THE CANCER LETTER

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

Vol. 6 No. 14

April 4, 1980

Subscription $125.00 per year

NEW CORE GRANT GUIDELINE PROPOSALS DRAWN UP; OPPOSITION DEVELOPING AMONG CENTER DIRECTORS

Nearly three years after the NCI Cancer Centers Program staff first proposed drastic revisions in center core grant guidelines—proposals which were shot down by the heated, unanimous opposition of center directors—NCI has come up with new suggestions for revisions in the guidelines.

A draft of the new proposals, which Acting Centers Program Director William Terry insists are still preliminary and subject to change, was circulated to 23 centers. Terry asked for comments within 14 days and said they would be considered in the next revisions.

The key feature of these revisions is an attempt to relate the size of core grants to the total support centers receive from NCI. Centers would not be eligible for core support unless they receive at least $750,000 a year in NCI funds through other mechanisms. Size of core awards would not exceed in direct costs 50 percent of total NCI support.

(Continued to page 2)

In Brief

$100 MILLION BEING SPENT ON INTERFERON IN U.S., RAUSCHER SAYS; DEVITA: CRITICISM DESERVED

"BY SHOWING our confidence in interferon, we hoped to stimulate other agencies and industry to get in," American Cancer Society Senior Vice President Frank Rauscher told science writers last week. Rauscher said 11 U.S. firms have committed space, money and other resources to interferon research and that "a conservative guess" on total U.S. investment in biological studies of interferon and for production would be $100 million. . . . **"CRITICS SAY** NCI hasn't done enough in prevention, and frankly I think we deserve that criticism," NCI Acting Director Vincent DeVita told the writers. DeVita said the National Toxicology Program has high priority but not high enough for the entire 45 percent increase in NCI's 1981 contribution (to $65 million) to survive further budget cuts. . . . **REPLACEMENT** for NTP Associate Director Richard Griesemer will be the topic of discussions with the program's senior scientists over the next month, NIEHS Director David Rall told ***The Cancer Letter.*** "We'll miss him. There are not many people around who could do as good a job as Dick has done," Rall said. Griesemer will return to Oak Ridge in July (***The Cancer Letter,*** March 28). . . . **BOARD OF SCIENTIFIC** Counselors of the National Toxicology Program will meet April 7-8 at the Bethesda campus, NIH Bldg 31, Room 7, 9 a.m. both days. The entire meeting is open. Among other items on the agenda will be a discussion of how to replace the Clearinghouse function of peer review of test reports. . . . **MICHIGAN CANCER** Foundation has scheduled a conference on biological carcinogens for June 11-14. Contact MCF, 110 E. Warren, Detroit 48201.

NEW CORE GRANT GUIDELINE PROPOSALS DRAW OPPOSITION—"TOO INFLEXIBLE"

(Continued from page 1)

Other provisions would spell out in more detail administrative requirements for centers, require chargeback for some use of shared resources, permit NCI staff to screen out centers which do not meet "minimum criteria," and provide more structured and uniform grant applications.

In a letter accompanying the draft to the 23 centers, Terry said the revisions represent an attempt to:

"1. Set some limits on the size and rate of growth of core grants.

"2. Relate the size of core grants to cancer research efforts at the institution.

"3. Provide some new features that should increase stability at a center.

"4. Clarify some aspects of the existing guidelines, including chargeback for use of shared resources.

"In order to relate the size of the core grant to a definable variable," Terry continued, "we have chosen to use the amount of peer reviewed research and research training support from NCI. We know that not all cancer research and training is supported by NCI and that significant amounts are supported by NSF, NIGMS, etc. We have not, however, been able to devise a practical alternative. This is not an ideal solution, but is the best one we can identify. There are other elements in these guidelines that are less than ideal but which also represent the best solution we have been able to find."

Terry asked the centers to provide an estimate of the impact the proposed guidelines would have on them. "This is a request for an estimate of the size of your current core grant if the proposed new policies had been in effect at the time your application was submitted and the grant awarded. This is a draft proposal and is not final, and whatever policies are finally adopted reductions of currently awarded grants will not occur. Consequently do not hesitate to estimate significant reductions for your Cancer Center Support (core) Grant if the proposed new policies had been in effect."

Terry told ***The Cancer Letter*** he did not know how many of the centers presently with core grants would be ineligible under the $750,000 rule. He said he hoped information in comments by the centers would help make that more clear. NCI does not keep a running score on where its grants and contracts are going, institution by institution. If that requirement is adopted, applicants would have to list their NCI support sources, and NCI staff would check them out in the screening process.

If existing core grants go to centers with less than the minimum NCI support, would they be grandfathered?

"I don't know," Terry said. "They might not be if they are way off, say $200,000 under."

Cancer related support from the National Science Foundation and other NIH institutes was excluded because of the difficulties in separating it out from non-cancer work, Terry said. An earlier draft did include American Cancer Society grants, since there would be no problem identifying them with cancer, but the center profiles compiled two years ago indicated ACS totals would not change anything, so they were dropped from the new guideline proposal.

Terry offered this justification for charging back to individual grants or contracts some shared resource costs: "The budget for individual investigator initiated grants has increased while the centers budget has remained constant. The result has been an increase in the number and size of individual grants, placing greater demands on shared resources, and on the staff supported by core grants. Core grants are not keeping pace. By charging part of the cost of shared resources to the users, some of the burden can be shifted back to individual grants."

It is unlikely that this round of guideline revising will be any more acceptable to center directors than the previous one. The Assn. of American Cancer Institutes has called a meeting for April 27-28 in Bethesda to discuss them and to draw up alternative proposals.

"A formula approach to such a diverse group is bound to be inequitable," said AACI President Alvin Mauer, director of St. Jude Children's Research Hospital. Loss of flexibility is a prime concern of many AACI members, Mauer said.

John Durant, director of the Univ. of Alabama Comprehensive Cancer Center, said in a memo to AACI board members and his fellow comprehensive center directors, "It is my opinion they [the guideline proposals] would destroy the Cancer Centers Program and should be resisted in the strongest possible terms. . . . I personally believe that there is no need for new guidelines. These are particularly bad."

Expanding on those remarks for ***The Cancer Letter***, Durant said the proposals "reduce the core grant to a formula grant. In my opinion, that is the next step to discontinuing the program. When budgets are tight, flexibility should be increased, not decreased. These proposals decrease flexibility."

The provision permitting NCI staff to screen and reject applications "places a lot of control in the hands of staff at a time when NCI staff is becoming fewer and fewer, and less and less experienced."

To implement chargebacks for shared resources, study sections have to be prepared to include those costs in individual grants, Durant pointed out. "That won't always happen."

Placing a cap on core grants at this time will result in "bad strategy," Durant said. "The result will be that we will have a relatively small number of approved unfunded grants. When you are cut back fiscally, to regain your funding you need a large number of approved but unfunded grants. If you reduce

that number, you take the steam out of the effort to get your money back. When Congress looks at your projects and sees you are funding just about everything, they can say, great, we can cut you back some more."

Basing the formula on NCI support is a disincentive for centers to broaden their research support, Durant said. "If we have a choice, and we sometimes do, we will take it from NCI."

With the formula approach, "We can't do intelligent fiscal planning, when we can go up or down depending on how the R01s fare, perhaps just on the basis of a few priority points."

The guideline proposals do not take into account the commitment to the Cancer Program by an institution, Durant said. The Univ. of Alabama has recruited 80-100 people and has spent more than $15 million on construction for the center. "We take the Cancer Program seriously, but there is nothing regarding commitments in the guidelines."

The guideline proposals "are another attempt to make bureaucrats' lives easier by applying formulae rather than wisdom," Durant said.

Excerpts from the draft proposals follow:

In order to qualify, applicants must meet the following criteria:

1. There must be research activity in a variety of disciplines and there must be evidence of a high degree of interdisciplinary coordination, interaction and cooperation among center members. Scientists or clinicians, each pursuing his or her research effort independently so that interdisciplinary interactions are limited or nonexistent, cannot be considered to be functioning collectively as a center. Such individuals are supported more suitably by other mechanisms such as individual project grants (R01). A center's core support should facilitate creative interactive activities such that "the whole is greater than the sum of its parts," and should increase efficiency by providing support for shared equipment and centralized multi-user facilities.

Examples of suitable activities for a cancer center include, but are not limited to: a) collaborative, interdisciplinary laboratory research efforts; b) collaboration between laboratory and clinical investigators; c) publications resulting from such efforts; d) significant sharing of facilities and equipment; e) seminars involving all center members; f) multidisciplinary clinical research or trials.

2. There must be an adequate base of established programs of high quality in laboratory and/or clinical cancer research. The high quality of the programs should be evident from the fact that they have been awarded support through national peer reviewed competition, such as in the form of NCI grants and contracts. IN ORDER TO QUALIFY FOR A CCSG, AN INSTITUTION MUST BE RECEIVING ANNUALLY AT LEAST $750,000 (DIRECT COSTS IN 1980 DOLLARS) IN RESEARCH AND RESEARCH TRAINING SUPPORT FROM THE NCI. (Defined as including NCI awards with identifying numbers with the following prefixes: Research Grants: R01, R10, R26, R23, P01; Training: K04, T32, F32; and Research Contracts: N01-CB, N01-CP, and N01-CM. Contracts that support primarily the production of materials in support of research, e.g., virus production, animal production, will not be included.)

This requirement is not meant to imply that the center must "control" all of these NCI supported programs. Programs supported by other sources such as ACS, other institutes of NIH, NSF, etc., although considered important components of the overall program, cannot be counted in the base.

3. There must be a qualified director of the cancer center program serving on a fulltime or on a significant parttime basis.

4. The center should be recognized as a major element within the organization structure of the parent institution.

5. The proposed cancer center and its director should have sufficient autonomy to accomplish program objectives. The center director should have the following authority:

a. Control of appointments or, at a minimum, joint control (with department chairmen) of appointments within the center; these appointments should be administratively indistinguishable from department appointments.

b. Full control of center space and equipment, or control equivalent to that of a department chairman at that institution.

c. If the center has a clinical component, the center director or his designee must have control of grouped beds dedicated to research.

6. Physical facilities should be adequate to house the center's activities and to promote collaboration among its constituent programs.

7. There should be an established mechanism to ensure adequate planning and evaluation of the cancer centers program.

It should be emphasized that the degree to which an applicant meets these criteria will be a major determining factor in the acceptance and in the review and approval of applications for cancer center support grants. LETTERS OF INTENT TO SUBMIT APPLICATIONS WILL BE REVIEWED BY THE CANCER CENTERS PROGRAM TO ENSURE THAT MINIMUM CRITERIA ARE MET BEFORE GRANT APPLICATIONS WILL BE ACCEPTED FOR REVIEW.

The CCSG provides funds for salaries of selected staff, for the operation of certain centralized resources and services and for the administration of the center. In addition, the CCSG may provide for salaries and research costs of young investigators at the parent institution who have not previously had funded grants and/or for investigators newly recruited from outside the parent institution. Funds for new investigators are limited in duration and amount. Support of all other cancer center functions must depend upon other federal and nonfederal funding mechanisms, e.g., regular research grant projects, program project grants, cancer control grants, training grants, education grants, research contracts, state funds, institutional funds, and private donations.

The number and size of the research projects and programs of the center to a large extent will determine the amount of funding requested in the CCSG application. . . . The annual direct cost amount requested (excluding support for new investigators) may not exceed 50 percent of the institution's current annual research and research training support from NCI.

In the case of consortium centers, the amount requested may not exceed 20 percent of the NCI research and research training support to all the institutional members of the consortium. Although this establishes an upper limit, the amount requested will normally be considerably less. The amount of the final grant will be determined by peer review and available funds. In no case may an application request more than $5 million in direct costs for one year, the limit prescribed by law. The Cancer Centers Program will determine the limit for each new and renewal application based on NCI support levels AT THE TIME OF SUBMISSION OF THE LETTER OF INTENT. The letter authorizing submission of the application will specify the maximum amount which may be requested.

New (Type 1) CCSG applications may request up to three years support, renewal (Type 2) applications up to five years. The actual length of project periods will be determined by peer review.

The CCSG may include funds for laboratory and clinical facilities, equipment and services which will be utilized by

multiple staff, projects or programs. . . . These types of resources may require partial funding not possible or desirable from individual grants or contracts. Funding by the CCSG may also result in a cost saving to the center. For such shared resources and services, most of the operating costs are usually not charged to the CCSG; costs directly identified with individual research projects are charged to individual grants or contracts. The ratio of these "chargeback" costs to CCSG costs may vary widely.

The funding requested from the CCSG should be the minimal amount necessary to lend viability, stability and continuity to the resource or service. In many instances such stability can be achieved by provision of one or two senior technicians' (or equivalent, such as nurses) salaries. Consumables and technical helpers and/or assistants' salaries, on the other hand, usually can be allocated through the "chargeback" system to individual grants. It is realized that costs on the core grant may be proportionately larger during the initial development of a new resource when large equipment purchases are necessary and when user charges are being established. In any case, applicants must not only justify requested costs in terms of their necessity for the particular service or resource but also justify them as necessary "core" costs for funding by the CCSG rather than from other sources.

[In the section on budget preparation, more details of the chargeback are presented]:

A separate budget and narrative should be prepared for each resource or service for which funds are requested. On the budget form, indicate the costs requested for the personnel, equipment, supplies, etc., for that resource or service.

The narrative in support of the request for a shared resource or service should describe the resource or service, including the personnel, its scientific purpose or necessity, and should list those programs, projects, and investigators who will be using the resource or service. At the time of the site visit, user logs or similar information should be available to validate extent of use and degree of sharing. The application should also indicate any grant or contract support for the programs and projects that will be utilizing the resource or service. The narrative should describe any chargeback system operative or planned for that resource, and specifically explain why the costs requested should be on the CCSG rather than on individual grants or contracts.

COOPERATIVE GROUPS TO GET INTERFERON WHEN AVAILABLE; RECOMPETITIONS OKAYED

Representatives of the Cooperative Groups, who have seen NCI clinical trials money go to contract supported investigators instead of their grant supported groups far too often in their opinion, were upset over the prospect that the Biological Response Modifiers Program might bypass the groups.

James Holland, chairman of Cancer and Leukemia Group B and a member of the Div. of Cancer Treatment Board of Scientific Counselors, challenged DCT's use of "task orders" for clinical tests of new agents.

Task orders are "quick reaction" contracts with institutions capable of performing specific jobs on request. Contracts are awarded on a cost reimbursement basis with individual task orders awarded on a completion or level of effort basis as determined by the contracting officer.

DCT issued RFPs earlier this year (*The Cancer Letter*, Jan. 4) for phase 1 and 2 studies of biological response modifiers and other agents. The deadline for proposals was March 17, and negotiations are in process now with a number of institutions.

Task orders, Holland said at last week's Board of Scientific Counselors meeting, are "the tool of the devil. . . . What's the matter with looking at the clinical grant supported investigator community?"

John MacDonald, director of DCT's Cancer Therapy Evaluation Program, agreed that the Cooperative Groups "are the ideal mechanism for phase 2 studies." The task orders are designed for fast turnaround when needed, with the majority of work they will support being phase 1 trials, MacDonald said.

Noting the concern of several Board members that biologics might not be available to those not awarded task orders, MacDonald promised that when supply problems are overcome, they would be made available to the groups and other investigators.

NCI has awarded or is negotiating contracts for production of leukocyte, fibroblast and lymphoblastoid interferon, with some deliveries to start in June. All or nearly all of NCI supported interferon phase 1 studies will be accomplished through the task orders.

MacDonald said he was not certain how much time would be required to complete the phase 1 interferon studies. With chemotherapy, about 30 patients are needed to determine maximum tolerated doses. "We don't know yet how many will be needed for interferon," he said, but estimated it would be well within a year.

Holland brought up the contract vs. grant supported group issue again when the Board conducted its concept review of several DCT contract programs presented by staff either for recompetition or noncompetitive renewal. One of those was the Gastrointestinal Tumor Study Group, which is supported by 10 contracts. Four of those contracts—Albany Medical College, Roswell Park, Mayo and Sidney Farber—expire this year and the others in 1981. DCT asked that the four be extended for one year, after which all 10 will be recompeted.

Holland, contending that per patient costs of the contract supported group is double that of the counterparts in the Cooperative Groups, argued against renewing the contracts and in favor of requiring them to compete for grants through the Cooperative Group Program. The Board did not go along with him, voting 6-1, with five abstentions, for the one year noncompetitive renewal, at an estimated award of $430,000.

MacDonald said that when the cooperative agreement mechanism becomes available to NCI, the group may be converted to that type of funding.

The group currently has three active colon adjuvant protocols as well as one recently terminated protocol which is in active followup. That one was a four armed study addressing the benefits of chemotherapy and immunotherapy, and accrued almost 600 patients. It is in the early stages of evaluation. The three active protocols:

–GI 6178–Recently activated adjuvant study of colon cancer on the usefulness of intrahepatic 5-FU after surgery in Dukes B_2 and C cases.

–GI 6179–A companion study in which the same types of patients are treated with hepatic radiotherapy plus 5-FU after potentially curative surgery.

–GI 7175–A radiotherapy/chemotherapy study of adjuvant rectal cancer patients which is in its third year of accrual with significant results beginning to accrue, allowing for the discontinuation of the no-treatment arm.

The Board approved five year noncompetitive renewals of the contract support for the breast and colorectal studies headed by Bernard Fisher (who also has grant support as a Cooperative Group, the National Surgical Adjuvant Breast Project). Fisher's Primary Breast Cancer Study Group contract was renewed through June, 1985, with a first year award of $1,126,000. The DCT narrative justifying the request said:

During FY 79, NSABP participants continued their excellent performance with respect to clinical trials in resectable breast cancer. The following are the most significant results of NSABP's clinical trials:

–Protocol B-04–For evaluation of radical mastectomy and total mastectomy with and without radiation in the primary treatment of cancer of the female breast. From 7/71 to 9/74, 1,765 patients were randomized. As of 3/79, with 60 months of followup, there is no advantage for particular treatment groups among either the clinical negative or clinically positive node groups.

–Protocol B-05–For evaluation of prolonged therapy of mammary carcinoma with L-PAM as an adjuvant to surgery. From 9/72 to 2/75, 418 patients were entered. The overall results continue to indicate a significant difference in favor of patients receiving L-PAM, with respect to treatment failure.

Protocol B-06–To compare segmental mastectomy and axillary dissection with and without radiation of the breast and total mastectomy and axillary dissection. Patient accrual began 4/76. As of 12/78, 308 patients have been randomized. This protocol had slow accrual initially, but has steadily increased over the past year.

Protocol B-07–To compare prolonged therapy of mammary carcinoma by the administration of L-PAM with L-PAM plus 5-FU. Patient entry began 2/75 and terminated 5/76, with 741 patients randomized. At 30 months, life table analysis shows a significant difference in favor of patients receiving L-PAM plus 5-FU.

Protocol B-08–To compare prolonged therapy of mammary carcinoma by the administration of L-PAM plus 5-FU with L-PAM plus 5-FU plus MTX. Patient entry began 4/76 and terminated 4/77. 737 patients were randomized. Further followup is required before statistical analysis can be completed.

Protocol B-09–To compared combined chemotherapy with and without tamoxifen, in the management of patients with surgically curable breast cancer. Protocol opened 1/77. As of 3/79, over 1,000 patients have been randomized. All patients have ER and PR assays on their tumor. The protocol is still open.

Protocol B-10–A protocol to compare combined chemotherapy with and without C-parvum and solucortef in the management of patients with surgically curable breast cancer. Accrual began 5/77. The protocol is still open. Over 175 patients have been entered thus far. Accrual is slow. It is too early to make meaningful treatment comparisons.

New protocols are being planned in stage 1 breast cancer and a replacement protocol for B-09 is also being discussed.

The NSABP contract for colorectal cancer studies also was renewed through June, 1985, with a first year award of $752,600. The narrative:

During FY 79, NSABP participants continued their good performance with respect to clinical trials in resectable colorectal cancer. The following summarizes their efforts to date:

Protocol C-01–To evaluate postoperative immunotherapy and postoperative systemic chemotherapy in the management of resectable colon cancer. Patient accrual began 11/77; as of 6/30/79, more than 292 patients have been entered onto the study. The followup time is too short for information on end results.

Protocol R-01–To evaluate postoperative radiation and postoperative systemic chemotherapy in the management of resectable rectal carcinoma. Patient accrual began 11/77; as of 6/30/79, more than 91 patients have been entered onto the study. Followup time is too short for information on end results.

DCT anticipates that there will be a continued need to perform well designed studies in the adjuvant therapy of colorectal cancer. NSABP has demonstrated its ability to carefully perform such studies. NSABP has also established a referral pattern assuring the accrual of adequate numbers of carefully staged patients to surgical adjuvant studies.

Both of Fisher's contracts are candidates for cooperative agreements, if and when.

The Board agreed to one final year of the interagency agreement with the Veterans Administration for support of the studies in VA hospitals around the country, at $745,000. Starting next year, the group, headed by George Higgins, will have to compete for grant support through the Clinical Cancer Investigation Review Committee. The group has a choice either of organizing as a formal Cooperative Group or of breaking up and individual members joining other Cooperative Groups. Higgins will hold a meeting in May to discuss the question.

The DCT narrative:

The Veterans Administration group has been a national leader in doing multimodality therapy studies

in primary cancer in the last 20 years. They have made major contributions to our knowledge of the value (or lack of it) of chemotherapy after resection in colon, gastric, and lung cancer. These studies have pointed out the continual need for surgery-only controls in evaluating the effect of any chemotherapy in primary cancer. They are currently completing studies testing CCNU plus hydroxyurea as an adjuvant in lung cancer and methyl CCNU plus 5-FU as an adjuvant in colon cancer. Neither chemotherapy regimen has shown an advantage over surgery alone. They are in the process of activating three new studies:

A new multimodal trial in colon cancer comparing postoperative 5-FU via portal vein infusion vs. two months of intravenous postoperative 5-FU.

Intrapleural vs. intradermal BCG in $T_{1,2,3}N_0$ non-small cell lung cancer.

Comparison of resection alone vs. resection plus irradiation in $N_{1,2}M_0$ non-small cell lung cancer.

The Board approved recompetition of two contracts in the Cancer Therapy Evaluation Program:

–Support services for extramural clinical trials, estimated at $250,000 for the first year of a five year contract. Georgetown Univ. is the present contractor, providing special assistance to investigators and groups supported by CTEP, including randomization procedures, protocol writing and assembly, data management, communication to and from project officers, chairmen and members, quality control, data collection, statistical analysis and file maintenance.

–Support services for investigational new drugs, estimated first year award of $173,000 on a three year contract. Information Planning Associates of Rockville, Md., is the present contractor. The contractor deals with FDA requirements, including gathering and assembling information on screening, animal toxicology, chemistry, bibliographic data, drug labeling, and the clinical protocol. The contractor maintains microfilm files, assists with annual IND reports, preparation and distribution of clinical brochures, and dissemination of adverse drug reaction information.

The Board approved one final year of the interagency agreement with the Veterans Administration in support of the NCI-VA Medical Oncology Branch of the intramural Clinical Oncology Program, costing $2.5 million. That entire branch, headed by John Minna, will move to the National Naval Medical Center in Bethesda. Initial clinical collaboration with the Navy is scheduled for June or July of this year, with the laboratory scheduled to move in the fall of 1981.

The Board went along with the recompetition of two contracts in the Developmental Therapeutics (drug development) Program and the renewal of two others on a noncompetitive basis. The recompetitions:

–Study of the clinical pharmacokinetics of anticancer drugs, estimated first year award of $102,000 of a three year contract. Ohio State Univ. is the present contractor. The principal objective of this contract is to collect pharmacokinetic data on new and established antitumor agents in patients undergoing treatment for malignant disease and to analyze these data for individual variability which can be correlated with clinical response or some other pharmacologic parameter. Specifically, these studies will be primarily concerned with the measurement of drug and/or metabolite levels in the plasma with time (μg/ml x min) after a standard dose of the drug. Apparent volume of distribution and plasma protein binding should be determined. These studies may also require measurement of urinary, biliary, and fecal excretion of drug and/or metabolites. Measurement of other fluids, e.g., cerebrospinal fluid and tissues may be necessary. Approximately 30 patients per drug per 6 months will be required to provide adequate statistical documentation of individual variability in pharmacokinetic behavior.

It is expected that two drugs will be evaluated annually and these are to be selected by the project officer in consultation with other investigators of DCT, and with the consent of the contract's principal investigator. Information on the analytical methodology for the measurement of the drug and/or metabolites in body fluids and tissues will generally be provided by NCI. Circumstances may arise which require modification, use of other analytical procedures, or development of new analytical procedures.

–Acquisition of chemicals and drugs for evaluation in cancer chemotherapy, estimated first year award of $402,000 on a three year contract. Starks Associates, Buffalo, is the present contractor.

The major focus of this contract is the active solicitation, acquisition and management of approximately 13,500 compounds per year of diverse structural types. These compounds are selected by the Drug Synthesis & Chemistry Branch from a much larger pool of compounds located through this contract in quantities adequate for the primary anticancer screen. Many new leads are identified, and this contract acquires a significant proportion of the larger samples needed for secondary screening (tumor panel).

A highly professional staff is needed. The project team must include individuals capable of representing NCI in their liaison activities with domestic and foreign industries, universities and research institutes. The individuals must be highly qualified in organic and medicinal chemistry especially as related to anticancer research. Additional team members are required with special skills in information and documentation control including automated information systems.

One of the noncompetitive renewals went to Biotech Labs for supportive services in molecular biology and tissue culture. Estimated first year award is $160,000 on a three year contract, which provides routine laborlatory support for DCT's Laboratory of Tumor Cell Biology, headed by Robert Gallo.

The other is an interagency agreement with the Dept. of Agriculture, at $450,000 for the first of a three year renewal, for collection of plants for the anticancer screening program.

GAO COMPLETES PROBE OF NCI'S PLANT SCREENING, OFFERS TWO SUGGESTIONS

The General Accounting Office, after investigating at the request of Sen. Edward Kennedy NCI's effort in acquiring and screening plant extracts as possible anticancer agents, offered only two suggestions for improving the operation, one of which was well under way toward implementation before the report was written.

The congressional watchdog agency noted that in vitro prescreens are much faster and less expensive than in vivo tests used by the Developmental Therapeutics Program to determine if a compound has any anticancer activity. GAO said, in its letter to Kennedy, "DTP's proposed project to develop new in vitro prescreens was given final approval by the Div. of Cancer Treatment's Board of Scientific Counselors on Oct. 29, 1979. Since current in vitro prescreens do not perform many of the analyses DTP desires, new in vitro tests must be developed. The DTP officials plan to issue a request for proposals for developing prescreens [this was done, and the RFP announcement seeking proposals for application of the human tumor stem cell cloning assay to drug screening appeared in ***The Cancer Letter*** March 21]."

To reduce duplication, DTP had established a policy of not accepting more than six samples of a particular plant species for screening. GAO observed that the chemical makeup of a plant grown in one country might differ from that of the same plant grown elsewhere and suggested that samples from at least two different countries be collected. "We believe that the Natural Products Branch should review the list of 67,000 plants categorized as not wanted and reinstate those plants collected from only one country," GAO said.

NCI 1980 RECISION SET AT $17 MILLION, FY 1981 REDUCTION AT $42.7 MILLION

The budget ax, which has been dangling over the necks of NCI, NIH and other federal agencies for weeks since President Carter announced his intention to balance the budget, finally fell this week.

It was not as drastic as some had feared, but it will still hurt, if Congress goes along.

The Administration is recommending a recision in NCI's 1980 budget of $17 million, trimming from the $1 billion already appropriated. This will require concurrence of both houses of Congress.

The White House also is reducing its request for NCI's 1981 fiscal year funds by $42.7 million, down to $965.1 million.

NCI is bearing about 40 percent of the reductions sought for all of NIH. The 1980 recision for NIH, including the NCI reduction, is $43.2 million, from a budget of $3.443 billion; and the 1981 cut for NIH amounts to $91.1 million, down from $3.581 billion.

Furthermore, the Administration's policy of stabilizing the total number of R01 grants at 5,000 remains in effect, meaning that the cuts will have to come from other programs such as centers, construction, intramural staff, contracts, cancer control, etc.

The devastating effect the level budget would have on the Centers Program, program projects, construction, Cooperative Groups and others has been documented (***The Cancer Letter***, March 28). NCI executives undoubtedly will make a major effort to shift a substantial portion of the cuts in both years to the National Toxicology Program, due to get $45 million from NCI this year and $65 million in 1981.

Congress must take action on the recision requests within 45 days; if not, the requests die. The appropriations subcommittees, which must consider the recisions, are due to mark up their bills during the same time period, possibly extending into June or July. The next two to three months, then, will be critical for the Cancer Program.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Address requests to the contract officer or specialist named, NCI Research Contracts Branch, the appropriate section, as follows:
Biology & Diagnosis Section and Biological Carcinogenesis & Field Studies Section—Landow Building, Bethesda, Md. 20205; Control & Rehabilitation Section, Chemical & Physical Carcinogenesis Section, Treatment Section, Office of the Director Section—Blair Building, Silver Spring, Md. 20910. Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP N01-CP-05612-72

Title: *Chemical respository*
Deadline: *May 27*

NCI is interested in recompeting a resource contract effort for the maintenance of the NCI Chemical Carcinogen Standard Reference Repository (DCCP). The repository provides a centralized source of well characterized and documented reference compounds for distribution to the carcinogenesis research community.

The contractor must provide safe storage for stock quantities of many types of chemical carcinogens and related chemicals in a laboratory suitably designed for that purpose. The majority of chemicals in the repository will range from less than one gram to a kilogram. Current chemical holdings include about 500 different compounds.

Upon authorization by the NCI project officer, the

contractor will subdivide samples, carefully package them and ship to designated requestors worldwide. The contractor will assemble analytical data as well as information on safe handling of each chemical for provision to the recipients. Besides commercial supplies, which are verified for purity, repository stocks are received from various NCI synthesis programs and from reanalyzed surplus stocks of the Carcinogenesis Testing Program.

The repository contractor will maintain a computerized inventory system which can generate monthly status reports on shipping and receiving activity.

In addition, the inventory system shall provide storage of data on chemical and physical properties and information on safety and disposal. Property and safety data sheets, which accompany chemical shipments, are to be generated from the inventory system.

Analytical protocols and quality control procedures are to be developed by the contractor to ensure that compounds of uniformly high quality are shipped to prospective users.

Procedures used by the repository contractor should ensure minimum hazard to personnel and the environment, conformance with all transportation regulations and minimum risk to the user upon receipt of the materials.

The repository, for the last five years has been operated under contract to NCI at IIT Research Institute in Chicago. This competition is expected to result in a single award for a 62 month incrementally funded contract.

Contract Specialist: Jackie Matthews
Carcinogenesis
301-427-8771

RFP N01-CB-04342-39

Title: *Molecular biologic studies of tumor viruses*
Deadline: *May 5*

NCI is interested in establishing a contract with organizations having the capabilities to grow tumor virus cells. In view of the requirements of the proposed contract, it is essential that the offeror's facilities be within a 50-mile radius of the NIH headquarters, Bethesda, Md.

Contract Specialist: Thompkins Weaver
Biology & Diagnosis
301-496-5565

NCI CONTRACT AWARDS

Title: Breast cancer detection demonstration project, renewal
Contractor: St. Joseph's Hospital, Houston, 15 months, $248,579.

Title: Clinical Oncology Program, renewal
Contractor: St. Mary Community Hospital, Walla Walla, Wash., eight months, $46,992.

Title: Biomolecular studies of herpesvirus Samiri, continuation
Contractor: Harvard Univ., $99,730.

Title: Support services to maintain studies on the role of viruses and experimental oncogenesis and human cancer, continuation
Contractor: Hazleton Laboratories, $79,400.

Title: Immunological assays for DNA and RNA viruses, continuation
Contractor: Litton Bionetics, $51,095.

Title: Metropolitan Atlanta SEER Program, continuation
Contractor: Emory Univ., $492,624.

Title: Preparation of antisera to oncogenic or potentially oncogenic viruses, continuation
Contractor: Huntingdon Research Center, Brooklandville, Md., $364,464.

Title: Provide and maintain nonhuman primates for cancer research, continuation
Contractor: Litton Bionetics, $62,875.

Title: Repository and distribution center for biological materials, continuation
Contractor: Microbiological Associates, $216,787.

Title: Oncogenic potential of defective human viruses, continuation
Contractor: Pennsylvania State Univ. (Hershey), $25,000.

Title: Replication of oncogenic RNA viruses and its replication to human cancer, continuation
Contractor: Columbia Univ., $366,090.

Title: Immunological and biochemical studies of mammalian viral oncology, continuation
Contractor: Meloy Laboratories, $83,350.

Title: Cancer mortality studies, continuation
Contractor: Univ. of Minnesota (St. Paul), $253,254.

Title: Immunoprevention of spontaneously occurring neoplasia, continuation
Contractor: Microbiological Associates, $37,100.

Title: Mouse typing and diagnostic reagents, continuation
Contractor: Microbiological Associates, $526,520.

Title: Support services for epidemiological studies of lung cancer in communities with nonferrous smelters, continuation
Contractor: Lehigh Univ., $77,233.

The Cancer Letter _Editor Jerry D. Boyd
Published fifty times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter.