THE CANCER LETTER

Vol. 11 No. 16
April 19, 1985

Subscription $150 year North America
$175 year elsewhere

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

PB-85041-01974

CENTER LEADERS OK CONSORTIUM CENTER GUIDELINES, GO ALONG WITH MOST CORE GRANT CHANGES BACKED BY NCI

Cancer center executives surprised NCI staff and probably themselves when they accepted with only modest modifications the concept and draft guidelines for a new consortium cancer center grant and in the same day went along with most staff changes

(Continued to page 2)

In Brief

BREAST CANCER DIET STUDY PROBLEMS RESOLVED, FUNDING RESUMED FOR NUTRITION COORDINATOR

PROBLEMS FACING the Stage 2 low fat breast cancer trial initiated by NCI's Div. of Cancer Prevention & Control have been resolved and the study will start May 1 (**The Cancer Letter,** Feb. 1). Funding for the Nutrition Coordinating Unit at the Univ. of Minnesota has been resumed after modifications in the management process recommended by the DCPC Board of Scientific Counselors were implemented. The committee also accepted advice of the study's steering committee to limit it to patients age 50 and older so that it could be done without chemotherapy. It will be a nutrition adjuvant study, with patients randomized to 15 per cent fat diet or their normal diet. Controversy had arisen whether to include chemotherapy following surgery; some felt drugs might make compliance with diet changes difficult and would add too many variables. Not offering chemotherapy to women under 50 is considered unethical by many since survival seems to be significantly improved by many drug regimens in premenopausal patients. The first phase of the trial will monitor accrual rate and patient compliance to the low fat diet. DCPC had intended to complete the first phase in time for consideration by the BSC in September on whether to proceed to the full study. That decision probably will have to wait now until the Board's February meeting.... **JOSEPH AINSWORTH,** who has more than 35 years experience in medical practice and administration, has been named vice president for patient care at M.D. Anderson Hospital & Tumor Institute. Ainsworth joined MDA staff in 1977 after practicing family medicine in Houston for 28 years. He has been associate VP for patient care.... **ADDENDUM:** During the National Cancer Advisory Board's discussion of the resolution against smokeless tobacco (**The Cancer Letter,** April 12), Victor Braren said, "My hometown has the largest facility in the world for production of smokeless tobacco, but I heartily endorse this resolution. I'm negatively impressed each time a see a young athlete with a chew of tobacco in his mouth." Ed Calhoon, an American Medical Assn. delegate member, added, "We at AMA oppose any kind of subsidy for tobacco, and we heartily endorse this resolution."

CENTER EXECUTIVES OBJECT TO KEEPING PRESENT CORE GRANT RENEWAL CEILING

(Continued from page 1)

in cancer center core grant guidelines. The April 12 meeting of NCI staff with centers personnel was in pleasant contrast to the four year long series of contentious meetings that resulted from the last major revision of core grant guidelines.

Only one serious disagreement emerged this time. Staff had recommended that no changes be made in the core grant ceiling which holds renewals to budgets no more than 50 per cent higher than their current levels. Newer centers, smaller centers and others whose core grants for whatever reason are smaller than the average complained that the percentage cap unfairly restricts their growth. The majority of centers staff at the meeting agreed to go along with keeping the cap for now but with the provision that a study group be established to develop for consideration alternative methods of holding down core grant budgets.

NCI Director Vincent DeVita had hoped that he could present a complete package of guideline changes along with the new consortium mechanism to the National Cancer Advisory Board in May. He asked that the cap issue be reconsidered and that the centers representatives come up with an alternative to the percentage cap. They reconsidered, but the answer was the same.

The NCAB will be get the guideline changes with no change in the cap, but the current budget situation with the centers program may force some revision eventually. (see following story).

The consortium cancer center grant is aimed at developing regional cancer control entities.

A preamble to the draft guidelines states:

"The primary intent of this grant program is to stimulate and facilitate development of research in cancer control by encouraging the formation of an effective consortium among public health agencies and other organizations with competence in disease control research such as universities, cancer centers, centers for the study of the control of other diseases, health maintenance organizations, private foundations and community based organizations; such a consortium to have as its goal developing and implementing a program of cancer control and related research within a defined region. The establishment of linkages between such research institutions and public health agencies should provide the infrastructure by which a logical progression of cancer control research, technology transfer and cancer control application can take place regionally. This type of center addresses an area of special importance in accomplishing the Year 2000 goals for cancer prevention and management of the National Cancer Program.

"This program is intended to provide support to a consortium cancer center for developing a cancer control research program relevant to the populations in the region in which the consortium is formed. The grant will support planning and advisory committees, an administrative core, senior leadership, and shared resources and services. In addition, the grant will provide developmental funds for qualified researchers for pilot cancer control research projects and new shared resources. The developmental funds will be provided with the intention that pilot efforts will later be developed into applications. Research projects and researchers should be self supporting through other grant support after no more than three years of support from this grant.

"This program is intended to involve agencies responsible for regional public health programs in the research process. Thus, a requirement of the grant program will be an established cooperataive working relationship between cancer oriented cancer control research staffs of health organizations and other institutions of the consortium."

Uppermost in the concerns of the centers representatives was where the money to support the new program would be found. "We're all positive about the concept," John Ultmann, Univ. of Chicago, said. "But it should be done with new dollars and not be taken from the present core grant budget."

"I assume there is unanimous acceptance for that position," Cancer Centers Branch Chief Lucius Sinks said.

Saul Rosenberg, Stanford Univ., who has had considerable experience in getting a consortium center (Northern California Oncology Program) through the review process under existing center guidelines, said "It has been extremely difficult over the years to get appropriate review for consortia. Review must recognize the different strengths and compromises." Rosenberg also expressed concern that the consortia guidelines not preclude basic research. The guidelines "need to be tailored to institutions and regions," he said.

"That has to be looked at from the standpoint of the review process," Ross McIntyre, Norris Cotton Cancer Center, said. "I urge that whatever form the centers program falls into, the review be of as high quality as possible."

Gilbert Friedell, Univ. of Kentucky, questioned "the issue of eligibility. Even before you get to review, you have to qualify (by having a base of cancer control and related research). Are areas which do not now have funded cancer control programs going to be eligible?"

"That is an important question," Sinks said.

Palmer Saunders, Univ. of Texas (Galveston),

noted that "two outstanding examples of consortium centers are the Northern California Oncology program and Illinois Cancer Council. They operate very effectively under the regular guidelines. Is it necessary to formulate a new program for consortium centers now, particularly in view of the budget problems? Is there money available?"

Shirley Lansky, Illinois Cancer Council, commented that "the problems we have had have been with review."

"Our position is that the present core grant guidelines are primarily for the support of basic science," Sinks said. "The intention (with the consortium grant) is to help centers extend their activities to cancer control research. No exclusivity is intended."

Richard Steckel, UCLA, noted that the consortium grant would be based on the "ability to generate peer reviewed support. You might want to consider exploratory or planning grants." The proposed guidelines do contain provisions for support of developmental projects which are intended to be self supporting within three years.

David Kiszkiss, Dana-Farber Cancer Institute, commented that the guidelines provide no support for the application of cancer control activities. Sinks responded that some states are appropriating money for cancer cantrol application. "We've viewed this instrument (consortium grant) as giving centers in the consortia ability to do cancer control research and to interface with state agencies, with the application (of the research findings) being funded by those agencies."

John Hisserich, Univ. of Southern California, commented that in Los Angeles there are two comprehensive cancer centers, either of which could be the lead institution in a consortium that would include the other. "We work together, frequently and well, but the question of who is the lead institution involves indirect costs, subcontracts, etc. The problem (with agencies not universities or cancer centers serving as the lead institution) is that they seldom have peer reviewed research (to form the qualifying base). That implies that the lead center has to be a cancer center or university."

"The door is open in that regard," Sinks said. "The lead institution can be a university, or a city or state health department. The amount of peer reviewed research (for the qualifying base) would be that credited to all the partners in the consortium."

"This is a timely proposal," Ultmann said. "The idea of flexibility can't be overemphasized. Existing cancer centers are aware of relationships in their own areas that can be enhanced. But centers are under severe pressure, with a terrible strain on our resources. We need to bring this to the attention of Congress. We need this (consortium grant) as a national program. My feeling is that it is an issue that can capture the interest of Congress."

Charles Moertel, Mayo, added a cautionary note. "I'm a bit concerned that we might be going down the road of confusion that we've traveled before. What constitutes cancer control, and what is cancer control research? We have to be careful that this not evolve into service programs. The states look at cancer control as service to patients. On the other hand, as your division recently has determined, cancer control is research, not service. We've been hung up over that in the past."

Also, Moertel added, "You've had a very hard time getting competent (cancer control research) proposals past peer review."

Jerome Yates, DCPC associate director for the Centers & Community Oncology Program, said "The intent is to maintain cancer control as a research activity. As we do more cancer control research, the expertise we develop will spill over into other areas. In the past, there was some excellent cancer control research, but there were also some cases where the dollars went to communities for service. We do not intend to do that."

"We've been hearing that for a long time," Michael Brennan, Michigan Cancer Foundation, said. "But you can't do cancer control research without doing cancer control service. Otherwise, it will just be research in books."

Jon Kerner, Memorial Sloan-Kettering, observed that phase 3 and 4 cancer control research studies require the evaluation of cancer control service. Yates added, "Obviously, you can't always cleave research from service when the service arm is part of the research. The intervention arm would have to be supported. But we're not interested in supporting willy nilly service programs."

F.J. McKay, Fox Chase, asked if funds from the consortium grant could be used to recruit senior people. "Can you or can you not support staff investigators with developmental funds?"

"Part of this is to help institutions build up staff until they can compete for a CCRU (cancer control research unit grant) or something similar. That's part of the intent of this whole instrument. We can make that clear in the rewrite."

"It would be an anachronism to restrict this to people without prior NIH support," Steckel insisted.

Barbara Bynum, director of the Div. of Extramural Activities, said she agreed "on the need for flexibility in reviewing consortium grants. We intend to tailor the review group to the participants in the consortium being reviewed."

Charles Mittman, City of Hope, commented that the

"review process is designed to evaluate center administration and other aspects to arrive at a priority score and to determine the budget. But when the final budget bears no relation to the review process (as when NCI reduces the budget to an amount less than the recommended level), it corrupts the process."

Sinks wrapped up consideration of the consortium guidelines by commenting, "Unless I hear a wave of negativity, we intend to take your comments, rewrite these guidelines and present them to the Board of Scientific Counselors in May."

Revising the guidelines for regular cancer center grants generated little heat, mostly agreement.

NCI proposed eight changes; center executives dragged their feet only on retention of the ceiling for renewals. Possible changes to the cap of 50 per cent over the current level listed by staff included no change; lowering the cap to 25 per cent; raising it to 100 per cent for either all centers or for those with direct costs in the current core grants less than $1 million a year; and eliminating the cap entirely.

Reasons listed for maintaining or lowering the cap were (a) applications are more realistic in relation to funds available; (b) a cap is desirable because of the "entitlement" nature of staff investigators salary support from the core grant; (c) it limits the size of core grants thus allowing more centers to be supported.

Reasons for raising the cap or eliminating it were (a) it limits growth of rapidly developing centers; (b) the actual increase is small for centers with small core grants.

Sinks noted that of the 59 centers with core grants, 43 have direct costs under $1 million.

NCI's position was that the ceiling should remain as is, but the center representatives were split. One suggestion was offered that centers be offered the option of no cap if they would waive the support for staff investigators.

Enrico Mihich, Roswell Park, suggested that "a certain cap should be there, if for no other reason because of the funds limitation. Also, we're being eaten up by inflation." He said the 50 per cent limit might be acceptable if inflation could be taken into account.

"You want an adjustable rate mortgage," Sinks quipped.

"Let's drop the cap," Saunders said. "It is a terrible trick on new centers, who can grow only at a slow rate, even if the money is available. I would recommend we drop the cap and leave the budgets to reviewers. Their recommendations are reasonable and not too generous."

"They're generous to the point where for the last two years they have recommended increases of 30 per cent," Sinks answered (see following article).

"I support the concept of allowing smaller centers to develop," Rosenberg said. "The current system is very limiting."

"My bias is that staff investigator support should be totally eliminated," Mittman said.

"It would be a disaster to remove the cap," Harry Eagle, Albert Einstein, said. "We need to adjust the cap to the needs of institutions. To remove the cap in return for eliminating staff investigator salaries is a shell game. I'm writing a renewal application now, and 50 per cent gives us everything we need."

"I'm in favor of dropping the cap," Robert Hickey, M.D. Anderson, said. "Smaller centers are disproportionatey handicapped."

"As one of the small centers, I appreciate that sentiment," Friedell said. "The present cap restricts us unduly."

The group in general agreed that the issue should be presented to an ad hoc group which would be asked to develop alternative recommendations. Sinks pointed out there would not be time to do that before the May meetings of the DCPC Board and the National Cancer Advisory Board, and the group agreed the recommendation to the Boards now would be not to make any change in the ceiling but inform them that future changes were being considered.

The discussion resumed after the group was informed that DeVita was pressing for firm recommendation now.

Yates referred to what he called the "Mittman and Yale plans," in which core support would be based on the amount of peer reviewed research of a center. He said that would be very difficult to administer. "Removal of the cap entirely creates a problem for review. We would see extraordinarily inflated applications. The review committee would have to rewrite the grant."

"None of the cap formulas make much sense," Moertel said. "Clearly, this program is designed to provide core support for peer reviewed research. That's all it is. You have to hone in on how well the funds are being administered. We depend on peer review to do that."

"All these years we've had the centers program, it is strange that a set of guidelines should produce such a range of species," Brennan said. "NCI probably has abandoned the idea it can use these funds to stabilize support for investigators in large institutions around the country. We're past the time we can use them for that purpose. Now it is for coordinating work, with some developmental funds. I doubt if anyone can show merit for much more than a million a year. The large amounts for core investigator salaries should be looked at."

When Sinks asked for a show of hands on various options, a majority voted for the previous recommendation—make no changes now but reexamine the issue; only four voted for eliminating the cap entirely; and about a third voted for a cap with a sliding scale, adjusted to the size of the grant.

"The show of hands indicates a large majority is not in favor of removing the cap," Eagle said. "So the issue is how to adjust the cap, to make it more flexible and fair."

Sinks said he agreed and would convene an ad hoc group to develop alternatives.

Other changes and potential changes presented to the group included:

*Developmental funds. Present guidelines prohibit rebudgeting of developmental funds for nondevelopmental purposes. A reason for changing the policy is that center directors cannot always anticipate changing needs and flexibility to budget to other areas may be desirable. Staff recommended no change, however.

Saunders suggested that centers be permitted to carry over developmental funds from one year to the next. "There has been a tendency on the part of NCI not to allow carryover. I urge you to put it into the guidelines that carryover of developmental funds may be permitted, with NCI approval."

Albert LoBuglio, Univ. of Alabama, had a different view. "My concern is that when NCI cuts 20 per cent, the director should be able to switch money around. It is important to keep the wording as is. I need to protect my developmental money."

Leo Buscher, chief of the Grants Administration Branch, said that carryovers are looked at on an individual basis and are sometimes permitted.

The group agreed on no change.

*Cap of $60,000 per year investigator ceiling for developmental changes. Staff suggested deleting the requirement because inflation makes it overrestrictive. Also, "the track record of a center can be adequately reviewed by review committees." Center representatives agreed enthusiastically with dropping the limit.

*Rebudgeting. Present guidelines permit the center director to rebudget funds for senior leadership, major program directors, shared resources, administration and eligible staff investigators. Staff recommended no change and the group agreed.

*Major program directors. Present guidelines say major program directors must now have a funded grant to be eligible. Staff recommended dropping this requirement because "an individual can be adequately peer reviwed as a major program director using criteria other than a funded grant. This requirement has caused difficulty in the past."

Henry Pitot, McArdle Laboratory, objected. "If you do this without any caveats, I would be against it. If you take a person with no grant or who has never had one, you would need to have some characteristics."

"To express the other point of view, that could be left to the review process," Mittman said. "It can be easily defined whether an individual is doing an effective job."

"The concern is in clinical centers," Yates said. "People are running clinical research programs who have never had a grant. The ability to meet this requirement is variable."

"Peer review groups are very astute," Saunders said. "We need to have senior people on review groups, people who understand the problems of scientists and clinical investigators."

Paul Carbone, Univ. of Wisconsin, said he supported the change. LoBuglio added that the guidelines should have some statement of qualifications for program leaders.

"If we tighten up the qualifications, would that meet the objections of Dr. Pitot and Dr. Eagle?" Sinks asked. Pitot insisted that "some sort of track record in research" would have to be required. "The way this reads opens the door to anyone. You could have a hospital administrator as director of a comprehensive cancer center."

Nevertheless, the group agreed on the recommended change, with some qualifications written into the guidelines.

*Substitutions for staff investigators. Present guidelines do not permit substitution of additional staff investigators for those ineligible at time of award. Eligible support is defined as unfunded salary representing the peer reviewed percentage of effort in awarded research grants or contracts. Ineligible amount is now deducted at award time from the recommended level.

Staff suggested dropping that limitation, making the principal investigator of the core grant responsible for determining eligibility. "As long as there is a 25 per cent cap, the staff investigator level will be contained; core grant awards can be contained by the 50 per cent limit; and policies should permit any investigator to be charged to the core grant and responsibility for determining eligibility should be the grantee's," the staff rationale said. There was no disagreement from center representatives.

*Staff investigators cap. The current guidelines place a maximum of 25 per cent of the previous award, with phase down required if the current award is higher. Excess funds cannot be rebudgeted but are deleted in subsequent years. Staff recommended no change, and the group agreed.

*Staff investigators duplicate funds. Present guidelines limit retention to only 50 per cent of

funds in the core grant when staff investigators get duplicate salaries elsewhere. Staff proposed that be changed to retention of 100 per cent, with rebudgeting of staff investigator salaries and substitutions are permissible.

The rationale for the change said, "The staff investigator budget will either be in phase down or will soon be in phase down. Therefore, there is no need to bother about single adjustments. The amount of funds returned to NCI now is not worth the staff time involved because center directors are currently rebudgeting in order to avoid duplicate support."

Center representatives went along with the staff recommendation.

PB-8504-017975

CORE GRANT BUDGETS SHORTED BY BIG INCREASE IN LEVELS APPROVED, OMB

The 11 cancer centers whose core grants were up for renewal this year have been presented with a mixed bag in the amount of money they will get.

The four whose renewals were awarded in the first cycle of the 1985 fiscal year made out all right. They received 95 per cent of the peer review recommended funding levels.

The seven who were unlucky enough to have their grants renewed in the second cycle are facing a much different situation. They have been told that for now, they should count only on receiving a five per cent increase over their current level.

Two factors contributed to this seemingly unfair and unreasonable situation. First, even with the cap on renewals of core grant budgets, those budgets grew 30 per cent more than NCI staff had anticipated. When the decision was made to fund the first four at 95 per cent of recommended levels, it appeared the centers program budget of $84 million would be enough to support all renewals at that level.

Second, the policy of the Office of Management & Budget to hold down the number of NIH grants by "forward funding" some of them was applied to centers, although to a much lesser extent than RO1 and PO1 grants. NCI was told that it would have to fund one center renewal for three years with 1985 money. That took $1.2 million from the 1985 budget which NCI had expected to use for this year.

To fund all seven of the second cycle renewals at the 95 per cent level, NCI would have to add $2 million to the centers budget in addition to recouping the $1.2 million lost to forward funding. The first possibly could be achieved through reprogramming, scrounging money here and there from other programs, delaying some start ups, canceling some contracts—exercises NCI has accomplished in the past.

Getting the $1.2 million back from OMB's folly depends on whether the Administration will back down in the face of possible court or congressional action and the tremendous pressures being generated by the scientific community.

The Administration inched back a bit from its stand to limit NIH to 5,000 competing grants in the FY 1986 budget, agreeing in a compromise worked out with Senate Republican leaders to go along with 5,500. The compromise was part of a deficit reduction package which so far has not fostered much support in either house of Congress. And it avoided entirely the dispute over forward funding 1985 grants, reducing the number from 6,500 approved by Congress to 5,000.

Sen. Lowell Weicker (R.-Conn.), chairman of the Health Appropriations Subcommittee, said he still wants to provide 6,500 grants this year and for the next three years. Congressman Henry Waxman (D.-Calif.), chairman of the authorizing Health Subcommittee in the House, and Sen. Edward Kennedy (D.-Mass.), ranking minority member on the authorizing Senate Labor & Human Resources Committee, also said they were not happy with the 5,000 grant limit.

PB-8504-017976

NATIONAL COALITION FOR CANCER RESEARCH FORMED TO SUPPORT PROGRAM

"The National Coalition for Cancer Research" has been established as an educational organization whose goals will be to develop the broadest possible support for the National Cancer Program. The Coalition has established as its primary mission for the present renewal of the National Cancer Act and adequate research budgets for NCI and NIH.

Chairman of the Coalition is John Ultmann, current president of the Assn. of American Cancer Institutes, which is one of the Coalition members. Diane Kaneb is the layperson cochairman. John Durant, president of Fox Chase Cancer Institute, is secretary treasurer. Mary Lasker, legendary supporter of health causes and a primary figure in the movement that led to approval of the National Cancer Act in 1971, is also a Coalition member.

Other organizations which are Coaltion members are American Assn. for Cancer Research, American Society of Clinical Oncology, American Society of Hematology, Society of Surgical Oncology, American Society of Therapeutic Radiologists & Oncologists, Assn. of Community Cancer Centers, Candlelighters, and the Oncology Nursing Society.

The American Cancer Society, which traditionally has refrained from joining such groups, has expressed strong support for the Coalition and endorses its current objectives.

Ultmann said that other organizations would be encouraged to join the Coalition. They may contact him at the Univ. of Chicago Cancer REesearch Center, 5841 S. Maryland Ave., Chicago 60637, 312-962-6180.

PB-85204- 017977

PRIVATE INSTITUTE TO FUND SOME NCI GRANTS JEOPARDIZED BY OMB CUTBACKS

One organization in the private sector has decided to do what it can about high quality grants going unfunded due to federal cuts by putting up some of its money to help fill the breech.

The Cancer Research Institute, a private, not for profit organization that promotes research on the immunological dynamics of cancer, announced that it will provide $1 million in interim support for selected research projects jeopardized by anticipated reductions in federal expenditures for medical research.

The emergency allocation is to be earmarked for immunology research affected by the Office of Management & Budget's rollback in NIH competitive research grants for 1985.

Lloyd Old, director of the Cancer Research Institute's Scientific Advisory Council, cautioned that his organization's funds will have a limited impact given the scale of projected federal cuts. "At a time when extraordinary progress is being made both in cancer immunology and in the overall field of immunology, a great deal of highly significant work is awaiting funding," Old said. "Our program will be able to support a small number of projects that we feel have exceptional merit out of a pool of dozens of first rate immunology investigations."

NCI and the National Institute of Allergy & Infectious Diseases are notifying immunology investigators whose proposals received NIH priority scores of 200 or better but have not been awarded federal funding for 1985 of the availability of designated support from Cancer Research Institute. The Institute's Scientific Advisory Council, which includes many of the world's foremost immunologists, will independently review applications submitted for its consideration and assign its own priority scores to rank them for funding.

"The purpose of this second review will be to reassess the potential significance of these proposals in the context of the federal retrenchment," Old said. "To the extent possible, we will attempt to stretch the Cancer Research Institute's limited resources to touch the widest range of affected research that we can."

The Council will begin reviewing proposals in June. Approximately 10 two year grants will be awarded with grants averaging $50,000 per year. Funding for selected projects will be available as of Oct. 1, 1985.

The Cancer Research Institute was founded in 1953 to promote research investigating the relationship between cancer and the immune system. It awards grants and fellowships to scientists in the U.S. and overseas, totaling nearly $2 million this year.

PB-85204- 017978

GRANTS APPEALS PROCESS DESCRIBED; ASSIGNMENT, REVIEW QUESTIONS HEARD

NIH has initiated an appeals process whereby applicants may request an examination of their concerns about the referral and peer review of their applications for grants and cooperative agreements.

This process is intended, NIH said, to resolve those concerns which arise from perceived shortcomings or errors in the substance or procedure of peer review—i.e., from receipt and assignment of an application through its review by the national advisory council or board. Such concerns may involve NIH's refusal to accept an application; a disputed assignment of the application to an initial review group or to an NIH bureau, institute or division; perceived insufficient expertise on the initial review group or site visit team or conflict of interest on the part of one or more of its members; apparent factual or scientific errors, oversights, or bias associated with the review of an application at the initial or advisory council review; and possibly inappropriate handling of the review or of the application.

On the other hand, NIH pointed out, the appeals process is not intended to resolve purely scientific disputes between peer reviewers and the investigator; to provide a mechanism for allowing investigators to submit information that should have been presented in the original proposal; or to provide a forum for disputing priority score determinations in the absence of specific and substantive evidence pointing to a flawed review.

The appeals process will not supercede or bypass the peer review process, but if serious shortcomings are found to have occured in the review of an application, they will be rectified by one of the following actions, NIH said: rereview by the same or another initial review group; special consideration by the advisory council; or administrative action authorized by the institute director or staff.

NIH said it encourages investigators to discuss their concerns with the appropriate NIH staff before requesting an examination of those concerns under the appeals process. When requesting such an examination, principal investigators should clearly describe their concerns and support their position by pertinent facts and reasons.

Under the appeals process, all concerns must first be directed to the NIH component which at the time is responsible for the application. Appropriate officials will thoroughly examine the investigator's concerns, frequently with the help of the initial reviewers or other experts, and if shortcomings are found to have occurred, every effort will be made to rectify them in a timely manner, NIH said.

If the PI seriously disagrees with the resolution

of the concerns by the responsible NIH component, the investigator may appeal to the Office of Extramural Research & Training. To allow for a complete and independent examination of the appeal, the application will be withdrawn from the regular review process until the appeal is resolved. An amended application submitted during consideration of the appeal will inactivate the original application and accompanying appeal. The NIH deputy director for extramural research and training will render the final NIH decision on the appeal.

Concerns about the assignment of the an application may be directed to the Deputy Chief for Referral, Referral & Review Branch, DRG, Westwood Bldg Rm 248, Bethesda, Md. 20205. If an appeal is to be made following receipt of the summary statement, it should be directed to the responsible institute staff or to the Office of the Associate Director for Extramural Programs in the awarding organization, NIH, Bethesda 20205. After having received the definitive response from the awarding organization, further appeal should be directed to Appeals Officer, Shannon Bldg Rm 213, NIH, Bethesda 20205.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda, MD. 20205. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, Md., but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-57731-68

Title: Support services in virology, tissue culture and immunology

Deadline: Approximately June 20

The Developmental Therapeutics Program of the Div. of Cancer Treatment is seeking an organization qualified to provide serological testing of up to 1,500 samples of serum per week for antibodies against HTLV-1 and HTLV-3 by ELISA assays and western blotting; provide cytogenetic analysis and mycoplasma testing; provide 30-50 grams per year of tissue culture cells from well characterized cell lines; and provide small quantities of purified human retroviruses.

It is anticipated that a cost reimbursement incrementally funded type contract will be awarded as a result of this RFP for a period of 48 months, beginning about the end of January, 1986. This RFP represents a recompetition of a contract being performed by Biotech Research Laboratories Inc. Proposed contract listed here is a 100 percent small business set aside, and will utilize the size standard of no more than 500 employees.

The concept from which this RFP was derived was approved last fall by the DCT Board of Scientific Counselors and reported in The Cancer Letter Nov. 2, page 8.

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

RFP NCI-CP-51011-74

Title: Synthesis or derivatives of polynuclear aromatic hydrocarbons

Deadline: Approximately July 1

NCI is requesting proposals for the synthesis, purification and characterization of selected derivatives (primarily oxygenated derivatives) of polynuclear aromatic hydrocarbons in gram quantities. The compounds are to be prepared in exploratory syntheses on small scale and then prepared in a production run to yield one to several grams of sufficiently pure material (generally 99+%). Compounds are to be characterized by a meaningful combination of appropriate techniques including possibly infrared and ultraviolet visible spectroscopies, melting point, elemental analysis, NMR, mass spectrometry, HPLC, thin layer chromatography, and optical rotation.

Characterized compounds are to be shipped to the NCI repository according to shipping protocols established by the repository. Distribution to the research community will be handled by the repository contractor for all unlabeled compounds. Labeled compounds will be subdivided and shipped to designated recipients in the research community by the synthesis contractor. The contractor shall be required to provide analytical, handling and storage data with all shipments.

A high degree of cooperation with NCI, the repository contractor, and other synthesis program contractors is necessary. Incumbent contractor currently performing this effort is Eagle-Picher Inc.

The concept from which this RFP was derived was approved by the Div. of Cancer Etiology Board of Scientific Counselors last fall and reported in The Cancer Letter Nov. 30, page 5.

Contract Specialist: Odessa Henderson
RCB Blair Bldg Rm 119
301-427-8888

NCI CONTRACT AWARDS

TITLE: Inter & intraspecies identification of cell cultures, modification
CONTRACTOR: Children's Hospital of Michigan, $797,206.

The Cancer Letter _Editor Jerry D. Boyd

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