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NCI ADVISORS TO GAIN INCREASED RESPONSIBILITY FOR CONCEPT, TECHNICAL MERIT REVIEW OF CONTRACTS

NCI once again is tinkering with its system for the development, review and monitoring of contracts. Although the institute's executives say it will not result in any changes noticeable to those submitting contract proposals, significant changes are being made in the selection of those who approve initiation of the projects and those who review the resulting proposals. (Continued to page 2)

In Brief

HOWARD SKIPPER RETIRES; OGLESBY TO HEAD SRI; JOHN MONTGOMERY NAMED KETTERING-MEYER DIRECTOR

HOWARD SKIPPER, whose research led to the development of effective cancer chemotherapy, will retire at the end of this year as president of Southern Research Institute. He will become president emeritus and will continue his research and writing. **SABERT OGLESBY JR.**, an SRI vice president and an electrical engineer known for his work in air pollution control, will become president. **JOHN MONTGOMERY** has been promoted from vice president to senior vice president and director of the Kettering-Meyer Laboratory, the cancer research program, a position previously held by Skipper. Montgomery is internationally known for his research in drug development, particularly the design and synthesis of anticancer drugs. **PAUL SHARBEL**, treasurer, was named vice president for financial and administrative affairs. **ROLLIN OSGOOD JR.**, executive vice president, will retire at the end of the year. . . . **JAN. 29-30 MEETING** of the Board of Scientific Counselors of NCI's Div. of Resources, Centers & Community Activities has been moved from the Lister Hill Auditorium on the NIH campus to the Blair Bldg. Rm 101, in Silver Spring, Md. . . . **BARBARA HARRIS**, former member of the staffs of Sen. Edward Brooke and Sen. Birch Bayh, is the new legislative liaison assistant in the office of NCI Director Vincent DeVita. . . . **PRESIDENTS, OTHER** principals of Coalition for Cancer Issues member organizations are urged by CCI Chairman John Potter to attend a special meeting Feb. 6. DeVita will discuss future directions, initiatives and budgetary plans with them. . . . **SMOKING RATES** of young men 12-18 have declined by one third to the lowest level since 1964, Helene Brown said in an editorial in the autumn issue of *World Smoking & Health.* Brown is chairman of the American Cancer Society National Public Education Committee. "For the first time in history, the percent of the male population who are smokers is below that of women of similar ages," Brown wrote. "Even among young women the smoking rate has shown a relative decrease of 17 percent since 1974." The editorial called for increased emphasis on helping young people "to make decisions against coercion into smoking."

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NCI STAFF TO RELINQUISH CONTROL OF REVIEW OF RESOURCES CONTRACTS

(Continued from page 1)

Here are some of the changes which either have been made recently or will be made after NCI Director Vincent DeVita discusses them with the National Cancer Advisory Board in February:

• The Boards of Scientific Counselors of the four operating divisions will be required to approve the concept of all new initiatives before they proceed to requests for proposals (for contracts) or requests for applications or program announcements (for grants). This will include mandatory concept approval by the BSCs for resources and support contracts as well as for research contracts. Until now, only the Div. of Cancer Treatment BSC has reviewed concepts for resources and support contracts.

The various operations housed in the Office of Director are responsible for a substantial number of support and resources contracts, for which concept review has been provided by NCI staff. In keeping with DeVita's policy to place concept review entirely with the institute's outside advisors, OD concepts will be reviewed by a subcommittee of the NCAB. DeVita probably will suggest it be either the Planning & Budget or Board Activities & Agenda Subcommittee, but it is possible that NCAB members may wish to establish a new subcommittee.

OD contracts include those supporting the Office of Cancer Communications, the Office of International Affairs and International Cancer Research Data Bank, Office of Program Planning & Analysis, and *Journal of NCI.*

• Peer review for technical merit of resources and support contract proposals will be transferred to the Div. of Extramural Activities. Administration of research contract review was moved from the operating divisions to DEA when NCI was reorganized by Arthur Upton, with peer review by chartered committees of extramural scientists. But resource and support contract technical review was left with the operating divisions, with committees composed primarily of NCI staff performing the review. That will change, with all peer review for technical merit of all NCI contracts now to be administered by DEA, with DEA selecting committee members. Committees reviewing resources and support contracts for technical merit still will include some NCI staff under the assumption that people who work in intramural programs have a better understanding of the needs than those from the outside.

• Post-award monitoring and evaluation will be the responsibility of the division BSCs as part of their overall review duties. Contract renewals over $100,000 and extensions of six months or more will require BSC approval.

Ongoing merit review of contracts, such as that performed extensively by the old Div. of Cancer Control & Rehabilitation and which led to early termination of some, will not be established as a routine process. BSCs may, in their concept reviews, impose such a requirement, and NCI staff may initiate it if some problem arises prior to a contract's expiration date.

Staff control over concept approval and technical review of resource contracts has been a continuing cause of friction between staff and NCI advisors as well as a source of suspicion by the scientific community. NCAB and BSC members have objected to being excluded from advance consultation in the purchase of millions of dollars in supplies and services. The DCT BSC, which has been accorded concept review of resource contracts, frequently objected to the categorization of contracts as resource, contending they were really research and thus should be subject to outside peer review.

DeVita admitted to the President's Cancer Panel last week that there was some basis for suspicion about the assignment of procurements to the "resource" category.

"It depends a lot on what we think will happen whether it is called a research or resource contract," DeVita said. "I've done it myself, so I'm not talking out of school. If we think it is likely we would lose control of the research, we have called it a resource contract. . . . We have not been consistent on how we handle contracts."

From now on, it will not make much difference, since program staff will not be involved in either the concept or technical merit review, except for the minority membership on technical review of resource contracts.

"In handling the entire contract program, no program will be developed or renewed without the participation of and scrutiny by the division boards and the National Cancer Advisory Board," DeVita said.

NCAB members will receive minutes of the BSC meetings; BSC chairmen and division directors will review their programs each year for the NCAB at its November meeting; and BSC and NCAB members are invited to attend each others' meetings.

"One of our problems," DeVita said, "is that people who review the concept think they are reviewing for merit; and those who review for merit wonder who in God's name approved the concept."

DeVita insisted that 80 percent of NCI's contracts "are quite good." Problems with the other 20 percent frequently can be traced to failure to move early enough on switching the support mechanism to grants. DeVita referred to the Viral Oncology Program, initiated with contracts when the field needed stimulation and direction afforded by that mechanism. He said that brilliant research was performed through contracts, but when virology reached the point where it would have benefitted from infusion

of new ideas from investigators, NCI continued to use contracts instead of emphasizing grants.

"It was too convenient," Panel member Harold Amos commented.

"With review by the Boards of Scientific Counselors and National Cancer Advisory Board, we would have received the advice to go to grants earlier," DeVita said. In fact, the BSCs have demanded in their concept reviews that projects intended for contracts be moved to grants.

"The vitality of the managers is the make or break difference on achieving success," Panel Chairman Joshua Lederberg commented. He mentioned the difficulty DeVita has been having on getting permission of the department to fill key vacancies.

At its last meeting, the NCAB passed a motion aimed at improving interchange between it and the BSCs and to improve NCAB's capability of monitoring NCI programs. The motion recommended that:

"—Chairpersons of the Boards of Scientific Counselors or their designates be invited to attend all meetings of the NCAB and its subcommittees and are required to attend the November meeting of the NCAB and participate in the program reviews at that time. At this meeting, each chairperson will report on the year's activities of his/her BSC.

"—Copies of the minutes of each BSC meeting and those of their subcommittees shall be forwarded to all members of the NCAB as soon as they have been drafted. The activities and policy recommendations of the BSCs should be clearly delineated in such minutes. These will be given the most serious consideration by the NCAB in decisions on policy and program. A standing invitation for members of the NCAB to attend the meetings of the BSCs has been given by the director."

PANEL SEEKS WAYS TO OPEN GRANTS PROCESS TO FUND MORE NEW IDEAS

Joshua Lederberg has expressed his concern that the NIH system for awarding grants tends to penalize creativity and reward those who stay in the mainstream. The Nobel Prize winner, president of Rockefeller Univ. and chairman of the President's Cancer Panel asked NCI staff to prepare a paper reviewing grants policy, with suggestions for modifications which would expand opportunities for individual scientists to conduct creative research.

Margaret Edwards, chief of the Clinical Manpower Branch in the Div. of Resources, Centers & Community Activities, drew the task of writing that paper, which she presented to the Panel last week.

The paper outlines the history of NIH grants policy, describes grant programs of other agencies, and offers some possible improvements.

"Within the limits of the grants review and management policies and procedures at the National Institutes of Health, considerable flexibility exists," Edwards wrote. "The variety of available funding mechanisms is such that few sound research projects cannot be accommodated by one of them. The review process is not rigid but can be extended to include the most esoteric proposals. Program directors assist study sections and review committees by providing helpful background information and conscientious executive secretaries assist applicants by noting ambiguities or omissions in applications and obtaining clarification and supplementation prior to review.

"It must be remembered, however, that study sections and review committees must concern themselves with the assessment of scientific merit, and exceed their responsibilities if they do otherwise. It is for councils and advisory boards, program officers and agency officials to make judgments which transcend the scientific review process.

"It has been charged that the scientist, the individual who designs and implements the research project, has been lost sight of in increasingly detailed scrutiny of the research project per se, and that his sustained productivity seems to be of no concern to the funding agencies. This is a serious charge and requires careful examination. It is probably true that scientific review groups do focus principally on the proposed research project, but the record of the scientist and his competence for conducting the project are given most careful consideration. Review groups are not in a position, however, to concern themselves with maintaining the productivity of established scientists.

"Should this, then, be the concern of funding agencies themselves? Yes, if the reports of the Commission on Research are to be considered seriously. The difficulties faced by universities in the conduct of research are faced by individual scientists and their administrative partners, and where the system impinges on their productivity, the progress of research is retarded. How can funding agencies minimize these difficulties, and what new procedures may be used?

"One impediment to research mentioned frequently by scientists is the requirement for frequent peer review. Two funding agencies have developed special or experimental mechanisms which allow agency staff to extend, without additional peer review, research grants for special purposes. The first, initiated in 1980 by the National Science Foundation, is called 'Two-year Extension for Special Creativity.' This experimental mechanism would be applied only to three year continuing grants. A program officer may recommend the extension of certain grants beyond the initial period, up to two additional years, to offer the most creative scientists increased opportunity to attack adventurous high risk research questions, in the same general scientific area but not necessarily directly related to those pursued under any existing research grant. Only investigators who have made especially creative research accomplishments under an

existing NSF grant will be selected, and no more than 10 percent of the three year continuing grants within a program officer's program may be so designated. The eligible awards are limited to those with an average annual rate of $200,000 or less."

Edwards also described a Veterans Administration program known as 'retrospective peer review' in which selected grantees who have had funded research grants for at least 10 years would receive extensions at their current levels plus 10 percent for periods of up to several years. However, a study of the productivity of the investigators funded in that manner compared with those supported in the traditional peer review process shows no significant difference in the number and quality of their publications.

The NIH Director's Advisory Committee recently met to consider funding mechanisms and policies. Presentations were made on proposed modifications, including automatic carryover of unexpended grant funds; intermingling funds between closely related grants, changes in due date requirements for expenditure reporting, the fixed obligation grant and the organizational grant.

The committee agreed that further study would be given to the fixed obligation grant and NSF's master grant, Edwards said.

Fixed obligation grant:

"Under this mechanism, a grant application would be reviewed and awarded in the usual way, but most of the responsibility for post-award administration would be transferred to the grantee institution and the principal investigator, with the understanding that the funds would be handled in accordance with established institutional policy; any expenditure of funds would require the principal investigator's approval, and any major changes in the scope of the work, the appointment of a new principal investigator, his relocation to a new institution or a significant reduction in his level of effort, would require prior agency approval. Only technical reports would be required by NIH; no financial reporting would be required. Time and effort reporting would be restricted to the needs of the institution and the needs for developing indirect cost rate proposals. Audits would be for the purpose of assessing compliance with preconditions of the grants, or to develop information needed to negotiate prospective direct or indirect cost rates. The institutions' financial systems would be subject to periodic audit to assure that there were adequate controls against fraud.

"The use of this concept would signal a shift away from agency control and monitoring based upon careful selection of projects to be funded, scrutiny of past performance, and an awareness of the advantages of relying upon checks and balances within responsible institutions rather than imposing on them from without."

The NSF master grant:

"The existence of multiple grants from a funding agency within an institution or one of its large departments raises considerations as to whether some simplification of the grants management processes for numerous grants within the institution/department and of the requirements of the funding agency cannot be achieved. Presently certain cost transfers between closely related grants supported by NIH are permitted on a prospective basis only, and with strict application of the four criteria for "closely-relatedness."

"At the National Science Foundation an experiment has been in progress for one and one-half years with a mechanism known as the master grant, designed to facilitate the conduct of research within an institution and at the same time fulfill the objectives of the funding agency. At the outset the experiment was limited to nine institutions that had large departments of chemistry, each with ongoing multiple NSF grants. With the approval of all grantees, these grants in each chemistry department were aggregated under a common grant number (master grant) and authority was delegated to the department chairmen to negotiate pre-award costs, make no-cost extensions of grant periods, consolidate similar projects, and exchange funds between closely related projects. Major changes, such as in workscope, however, or in principal investigators, required agency approval.

"In 'phase 2' of this experiment, the NSF will now extend the concept to a number of institutions rather than departments (from nine to 12) and will modify the program so that each grant retains its number and identity. Authority will be transferred to the institution to carry out the modifications previously described, but only with the consent of the participating grantees. It is conceivable that this procedure could be extended to include grants from other federal agencies."

Edwards' report concluded:

"As federal support of research has grown and as the costs of research have accelerated due to technological advances and changes in national economy, problems have arisen within academic institutions in which the major portion of grant supported research is conducted. Not only has the research burden impinged upon their academic commitments but it has strained administrative and fiscal capabilities. Those conducting research have felt a web of constraints imposed on them from within and without their institutions, and have sought to identify the causes of their concerns. In turn, the review process, federal intent, and oversight policies have been examined.

"The results seem to indicate that experiments with new funding mechanisms are, indeed, needed, and those currently used can be improved with carefully planned modifications. The time for research into the conduct of research is at hand."

Panel members Harold Amos and Bernard Fisher agreed with Lederberg to proceed further with development of approaches for improving grants policy. "We need to elicit more specific testimony from those involved," Lederberg said. "The scientific community has been stifled by unintended side effects."

Director Vincent DeVita said that he would like to finish his improvements on the contract process before taclking the grants situation, but Amos said, "We don't have to wait for the director's action." He suggested the Panel could start by seeking advice from 15-20 scientists. "We should make some serious effort to invite unusual proposals. Some ideas don't fare too well, because study sections have become so entrenched." Much of the problem is due to the difficulty in finding people interested in or competent in certain areas for appointment to study sections, Amos acknoweldged.

DeVita suggested that people be invited to attend a future panel meeting to offer their suggestions.

"Let's not invite too many gurus," Amos said. "We need to hear from young people who might have some ideas."

"We could invite any 25 scientists and 20 will express experience with this type of frustration," Lederberg said.

FINAL ISSUE FOR 1980

With issue Number 50 of Volume 6, we conclude another year of publishing ***The Cancer Letter.*** The next issue, Volume 7 No. 1, will be dated Jan. 2, 1981.

The Cancer Letter office will be closed intermittently during the holidays. We'll answer the phone when we are in the office, so if you need to reach us before Jan. 5, give it a try. If you get the recording, accept our apologies and our best wishes for a happy holiday season and the New Year.

CONGRESSIONAL CHAOS COST CANCER PROGRAM ITS $20 MILLION INCREASE

The incredible display of incompetence which dominated the lame duck session of Congress apparently has cost the Cancer Program $20 million.

House and Senate conferees last week agreed on a Senate initiative to increase the 1981 fiscal year appropriation for NCI by $20 million, bringing the total to $1 billion, 21 million. It was part of a $70 million increase for NIH over the House-passed figure.

But then the lack of leadership, ridiculous efforts to cram the bill with pork barrel projects, the what-the-hell attitude of defeated members, and the attempt by the House to slip a congressional pay raise through all combined to play havoc with the continuing resolution to fund those agencies which still do not have a regular appropriations bill.

When the Senate refused to go along with the House on the pay raise, the House retaliated by throwing out the conference report and coming back with an entirely new bill which, among other things, returned to the original House passed figure for NCI of $1.001 billion. The extra $70 million for all of NIH also went down the drain.

The Senate was in session all night Monday, kept there because the affected government agencies could not operate after the previous continuing resolution expired at midnight Dec. 15 without an extension. The Senate finally passed the resolution, accepting the House language, at 5 a.m. Tuesday morning.

The continuing resolution will expire June 5, when the Congressional Budget Act is due to expire. That Act prevents impoundments by the President but provides for recisions from approved appropriations; recisions must be approved by both houses of Congress to be implemented.

NCI's budget thus is still subject to recisions. It is also possible that a regular appropriations bill will be approved by the new Congress which will supercede the continuing resolution. And there is the possibility that even without an appropriations bill, NCI could get additional money in a new extension of the continuing resolution after June 5.

In the meantime, NCI will have to spend at the $1.001 billion level, which will leave many programs underfunded, and probably will result in the demise of some. Center core grants and program projects being renewed this year will be limited to seven percent cost of living increases; the Cooperative Group Program will be held to the same amount it received last year; construction will be held to a miniscule $1 million; and so on.

The news out of Washington was not all gloomy for Cancer Program advocates last week. Consider this:

- Richard Schweiker will be the new secretary of the Dept. of Health & Human Services. Schweiker was a strong and consistent friend of the Cancer Program as the topranking Republican on both the Health Subcommittee and the Labor-HHS Appropriations Subcommittee.
- Leading candidate at this moment for the combined position of assistant secretary for health and surgeon general is Tim Lee Carter, retiring as the topranking Republican on the House Health Subcommittee and one of the leading figures in the passage of the National Cancer Act of 1971.
- Charles Mathias, who could be chairman of the Labor-HHS Appropriations Subcommittee if he wants it, may wind up taking another subcommittee, not a good development from the viewpoint of the Cancer Program since he has always been an enthusiastic supporter of it. But that chairmanship could go to Harrison Schmitt, New Mexico conservative who has supported increased funds for NCI and who argued last week on the Senate floor against an across the board cut that would have slashed HHS funds, including

NCI's by four percent.

Not so good news: William Proxmire, who has voted against reasonable NCI budgets, will be the ranking Democrat on the appropriations subcommittee.

Congress did manage during the turmoil to pass the simple two year extension of biomedical research authorization, including spending limits for NCI and the National Institute of Heart, Lung & Blood Disease.

In an appropriate gesture to the man whose bill created NCI and eventually NIH, Congress approved a resolution naming the NIH Clinical Center the "Warren Grant Magnuson Clinical Center."

SOLOMON GARB'S QUESTIONS AND ANSWERS ABOUT THE NATIONAL CANCER PROGRAM

Publication of questions and answers frequently asked of and answered by Solomon Garb, chairman of the Citizens' Committee for the Conquest of Cancer, continues.

CANCER CAUSES AND PREVENTION (Continued)

111. Is it possible to prevent cancer by taking vitamins?

We don't know. There are some studies in progress to see if vitamin C and/or retinoids might prevent cancer. As yet, we don't know the answer and may not know for many years.

112. I heard several statements that 80 to 90 percent of cancers are caused by the environment and therefore preventable. Why don't we concentrate on preventing them?

The statements you refer to are based on misinterpretation of a study by Dr. John Higginson of the World Health Organization. Dr. Higginson believes that 80 to 90 percent of cancers are caused by the environment, but he uses the term "environment" to include many factors over which man has little or no control. In 1979, Dr. Higginson gave several interviews correcting the misinterpretation of his findings by others.

113. I was told that effective cancer prevention measures cannot be taken until there is a thorough understanding of the basic mechanisms that cause cancer. Do you agree?

No. The first occupational cancer, described over 200 years ago by Dr. Percival Potts was cancer of the scrotum in chimneysweeps. Dr. Potts deduced that the cause was material from the chimney that remained in contact with the folded skin of the scrotum. Thereupon, the Danish Guild of Chimneysweeps ordered all its members to bathe each evening after work and cancer of the scrotum no longer developed among them. Neither Dr. Potts nor the Danish chimneysweeps understood the basic mechanisms of carcinogenesis. There are many other similar examples. In medicine, one often must make important decisions without waiting for a complete understanding of all mechanisms. This is as true for prevention as for treatment.

COSTS AND FINANCES

114. What does the cancer program cost in total dollars? How much goes to find better treatments?

For fiscal 1980, $1 billion will be spent on all NCI programs. Of that total, about $¼ billion will be spent on the search for better treatments.

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 Contracting Officer or Contract Specialist named, Research Contracts Branch, National Cancer Institute, Blair Building, 8300 Colesville Rd., Silver Spring, Md. 20910. Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

SOURCES SOUGHT

Title: *NCI budget formulation and fiscal projection model*

Deadline for statement of capability: *Jan. 16*

The NCI Financial Management Branch is seeking small business sources capable of responding to a potential request for proposals to maintain and further develop its budget formulation and presentation support system.

The budget structure of NCI has evolved over the last decade to keep pace with a changing organizational structure and more detailed reporting requirements from Congress, the Office of Management & Budget, and the Dept. of Health & Human Services.

The current budget structure is extensively stratified by:

- Functional component—research, resources development and cancer control.
- Research programs—epidemiology, biological carcinogenesis, physical and chemical carcinogenesis, nutrition, tumor biology, immunology, diagnostic research, preclinical treatment, clinical treatment, and rehabilitation.
- Research thrusts—cause and prevention, detection and diagnosis, treatment, and cancer biology.
- Resource areas—centers support, research manpower development, and construction.
- Mechanism of funding—research grants, training award, contracts, intramural research, direct operations.
- Status of funding—new, competing renewal, noncompeting renewal, supplements.
- Organization divisions and the Office of the Director.

The complexity of the relationships among these stratifications, the requirement to systematically allocate program management resources across programs and the need to ensure consistency among the many reports and budget submissions required necessitates comprehensive yet detailed program knowledge of the functioning of the NCI. Currently the programs outlined above are conducted under several authorizations; research, manpower and cancer control which must be separately identified in each budget stratification.

Qualifications: Sources responding must demonstrate the following minimum qualifications:

1. Staff proposed for working on this project must

be located within a 25 mile radius of Bethesda, Md. and be available for frequent consultation with the project officer.

2. Staff must have competency and experience in the government budgeting process as well as experience in computer modelling and programming;

—Competency should be demonstrated by education and professional experience. Please submit transcripts, resumes and professional references to demonstrate sufficiency in this area.

—Experience must be demonstrated in development and maintenance of an automated budget formulation system for a federal agency or corporation with a complex, large budget involving different funds, subdivisions and extensive programmatic stratifications and exceeding $700,000,000 annually. Please submit documentation of the system(s) as well as client references to demonstrate sufficiency in this area.

3. The proposed staff must include at least three professionals with experience in the system(s) described above. Submit detailed work histories for the proposed staff showing dates of employment, projects worked on, employers, and direct supervisors' phone numbers. The years of experience outlined below may overlap:

A. The project director must have eight years total experience in computer programming or systems design. Of this experience, five years must be in designing and implementing an automated budget system and three years must be in computer programming with PL1 and FORTRAN. Three of the eight years of experience must be continuous experience as the primary project director of one of the systems documented in 2 above.

B. A senior programmer is required for this project who has three years full time experience in both PL1 and FORTRAN, beyond educational courses, and two years experience with JCL on the IBM-370 system.

C. A junior programmer is required with one year of working experience in both PL1 and FORTRAN.

4. Offeror must be able to take over maintenance and operation of the current system without disrupting NCI's budget formulation. Smooth transition requires an extensive knowledge on the part of the offeror of the budget process in NCI, NIH, the Public Health Services, the Dept. of Health & Human Services, the Office of Management & Budget, and Congress. Offerors should demonstrate that they possess this knowledge or provide a plan for obtaining this knowledge prior to June 1, 1981.

5. The proposed staff must be able to provide documentation of the system which is understandable to budget personnel with no experience or formal training in computer languages or terminology. Please submit samples of documentation authored by the proposed project director. This documentation may be of the same system described in 2 above or it may be of a different system if the project officer did not author the documentation of the system in section 2.

6. The project director or other proposed staff must be able to provide training for non-computer personnel in the use and operation of the budget system. Submit evidence of ability to train non-computer personnel in the operation of an automated system such as training materials developed for another project with which the company or the proposed staff has been involved. Please also submit references and telephone numbers for clients who have been trained in operation of a system developed by the offeror.

7. The offeror must be stable, reliable and have resources available so that the staff proposed for this project may be devoted to full time effort during peak budget workloads which occur three to four times a year. Please provide evidence of stability and a plan for reallocating resources to full time effort during peak times.

Other pertinent information:

1. Documentation of the current system is available in the reading room in the Blair Bldg Room 327, 8300 Colesville Rd., Silver Spring, Md.

2. Questions should be directed to Diane M. Smith on 301-427-8877 or the Blair Bldg Room 327, Bethesda, Md. 20205.

3. Responses should be highly specific and include such information as dates of experience, telephone numbers of references, and employees' names and telephone numbers.

4. Please submit three copies of capability statements and supporting documentation.

Contract Specialist: Diane Smith
Biology & Diagnosis
301-427-8877

RFP NCI-CM-17397

Title: *Biochemical and biological characterization of antitumor drugs*

Deadline: *Approximately Feb. 6*

The NCI Div. of Cancer Treatment Developmental Therapeutics Program is seeking organizations having the necessary experience, scientific and technical personnel, and physical facilities to evaluate new antitumor agents of interest to DCT in a series of established biological/biochemical tests appropriate to the individual agent.

Experiments will be conducted to determine whether antitumor agents with novel structures have biological/biochemical activities similar to those of clinically evaluated chemotherapeutic agents, and whether structural analogs of clinical drugs have different biological/biochemical properties. The intent of the studies is to provide clear leads as to how a

developmental drug exerts its effects, and not to elucidate definitively the mechanism of action of the drug.

Test systems will be chosen on the basis of the agent's resemblance in effect or structure (if any) to other agents whose biologically important effects are known. Tasks will include (a) determination of the agent's effects on the proliferation rate viability and morphology of mammalian cells in culture; (b) determination of the agent's effects on the rate of synthesis of macromolecules in mammalian cells in culture; (c) determination of the reversibility of the agent's effects on cell growth and macromolecular synthesis by metabolites; (d) determination of the agent's effects on DNA, tubulin or specific enzymes. Compounds to be tested will be supplied by the government.

It is anticipated that one award will be made for a three year incrementally funded contract as a result of the RFP. Also, it is anticipated that the level of effort for the first year will be three staff years and that the level of effort will decrease to 2.7 and 2.45 staff years in the second and third years, respectively.

Contract Specialist: Charles Lerner
Cancer Treatment
301-427-8737

RFP NCI-CM-17285

Title: *Development and marketing of AZQ as an antitumor agent*

Deadline: *March 16*

The NCI Div. of Cancer Treatment is seeking an appropriate organization to engage in a cost sharing agreement for the joint development of the drug AZQ, which is 2,5-bis(1-aziridinyl)-3,6-dioxo-1,4-cyclohexadiene-1,4-dicarbamic acid diethyl ester, as an agent for the therapy of human cancer.

This compound shows promise in experimental tumor systems with reproducible activity against a number of solid tumors (murine and xenografts) as well as leukemias. In addition, AZQ has significant activity against experimental brain tumors. AZQ is currently undergoing phase 2 clinical trials. NCI has an approved IND from the Food & Drug Administration for AZQ.

As in the case with most other antitumor drugs, the potential market for AZQ, should it reach that stage, is considered to be low in comparison to the market level considered to be financially advantageous by the pharmaceutical industry. Since the market is considered small, it is deemed essential to the public need that the government maintain its involvement with the drug. It is planned that a written agreement will be consummated with a competitively selected organization to share in the further development of AZQ.

The U.S. government owns the U.S. patent rights to the use of AZQ as an anticancer agent (U.S. Patent 4,146,622) and anticipates granting a license to the successful organization in consideration for the significant sharing in further development of the drug in the preclinical and clinical stages.

Respondents to the request for proposal should include any request for license (exclusive or nonexclusive) that the offeror may require for the government under the patent in accordance with C.F.R. 101-4.104-2 or 41 C.R.F. 101-4.104.3. It is anticipated that the selected firm will use the data developed jointly with NCI to process a new drug application with FDA should such action be deemed worthwhile based on the clinical results obtained. This should lead to the eventual sale of the formulated drug by the selected firm to fill the nation's requirements.

The government does not intend any reimbursement for services rendered. Cost recovery and profit earned, if any, will be by means of sales of AZQ by the successful offeror.

Contracting Officer: Harold Thiessen II
Cancer Treatment
301-427-8737

RFP NCI-CB-14345-39

Title: *Morris hepatoma resource*

Deadline: *Feb. 17*

NCI is seeking a laboratory that is capable of (1) maintaining up to 1,200 syngeneic rats of the Buffalo strain according to National Research Council standards, (2) providing the technical staff capable of maintaining transplanting and monitoring the properties of Morris hepatomas, (3) supplying rats carrying Morris hepatomas to extramural and intramural laboratories requesting these tumors for their research purposes and (4) providing monitoring services for and reports to other laboratories which carry their own stock Morris hepatomas. All animals should be obtained from commercial sources.

Offerors' facilities must be located in metropolitan areas or areas where daily shipments of rats bearing tumors to all parts of the country are possible with minimum delay in handling. A three year contract is anticipated.

Contract Specialist: Thompkins Weaver Jr.
Biology & Diagnosis
301-427-8877

The Cancer Letter _Editor Jerry D. Boyd

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