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NCAB Agrees With NCI Recommendation To Drop PO1 Chartered Committees, Adopt Single Review

The National Cancer Advisory Board last week gave preliminary approval to the recommendations of an NCI working group which would make significant changes in how program project grant applications are reviewed. The changes include discontinuation of chartered review committees for program projects (PO1s) and use instead a "single tiered" system in which the site visit team would perform the entire review, eliminating what was called "poor information

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In Brief

NCI To Leave Blair, Landow Buildings; House To Hold Hearings March 5 On NCI's 1988 Budget

NCI STAFF members now working in the Landow Building, in downtown Bethesda, and the Blair Building, in Silver Spring, will be relocated into a single building later this year, according to the Institute's present plans. Bids are being evaluated from owners of buildings in the corridor between Bethesda and Rockville, and NCI expects to occupy the new quarters by late fall. Most of the Div. of Cancer Prevention & Control offices and Research Contracts Branch offices are in the Blair Building; many Div. of Cancer Treatment and Div. of Cancer Etiology offices are in Landow. The new quarters probably will be close to a Metro (subway) station, providing easy access to the NIH campus with its own Metro stop. . . . **NEWS CONFERENCE** has been scheduled for March 3 by Giant Foods, a Washington-Baltimore grocery chain, and NCI to announce a dietary fiber-dietary fat product sales study. . . . **HOUSE COMMITTEE** on Labor-HHS Appropriations will hold its hearing on NCI's 1988 fiscal year budget March 5. Only government witnesses will be heard then; public witnesses will be scheduled later, probably April or May . . . **PRESIDENT'S CANCER** Panel will hold its next meeting March 16 at UCLA. Open to the public, the meeting will start at 8:30 a.m. in the Louis Factor Auditorium of the School of Nursing. . . . **DATE OF NEXT** UICC Cancer Congress, to be held in Hamburg in 1990, will be Aug. 16-22, the German National Organizing Committee for the Congress has decided. The Atlantic Hotel will be the headquarters. Those planning to participate may contact for further details as they become available Dr. Carl Schmidt, Director, West German Tumor Center, Klinikum deo Ghs Essen, Hufelandstoasse 55, 4300 Essen, West Germany.

PO1 Review To Be "Single Tier", Chartered Committees To Be Dropped

(Continued from page 1)
transfer" from the site visitors to the parent chartered committee.

The Board accepted the recommendations and added two of its own, with the provision that NCI staff report back at the Board's meeting in May on the final shape of the new system. The only dissenting vote was cast by Louis Sullivan.

The major recommendations made by the working group were:

1. A single tiered review, whether conducted at the applicant's institution, in Bethesda, or elsewhere, should be employed.

2. All committees should be special committees convened to review one or several closely related applications.

3. Committees should be smaller, more focused teams with mail reviews or other types of collateral review being used to supplement areas of needed expertise.

4. Use of chartered review committee for POIs should be discontinued after a suitable transition period.

The NCAB, after extensive discussion, added two more changes:

*The procedure in which NCI staff selects members of review committees should be formalized.

*After reviewers have each submitted their priority scores rating an application, the high and low score should be disregarded in establishing the final score.

Paul Rambaut, deputy director of the Div. of Extramural Activities which is responsible for NCI review of grants and contracts, presented the working group's report and recommendations to the NCAB. Other members of the group were Faye Austin and Colette Freeman of the Div. of Cancer Biology & Diagnosis; Robert Browning, Suzanne Fisher, Paulette Gray and Robert Hammond of DEA; Carlos Caban of the Div. of Cancer Prevention & Control; Andrew Vargosko, representing both DCPC and the Div. of Cancer Treatment; Roy Wu of DCT; and Genrose Copley and Paul Okano of the Div. of Cancer Etiology.

Rambaut noted that program project guidelines were extensively revised about five years ago by an NCAB committee working with staff and outside consultants chaired by then member Maureen Henderson. The major change then resulted in streamlining of applications by requiring that reviewers consider all projects included in the application in establishing priority scores. Until then, reviewers routinely eliminated projects considered to be weaker, which encouraged applicants to "include everything but the kitchen sink," Rambaut said. The result was smaller, more tightly focused applications, which averaged about seven projects each.

That made review easier, but the workload has continued to increase at a time when the number of staff persons available to work in review became more restricted, thanks to Administration limits on NIH and NCI positions. The working group decided that the two tiered system was a luxury NCI was finding it increasingly difficult to afford.

It also contributed to "poor information transfer," Rambaut said. The site visit team, in reporting back to the parent committee, frequently was not able to convey full and fair impressions gained from its review. Other factors, such as the parent committee not being adequately representative of the appropriate disciplines, might intervene. The result sometimes was reduction in scores, if not complete reversal of site visitors' ratings.

Rambaut reminded the NCAB of the NIH definition of a program project grant: "An assistance award for the support of broadly based, multidisciplinary research program that has a well defined research focus or objective." Features of a PO1 are that (1) it supports a central theme through interrelated projects; (2) it enables coupling of clinical and basic research; (3) it promotes synergistic scientific interaction; (4) it more efficiently uses personnel, facilities, data, etc.

In the 1986 fiscal year, Rambaut said NCI funded 144 PO1 grants, compared with 2,508 ROIs and a total of 4,035 for all grants. Average cost of POIs was $962,000 ($142,000 for ROIs and $192,000 for all grants). NCI spent a total of $138.5 million on POIs, compared with $356.2 million for ROIs and $776.5 million for all grants.

The present application and review procedure starts either with preliminary dialogue between the applicant and NCI staff or submission of letters of intent. Applications go first to the NIH Div. of Research Grants, and when appropriate, are assigned to NCI. They are administrataively reviewed, assigned to a chartered or special review committee, site visited in either case, then reviewed again by the chartered

committee if so assigned. The NCAB by law must approve the awards before they are made, thus providing a secondary level of review, a requirement for all grants exceeding $50,000 in direct costs.

The working group, which has met twice a month since last July, determined that efforts should be made to promote more interaction between investigators considering PO1 applications and NCI. They also suggested that certain PO1s could be solicited with formal requests for applications or program announcements, a practice used to a limited extent.

The working group suggested that letters of intent might be made mandatory, although Rambaut acknowledged that that might require a change in HHS regulations.

Current guidelines call for PO1s to be large enough to achieve synergy and economy, small enough to allow effective interaction, and small enough to be reviewed on site in one day.

The working group determined that the one day site visit limit should be removed. Also, that size should be limited only by scientific objectives, not by the length and cost of review, nor by the number of projects, nor by the overall cost. It was acknowledged that large applications are difficult to review.

Current Process Advantages

Perceived advantages of the two tiered process, Rambaut noted, are that it permits ranking a PO1 in a "universe" of PO1s; it furnishes the nuclei of site visit teams; it can ensure consistency and continuity; it can moderate findings of site visit teams; it can provide advice to executive secretaries; it can consider updates, amendments, supplements, etc.

Among the disadvantages of the two tiered system are the aforementioned "poor information transfer" from site visit teams; chartered committees may duplicate review of science; chartered committees may have fewer experts; it requires redundant report writing; it encourages midstream rebuttal; and it entails more formalized committee management practices.

Alternatives considered by the working group included:

*Retain the two tiered concept by having site visit teams vote priority scores with later parent committee check (rather than the parent committee casting the final scores).

2. Retain the two tiered concept by increasing the number of site visitors brought back to the parent committee.

3. Abandon the two tiered concept by site visiting with subcommittees of enlarged parent committees.

4. Abandon the two tiered concept by having site visit teams, chaired by parent committee members, vote scores.

5. Abandon the two tiered concept by using special review committees exclusively.

The working group chose option 5, which was subsequently endorsed by the NCI Executive Committee.

Rambaut said that use of special review committees would eliminate communication problems, eliminate redundant report writing, permit inclusion of PO1 experts and experienced scientific managers, address special disciplinary problems, permit ranking applications in the universe of good science, permit easier scheduling of review, and would reduce costs.

The working group also addressed review of amended applications and came up with these recommendations:

1. NCI staff should determine whether acceptance of an amended application is justified and by what method its review should be conducted.

2. NCI staff should determine, as circumstances warrant, whether mail reviews, reverse site visits, or other types of review should be employed.

Rambaut noted that NIH policy on site visits is that they are not automatic for any type of application, they are supposed to be used to gather information not otherwise obtainable, and that the executive secretary must determine the need for one.

In practice, however, for NCI PO1s at least, site visits are automatic and preemptive, applicants expect them and that expectation encourages less complete applications.

NCI PO1 site visits have increased in cost from an average of $6,700 in FY 1982 to $7,300 in FY 1986, although the team size has shrunk slightly, from 8.8 to 8.4 persons. The length of the visit has gone up from 2.8 to 3.1 days.

In summary, the recommendations of the working group, endorsed by the NCI Executive Committee, are:

1. More interaction between program staff and applicants and between program review staff.

2. All initial reviews to be conducted by special review committees.

3. Automatic site visiting of amended

applications to be discontinued.

4. Other operating level changes will be made.

5. New guidelines to be developed based on these recommendations.

NCAB members endorsed the recommendations but expressed concern about making such sweeping changes without further discussion.

"The group that did this reevaluation is a heavyweight group," NCAB Chairman David Korn said. "To what degree was there consensus?"

The working group "quite often was polarized between program and review staff," Rambaut said. Consensus consisted of a majority of the members; "never on anything did everyone agree."

"I'm of ambivalent mind," Board member Enrico Mihich commented. "I participate heavily in this mechanism. The two tiered system works or doesn't work, depending on the quality of people involved."

Mihich said that without the chartered committees, "it may be difficult to retain a pool of experts."

Rambaut said that was an important point which was discussed "at great length" by the working group.

Board member Roswell Boutwell said he favored the single tier system. "There is such a demand on reviewers that many of us are saying no. Anything NCI can do to reduce demands on the scientific community will help. The quality of our own work suffers."

However, Sullivan said he was concerned about the proposed changes. "I've seen remarkable changes in scores (by the parent committees)." The proposed changes would "seem to weaken the peer review system. The present system has worked quite well."

"I'm pleased to see this issue dealt with in a sound way," Board member Bernard Fisher said. "I certainly can see how we can refine what we have. I favor the single tier approach provided the site visit team is adequately indoctrinated on its charge prior to the visit rather than after, as has been frequently the case."

Fisher added that "the heart of the problem is the people who are picked (for the review teams) and how they are picked. The persons being reviewed should have the opportunity to challenge those picked, or have a certain number of challenges."

Board member Louise Strong agreed that the single tier system would "eliminate a lot of problems." The question of whether a sufficient number of people would be available for review duties, people with expertise in program projects, could be answered by the fact that there have been "a lot of people on those teams who have rotated off. There is a large pool of people with expertise in POIs."

With the single tier system, Board member Gertrude Elion said, "the site visit group needs to be larger, and each discipline needs to be represented by at least two people." Just one expert in an area, who might be prejudiced, can affect the entire group, she added.

John Montgomery, member of the President's Cancer Panel, agreed. "But I'm not sure two is enough. One person can sink a review. Going back to the parent committee can be a check on that."

"The parent committee frequently has only one person with expertise in a discipline," NCI Director Vincent DeVita said. "One person can shout down a review by a site visit team."

Board member Helene Brown said she favors the changes but asked that consideration be given to eliminating the high and low priority scores, which would eliminate undue influence by individuals with extreme prejudices.

William Longmire, member of the President's Cancer Panel, said he supported the changes because it "simplifies the process."

Rambaut said the changes, if accepted, would be implemented in early 1988. Board member Phillip Frost suggested adopting them for a three year trial period, but Korn asked what criteria would be used to evaluate them.

"That would be difficult to quantitate," Rambaut said. "One could be the number of objections by applicants."

"I'm not sure that's too important," Korn said.

"He means the number of justifiable complaints," Brown responded.

DeVita suggested that reductions in workload, number of staff members and amount of time involved could be indicators of success.

"The Executive Committee all liked the idea (of the changes)," DeVita said. "They would save time and effort and would be cheaper. We could watch it, and change back if it doesn't work. Your main role, as the National Cancer Advisory Board, is not the review of specific grants but to oversee the integrity of the peer review system."

"These recommendations sound good to me," Board member Geza Jako said. Including terms on other NIH advisory councils, Jako has served 16 years as an NIH advisor, "and we have always looked for ways to improve peer review. Maureen Henderson's work (in the previous PO1 guideline changes) was a great improvement."

Mihich, who said he supported the single tier system, noted that one consequence will be "to put increased responsibility on executive secretaries to put together good site visit teams. Can we have a common think tank on selection of committee members, so that the responsibility is not always on one person?"

DEA Director Barbara Bynum said that is the way the present system works, although not in a formal procedure. The executive secretaries and other DEA staff members do discuss review committee and site visit appointments with program staff. But Mihich insisted that establishing a formal system for selections would increase the confidence of applicants in the fairness of those selections and more adequately assure that all appropriate disciplines are represented.

"I'm still not convinced," Sullivan argued. "I view this as a profound change, with elimination of chartered committees. Is there any reason we have to decide today, after an hour's discussion?"

Boutwell noted that the Outstanding Investigator Award represented an "extreme of lessened, simplified review, done entirely by mail ballot. This Board and NCI staff are very happy with it."

"There is a big difference, evaluating one person by mail, and review of a PO1," Korn said.

Brown's motion to accept the recommendations of the working group and to add Mihich's suggestion to formalize the selection of reviewers and her own to drop the high and low priority scores was approved, with only Sullivan dissenting.

DeVita said the complete recommendations with various refinements would be presented to the Board at its May meeting.

"Havoc Unleashed" By OMB Action; Organizations Consider Legal Action

In 1974, President Nixon called it "impoundment." The courts called it illegal, and forced Nixon's Office of Management & Budget to release about a half billion dollars of NIH appropriations which OMB was trying not to spend.

Congress then changed the law and specifically prohibited Presidents from withholding any appropriated funds without the formal approval of both the Senate and House of Representatives. In the late 1970s, President Carter tried to use that mechanism, known as "rescisions," on the NIH budget. He submitted NIH rescision requests every year of his term, always without success when substantive cuts were involved.

President Reagan's OMB, also striking out with NIH rescisions, became more creative. First they tried a form of illegal impounding, calling it "forward funding," in which outlying years of grants awarded in the current year were to be funded entirely with the current year's appropriation. OMB backed off in the face of threatened lawsuits and congressional action.

OMB has not given up, and this year the illegal impoundment is being presented as "extended availability" of funds. The money involved is more than $300 million of NIH 1987 fiscal year funds appropriated by Congress, $64 million of which is NCI's. This is the proposal included in the President's FY 1988 budget which has been submitted to Congress. OMB asked that that amount be delayed from obligation in 1987 for release in FY 1988.

Members of the National Cancer Advisory Board, among others, are outraged.

"Why was it illegal then (in 1974) and not now?" Board member Gertrude Elion asked.

"They're very clever," NCI Director Vincent DeVita responded. "It is tied into the 1988 budget. Congress still has to approve it."

Congress generally does not take final action on the next year's budget until September or even later. The fiscal year ends Sept. 30. Meanwhile, OMB has directed the affected agencies to allocate their 1987 funds as if the reductions will be approved. If Congress follows its normal schedule, the fiscal year will be over, or so close to being over that it will not make any difference. The money earmarked for "extended availability" would be spent in FY 1988 in any case.

That prospect has prompted some organizations to consider taking the Administration to court. The Assn. of American Medical Colleges, in particular, is discussing that prospect with its attorneys.

An AAMC spokesman told **The Cancer Letter** that the association hopes to make a decision by next week on whether to proceed with legal action. Other organizations and professional societies may join in.

"I think this business with OMB and the 1988 budget is unfortunate," NCAB Chairman David Korn said. "The degree of havoc being unleashed on the research community is alarming. No one knows when it will end. Cuts 18-20 percent under study section recommendations are crippling. OMB's implication that nothing occurs until Congress acts is untrue. Cuts are being made. The justification that this will 'stabilize' research also is not true."

Korn also objected to what he called "micromanagement" of NIH by OMB, referring to the present system of apportionment which makes it extremely difficult for institute directors to make more flexible use of their funds.

"Study sections are not philanthropic," Korn said. "They carefully review budgets in applications. They provide funds for what is needed to do the work. This is a terribly dangerous event. It is wreaking havoc with laboratories."

DeVita, who as a member of the Administration must refrain from openly taking issue with the President, said he would not join in the argument over the budget. However, "I will echo the comment on apportionment. It is terrible that, if you free up some money, you can't do anything with it."

DeVita told the NCAB Planning & Budget Committee some grants being recompeted this year which because of the $64 million cut might not be funded are being extended with interim funding. Some awards for new grants are being delayed, until the issue is resolved.

Board member Enrico Mihich noted grants in the second and third cycles of 1987 are taking most of the cuts, being funded at about 85 percent of their recommended levels. The cut was not imposed until after those in the first cycle were already awarded. "Can't you fund these cycles at higher levels and take that amount away from the first cycle of 1988?" Mihich asked. Sort of "extended availability" in reverse.

DeVita said OMB would not permit that.

Louise Strong, chairman of the Planning & Budget Committee, said the Administration's "capriciousness" is "worrisome" and is contrary to "the case we have presented for stability and flexibility."

DeVita said that every Administration from Nixon's through Carter's, knowing that Congress would add to their NIH budget requests, "came in low."

"But has any other Administration played these games with the budget?" Strong asked.

DeVita referred to Nixon's impoundment, leading Board member Helene Brown to comment, "and we took him to court."

Board member Bernard Fisher asked, "Can you remember two successive years when we haven't had a problem like this? I don't."

"In the past, before apportionment, we had flexibility and fixed a number of grants," DeVita said.

OMB is not the only culprit, and perhaps not even the primary one, DeVita intimated. "Apportionment can't be entirely layed onto OMB," he said. The problems began when then NIH Director Donald Frederickson sold Congress on the policy of supporting a fixed number of competing grants each year. "It was an effort to stabilize research," but it has prompted OMB to attempt to hold down the number of grants by "forward funding," "extended availability" and--worst of all--apportionment.

DeVita has had his problems with NIH Director James Wyngaarden on the apportionment issue. Wyngaarden has nixed at least one NCI effort to reprogram funds, when DeVita tried to shift some money out of research projects into the centers program last year.

DeVita noted that Congress in the 1987 appropriations bill report directed NIH to submit a report this year on apportionment and the problems it is causing. "The NIH director will be making the report, and it is my guess he will say it is working fine. I can't sit next to him (at the hearings before the congressional appropriations committees) and say it is a bunch of hooey."

Serious Problem

John Ultmann, director of the Univ. of Chicago Cancer Center and a member of the Div. of Cancer Prevention & Control Board of Scientific Counselors, expressed concern about the budget at the last meeting of that Board.

"This has been going on for the last eight to 10 years, regardless of whether a Democrat or Republican was in the White House," Ultmann said. "They have recommended cuts, forward funding, etc., and all have failed. OMB has to recognize the seriousness of these initiatives. We are having a serious problem

in attracting young people into biomedical research. Scientific organizations have to take a stand. For the record, everytime science has taken a stand, science has been supported."

Ultmann is chairman of the National Coalition for Cancer Research.

Further details on the impact of the 1988 budget submitted by the President have emerged.

The request asked $1.8 billion for NCI, but $508 million of that represented funds which would be reserved for the outlying years of grants awarded in FY 1988. It also included the $64 million proposed for "extended availability" from the 1987 budget.

When those figures are deducted, the total budget request is $1.302 billion, precisely $100 million than Congress appropriated for NCI for FY 1987.

That amount would support 3,090 grants, competing and noncompeting; would increase AIDS spending by $23 million, to nearly $85 million; and would provide funds to cover the full year impact of the new retirement system of the federal government. It eliminates entirely any funds for construction and renovation.

(The breakdown by mechanism appeared in **The Cancer Letter** Jan. 9).

The National Cancer Act gives NCI the unique authority to submit directly to the President its budget request, developed with the advice of the NCAB. Known as the "bypass budget" (it bypasses NIH and HHS), it asked $1.7 billion for the 1988 fiscal year, compared to the $1.3 billion sought by OMB.

Considering that Congress appropriated only $300 million less than $1.7 billion for 1987, the bypass request did not represent an unreasonable increase. Given the probability that Congress will reject OMB's $64 million cut (if it is not previously thrown out in the courts), $1.7 billion is still a reasonable request for cancer program advocates to seek.

Here's how the bypass budget compares to OMB's, by mechnism:

*Research project grants (primarily, RO1s and PO1s)--bypass, $713.3 million; OMB, $584 million.

*Cancer centers--bypass, $116.6 million; OMB, $93.2 million.

*Clinical cooperative groups--bypass, $78.7 million; OMB, $57.6 million.

*Other grants--bypass, $24.1 million; OMB, 19.8 million.

*Training--bypass, $36 million; OMB, $31.7 million.

*R&D contracts--bypass, $227.4 million; OMB, $202.9 million.

*Intramural research--bypass, $245.8 million; OMB, $245 million.

*Research management and support--bypass, $76.6 million; OMB, $65.2 million.

*Cancer prevention and control--bypass, $96.2 million; OMB, $67.4 million.

*Construction--bypass, $35.2 million; OMB, 0.

*Special initiatives--bypass, $50 million; OMB, 0.

The bypass budget was constructed with the requirements in each category to meet the Year 2000 Goals determining amounts requested. Each year those requirements are not met will push attainment of those goals that much farther down the road.

DCPC Board Okays Construction Architect/Engineering Support

Although there is nothing in the budget submitted to Congress by the President for construction and renovation grants, NCI is proceeding with the assumption that Congress will end up putting at least some money into that category.

The Research Facilities Branch of the Div. of Cancer Prevention & Control submitted for concept review to the division's Board of Scientific Counselors a proposal for a contract for architectural and engineering design review support.

The Board approved the concept without controversy, along with the estimated amounts to be set aside--$54,600 the first year, $74,800 the second and $36,800 the third.

Branch Chief Donald Fox is chief of the branch (see below for details of the concept).

The Board also approved the concept for a sole source contract with the National Academy of Sciences for participation in the National Research Council's Food & Nutrition Board project to develop a strategy for implementing guidelines on diet and health and to assess implications of those guidelines. The project will cost NCI an estimated $110,000 a year for two years.

NCI has already edged into making dietary recommendations; the broad NAS study should add clout and creditibility to them

The construction support concept follows:

The task of the support services contractor is to provide technical (architectural and engineering) review of design submittals for construction grant projects involving new construction, completion of shell space, and alteration and repair. Thre three stages for which review services are required are schematic design, design development and construction documents (final design). The objective is to provide NCI/RFB staff with review comments and recommendations concerning deficiencies and errors in design submittals made by grantees which can be transmitted to the grantee for correction and action by their A/E.

In order to meet the mandate of this program, the proper professional disciplines must be available including architects, mechanical engineers, electrical engineers, structural engineers, biohazards and animal facility experts and supporting staff. The present staff of the branch, in addition to the program director, consists of one architect and one secretary. Additional staff of the appropriate professional disciplines and support staff are needed to create the critical mass of personnel to meet the mandate of the program.

The contractor will provide the necessary professional personnel to perform the required A/E design review of construction grant projects funded by NCI.

The deliverable product for this support services contract shall be the review comments, in written form, referencing appropriate design/policy criteria, ready for transmittal by attachment to the grantees. Recommendations for design improvement may be made on an advisory basis. Turn around time for submittals reviewed by the contractor is expected to be no more than two weeks (10 working days) for routine submittals. Turn around time for extraordinary situations (e.g. large number of submittals at one time, exceptional complexity or size, etc.) will be negotiated with the contractor on a case by case basis.

Charges for services shall be according to professional discipline, administraative and clerical services rendered at a predetermined hourly rate for the actual time expended. Rates shall be graded according to the level of expertise and will include allowable overhead and profit. Rates shall be confirmed by government payroll and overhead audit.

This project is a continuation of a support contract previously approved by the DCBC BSC last year, for $15,000. That contract, which is currently being advertised, and its budget were based on the presence of a full time professional mechanical engineer and one full time professional architect on the NCI staff. The architect remains but the mechanical engineer has left and will not be replaced. The increased budget reflects the decrease in required personnel and an increase in the number of anticipated grant awards in FY 1987 due to the increased budget for this year.

One award will be made the first year with an option of an award in each of two more years.

RFPs Available

Requests for proposals 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 20892. 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-CN-75409

Title: Multidisciplined analysis of chemopreventive agents

Deadline: March 20

NCI's Div. of Cancer Prevention & Control, Chemoprevention Program, is seeking a contractor for a multidisciplined evaluation and analysis of data on inhibitors or potential inhibitors of any stage of carcinogenesis, in order to establish a prioritization of candidate chemopreventive agents for further evaluation.

The Chemoprevention Program has established a clearly defined integrated plan for evaluation of chemopreventive agents. This plan delineates detailed criteria for classifying the quantity and quality of experimental information that currently exists on any chemopreventive agent and thus defines what additional information and investigations are required to qualify the agent's experimental use in intervention trials of human cancer. The primary purpose of this project shall be to analyze and evaluate the existing scientific literature concerning chemopreventive agents, so that the most promising candidate agents can be prioritized for further experimental studies and clinical trial evaluation as appropriate and as funding permits.

The successful offeror shall:

1. Establish a master list of candidate chemopreventive agents which shall include at least 200 agents that have biological activity as potential inhibitors of carcinogenesis as indicated by epidemiologic, in vivo and in vitro evidence from the published scientific literature. This listing shall describe specific biologic activities that may indicate chemopreventive potential and shall be continually updated.

2. The successful offeror shall designate a panel of experts to perform a multidisciplinary evaluation and analysis of all available information on candidate chemopreventive agents. This must include, but not necessarily be limited to, the fields of epidemiology, carcinogenesis, cell biology, tumor cell biology, biochemistry, toxicology, nutrition and pharmacology. The successful offeror must include on this panel of experts doctoral level people with active programs in these specialty areas who would be available on an ongoing basis to participate in this effort.

3. Establish a computerized data base of potential chemopreventive agents that inhibit carcinogenesis in vivo in animal bioassays. The primary purpose of this data base shall be as an aid in the preliminary review of candidate agents. The data base shall be computer searchable to allow sorting of the information into tables organized by agent, target organ and species, carcinogen, and time during the carcinogenic process in which the agent is effective.

This proposed procurement is a 100 percent small business set aside, the size standard for which is a concern, including its affiliates having average annual sales or receipts for its preceding three fiscal years not in excess of $3.5 million.

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