announcement is open to all interested investigators. Applications must be received no later than Nov. 15, 1979. Applications received after this date will be returned. The original and six copies of the application should be sent or delivered to:

Application Receipt
Div. of Research Grants
National Institutes of Health
Room 240, Westwood Bldg.
Bethesda, Md. 20205

A brief covering letter should accompany the application indicating that it is in response to this RFA. A copy of the covering letter should be sent to:

K. Robert McIntire, M.D.
Director for Diagnosis Program
Chief, Diagnosis Branch
Div. of Cancer Biology & Diagnosis
Room 10A10, Westwood Bldg.
Bethesda, Md. 20205

Questions concerning this announcement may be directed to McIntire. His phone number is 301-496-1591.

NCI CONTRACT AWARDS

Title: Professional education in cytology related to bladder, lung, colorectal and cervical cancer
Contractors: Univ. of Washington, $387,203; and St. Louis Univ., $222,007.

Title: Data management support for the "hospice" demonstration project, 15-month renewal
Contractor: Information Management Services Inc., Bethesda, Md. $99,564.

Title: Cancer control program for clinical cooperative groups—Children's Cancer Study Group, six-month extension
Contractor: Univ. of Southern California, $357,455.

Title: Cancer control program for clinical cooperative groups—Southwest Oncology Group, six-month extension
Contractor: Univ. of Kansas, $499,289.

Title: Development of a course on prevention, focusing on cancer, for undergraduate medical students and/or residents, 3-year contracts
Contractors: Univ. of Wisconsin, $197,184; Michigan State Univ., $281,021; Wayne State Univ., $937,714; State Univ. of New York, Buffalo, $166,927; Maryland Cancer Program, $559,134; Baylor College of Medicine, $305,901, and UCLA Medical Center, $263,330.

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