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APPROPRIATIONS COMMITTEES LEAN TOWARD ADDING SOME TO NCI BUDGET; ACS TO ASK AGAIN FOR $1.5 BILLION

Congressional health appropriations subcommittees have completed their hearings of NIH witnesses and are well into the process of hearing public witnesses, so far with no strong indication that the

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In Brief

TWO MAJOR APPOINTMENTS MADE AT FOX CHASE; HHS NAMES TASK FORCE TO LOOK AT DRG RESEARCH IMPACT

TWO MAJOR new appointments to the Fox Chase Cancer Center staff have been made by Director John Durant: Michael Lieberman, professor of pathology at Washington Univ., St. Louis, has been named chief of pathology, with the responsibility of establishing a pathology service and research program; and Bob Comis, professor of medicine at State Univ. of New York (Syracuse), has been appointed medical director and chief of medical oncology.... **HHS SECRETARY** Margaret Heckler has complied with the request by Sen. Robert Dole to set up a task force to look at the impact of the DRG Medicare reimbursement system on clinical research. Asst. Secretary for Health Edward Brandt will chair it. Members will include James Wyngaarden, NIH director; Caroline Davis, head of the Health Care Finance Administration; Vincent DeVita, NCI director; Patrice Feinstein, HHS; John Yarbro, president, and Lee Mortenson, executive director of the Assn. of Community Cancer Centers; and representatives of the Assn. of American Cancer Institutes, American Society of Clinical Oncology, AMA, American Hospital Assn., and Assn. of American Medical Colleges. First meeting of the group is scheduled for April 24; it will not be open to the public.... **RICHARD CROUT**, head of the NIH Office of Medical Applications of Research, left that position this week to become vice president and medical director of Boeringer-Mannheim Corp., a German owned drug firm. Crout was director of FDA's Bureau of Drugs from 1973-82 and was instrumental in settling the squabbles between some of his staff and NCI, resulting in the smooth working relationship which now exists. A memorable moment in his career: Telling Sen. Paula Hawkins, who was scorching him at a hearing for discussing the previous day's testimony with an FDA chemist who had criticized the agency (the staff member said the discussion had intimidated her), "I don't need any lectures from you, Senator." Itzhak Jacoby, OMAR deputy director, will be acting director until a new one is named.... **ROSWELL PARK** Memorial Institute has established the John W. Pickren Surgical Pathology Lecture in memory of the chief of pathology at the Institute who died last month, RPMI Director Gerald Murphy announced.

FULL FUNDING OF ALL GRANTS, RAISING PERCENTAGE TO 40 WOULD ADD $73 MILLION

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committees will add substantially to the Administration's 1985 fiscal year budget request for the Cancer Program. But members of the House and Senate subcommittees have expressed concern about some areas that are underfunded and have indicated they will support at least modest increases to fill those gaps.

The Administration request was for $1.1 billion (actually, one billion, 101 million), an increase of only $24 million over the current, FT 1984 level.

NCI had originally requested, in the 1984 bypass budget submitted directly to the President, $1.189 billion, a rather modest increase now although seemingly larger a year ago when the bypass figure was drafted and NCI was working on a 1983 budget of $986 million.

Will Congress do as it did last year and add money up to the bypass request? It is not unreasonable to expect that it will—$88 million is only a speck in the overall federal budget, but it would make a tremendous difference in strengthening the National Cancer Program.

Considering actions of the House and Senate Labor-HHS Appopriations Subcommittees last year and comments at the hearings this year, here is how they conceivably could allocate an additional $88 million this year:

*Require that all investigator initiated (RO1 and PO1) grants be funded at their full, peer review recommended levels. The Administration's budget would require a reduction of 3.8 percent. The cost of fully funding those grants—$16 million.

NCI (and other NIH institutes) had been funding RO1s and PO1s, as well as cooperative group and cancer center core grants, at less than recommended levels in order to be able to fund more grants. In the congressional directives, NIH was told to fund all research grants at or close to the recommended levels; NIH chose to interpret that to include only RO1s and PO1s, although it was clear that Congress had not intended to exclude centers and the cooperative groups.

*Fund the cooperative groups at their full recommended levels. The Administration's budget would require a reduction of six percent. The cost of fully funding the groups—$4 million.

*Fund cancer center core grants at their full recommended levels. The Administration's budget would require a reduction of nine percent. The cost of fully funding the centers—$7 million.

*Increase the amount in the RO1/PO1 grants pool enough to fund 40 percent of approved new and competing renewals. The Administration's budget would support funding only 30 percent of approved new and competing RO1s/PO1s. The additional cost of funding 40 percent instead of 30 percent—$46 million.

The anticipated priority score payline with funding of 30 percent is 175; with 40 percent, it would be 195-200.

That adds up to $73 million. It would not be a bad idea for Congress to let NCI have the additional $15 million to bring the total up to the bypass request without earmarking it, but if the committees must justify the extra money, they easily could spread it over construction, training, drug development including biological response modifiers, cancer control, more clinical trials, additional center core grants, and intramural research. A strong case could be made for major increases in each of those categories, if the bypass budget figure is not to be considered as a limit.

That, in fact, is just what the American Cancer Society had in mind last year in requesting $1.5 billion for NCI, a request ACS is repeating this year.

The Society's pitch this year places it strongly behind NCI's insistence that the construction grant budget needs to be increased by substantial amounts. The bypass request was for $20 million; the Administration trimmed that to $1 million. ACS is paying for half the $150,000 cost of conducting a national survey of cancer research facility needs (Armand Hammer is paying the other half).

ACS also is asking for major increases for clinical trials, basic research, program projects, cancer centers, organ systems program, and training. The Society insists that at least $400 million more than the Administration requested could be wisely and effectively spent.

Sen. Lowell Weicker (R.-Conn.), chairman of the Labor-HHS Appropriations Subcommittee, at his hearing on the NIH budget asked each institute director to list important research which would be harmed if the President's budget were adopted without increases. When it was his turn, NCI Director Vincent DeVita indicated that research project grants, training, and intramural research would be affected. Training slots budgeted for 1985 are 1,181, compared to 1,280 in 1984, DeVita said.

Pressed by Weicker on NCI personnel cuts, DeVita said his share of the NIH cuts would be 95 positions and that he hoped to protect permanent employees by applying the cuts to summer and part time employees.

DeVita publicly stated at a meeting of the President's Cancer Panel his dissatisfaction with the Administration's policy regarding the expert consultants which NCI is permitted to hire, as

authorized by the National Cancer Act. That authority has greatly benefitted NCI and the Cancer Program over the past 12 years, permitting the Institute to bring in top people for one to two year assignments. In many instances, it has allowed NCI to take on people immediately for key positions while going through the lengthy process of acquiring permanent status for them, thus avoiding the situation of leaving important posts vacant for months at a time.

This authority now is severely limited by the Administration's policy of applying the expert consultants to the personnel ceilings despite the clear intent of the National Cancer Act.

Responding to Weicker's question about the problem, DeVita said that the policy has not been consistent in recent months. In March, he was told the experts would not count against the ceiling, but now it will. "This makes recruitment difficult," he said.

Weicker said that he had attempted to clarify the issue previously in reports on the appropriations bills. The HHS "watchdog" at appropriations hearings (whose primary duty there is to report on any "budget busting" attempts by HHS employees), Anthony Itteilag, deputy assistant secretary for budget, responded by saying, "We abide by the legislation, not the report language."

In fact, NIH does try to comply with directives in the reports which accompany most bills, especially when the language is similar in both House and Senate reports. However, HHS and the White House Office of Management & Budget sometimes ignore the reports when they are contrary to Administration policy.

Weicker indicated he would attempt to provide a directive on the expert consultants issue which the Administration cannot ignore.

Weicker argued with NIH Director James Wyngaarden's assertion that the budget request "is a realistic continuation of biomedical research and training." Weicker responded by referring to Wyngaarden's November, 1983, speech to the Assn. of American Medical Colleges in which he said that 45 percent of approved research applications should be funded.

"You want 45 percent funded, but the 1985 budget will fund only about 30 percent," Weicker said.

Wyngaarden said the historic NIH average is 45 to 50 percent and many institute directors would like that as a target. "We did 37.5 percent last year. This year it will be 33 to 34 percent. The budget is about 30 percent, but we can make a few adjustments. We can fund the very best applications."

"But that will eliminate many which are very good, won't it?" Weicker asked.

Wyngaarden said that restoration of the recent percentage approval rate would require about $150 million for NIH more than the President's budget and about $270 million total if new, competing, and noncompeting grants were taken care of.

Weicker hinted at his 1985 target for NIH when he asked Wyngaarden what a growth of five percent would cost. When Wyngaarden said $225 million, Weicker moderated his enthusiasm a bit. "It will be very difficult to get a five percent growth, but I will try to keep it at least at the 1984 level."

Sen. Daniel Inouye (D.-Hawaii) submitted questions in writing, on neglect of nurse research and on clinical trials. Wyngaarden said the approval rate for nurse research applications was about the same as for other applicants, and that NIH supported 26 clinical trials costing $220 million in 1984. In 1985, Wyngaarden said, there will be only two new clinical trials, in the heart and lung and digestive diseases institutes. (NCI's numerous clinical trials often are not included in the NIH hearing discussions because they are not unusual within NCI, whereas they are unique events at most of the other institutes).

DeVita, responding to questions about the cancer centers budget, cut by the Administration $1 million from $1984, said that two centers—the Univ. of Maryland at Baltimore and Stanford Univ.—did not seek renewal of their core grants. A new core grant will be funded, DeVita said, but did not identify it. At the hearing by the House Labor-HHS Appropriations Subcommittee, DeVita said the new center was located in Nebraska. NCI does not announce new grants until after the award is made.

At a hearing of public witnesses by the House Subcommittee, chaired by Congressman William Natcher, (D.-Ky.), the Delegation for Basic Biomedical Research appealed for an increase in the number of competing grants NIH commits itself to support each year from 5,000 to 6,200. Mahlon Hoagland, president of the Worcester Foundation for Experimental Biology, spoke for the delegation which also requested $90 million more for research centers, $20 million for NIH facilities, $25 million to upgrade animal facilities, and $86 million more for research career awards, clinical trials, and biomedical research support.

GALLO "BREAKTHROUGH" ON AIDS VIRUS TO BE REPORTED IN "SCIENCE" IN MAY

Rumors have been making the rounds of the scientific community for the past month or more that Robert Gallo, chief of NCI's Laboratory of Tumor Biology, might soon be making an announcement of a major development in research on the etiology of AIDS. The rumors are true. **The Cancer Letter** has

learned that "Science" magazine will publish in May findings by Gallo and his colleagues, and possibly other laboratories, that a variant of the human T-cell leukemia virus is found in AIDS victims.

A series of reports published last year by Gallo and others associated retroviruses, which include HTLV, with AIDS and that they were the leading candidate as the cause of the syndrome.

Gallo previously had gained worldwide acclaim for the discovery by his lab of HTLV, the first known human cancer virus to be isolated.

Because of professional publication restrictions, NCI and HHS spokesmen have declined to comment on the reports. Gallo has told reporters that it is premature to comment until the research had been reviewed.

However, the leaks have been persistent, and speculative stories appeared this week in the lay press. HHS Assistant Secretary for Health Edward Brandt is considering making an announcement next week because of the importance of the new Gallo findings and their public health implications.

A story April 17 in the "Washington Post" said, "Researchers from the National Cancer Institute and other laboratories have found persuasive evidence that a variant of a human cancer virus may be the major cause of the mysterious and deadly condition known as AIDS, according to medical sources.

"Experts familiar with the research say that a team headed by Dr. Robert Gallo has found 'very strong' signs that a newly discovered form of the human T-cell leukemia virus infects victims of AIDS," the Post story continued. "It also affects those with an illness that may precede AIDS.

"Promising work with the variants of HTLV is also under way in laboratories at France's Pasteur Institute and at the federal Centers for Disease Control, which is coordinating the United States study of AIDS, sources said.

"But, although the general findings have circulated, the details of the new research have not yet been published and have been closely held among AIDS researchers. Outside experts cautioned that until the findings can be scrutinized by the scientific community, the strength of the evidence that an HTLV type of virus causes AIDS cannot be evaluated completely.

". . . 'My understanding is that it appears likely this is the cause of AIDS. It's certainly the strongest candidate described thus far,' said an investigator familiar with the research.

"There is the 'potential of developing a blood test to screen blood donors, and there will certainly be an impetus to start looking at the possibility of vaccine development' to prevent the disease eventually, he said, adding that more research is needed to determine whether the virus implicated by Gallo's team is the same as that under study by the French and CDC researchers.

"... In the past, two forms of HTLV have been associated with cancer, particular a T-cell leukemia common in Japan and parts of the Caribbean and Africa. Sources indicated that Gallo's tumor cell biology laboratory recently isolated a third form of the virus in patients with AIDS and its precursor illness.

"The sources also indicated that more than three fourths of several dozen patients with varying forms of AIDS showed HTLV antibodies, a sign that they may have been infected with the virus, while such antibodies were rare in those without the disease.

". . . 'One option is to say it is by far the leading candidate, assume it is the cause and go ahead with that assumption,' " the Post source was quoted as saying. " 'The other approach is to say this still hasn't been proven and go on to prove it,' by giving the virus to animals to see if they develop AIDS, he added.

" 'It is important enough that some action needs to be taken," another source said.

An NCI staff member, confirming the development, told **The Cancer Letter**, "This is it, the breakthough we've been waiting for."

RAUB NOTES THAT NIH "ALERT" SYSTEM DOES NOT NOTIFY INITIAL REVIEW GROUPS

William Raub, NIH deputy director for extramural research and training, took exception to statements appearing in **The Cancer Letter** March 30 in the article on the Niagara Falls physician charged with fraud in connection with clinical investigations.

The article said that the physician's name had been placed into NIH's ALERT system "which requires that study sections and other review bodies be notified of the charges against (the accused) should he be involved in a grant application or contract proposal."

Raub pointed out that the ALERT system in fact does not notify initial review groups. "The ALERT system was established in 1981 to provide a mechanism for informing NIH staff responsible for funding decisions that an applicant is under investigation by another NIH component, another agency, or in some instances, an awardee institution," Raub wrote. "Such notification is limited to my office and the director of the affected awarding component. The only specific requirement is that the director consult with me prior to making an award... The ALERT policy does not require that initial review groups be notified. On the contrary, every effort is made to avoid compromising the initial review. We do encourage Institute directors to seek the advice of their National Advisory Councils and Boards in the belief that such consideration represents an

important safeguard against arbitrary or ill advised staff decisions."

The March 30 article further stated, "Implication of the (ALERT) policy is that, guilty or innocent, no one is going to be awarded NIH support while charges of fraud against him are being investigated." Raub's response:

"It is true that in general NIH would delay or elect not to make a new award if preliminary findings raise serious questions about the integrity of an applicant. Continuation awards allow for more flexibility; we can and do exercise all available options to avoid compromising individual reputations or the integrity of ongoing projects."

Raub added, "ALERT is also used as a device for implementing actions taken as the result of completed investigations. Such actions may include consideration of investigative findings in subsequent reviews for a specified period of time."

RADIOLOGISTS DISPUTE HOLLAND'S SUGGESTION ON REGIONAL NMRs

David Bragg, chairman of the Dept. of Radiology, and James Nelson, professor of radiology at the Univ. of Utah, argue with James Holland's suggestion that nuclear magnetic resonance installations might be developed and used on a regional basis, through sophisticated communications and computers, rather than allow them to proliferate the way CT scanning did.

In a letter to the editor, Bragg and Nelson wrote:

"We have read with interest the excerpts in the March 23, 1984, Cancer Letter, of the speech by Dr. James Holland, observing the 10th anniversary of the Assn. of Community Cancer Centers. Dr. Holland, whose opinion is greatly respected by all of us, expresses some views regarding medical imaging which we feel are inappropriate.

"Dr. Holland views with amusement the initial concern by economists over the use and increasing costs of computed tomographic (CT) scanning. He admits to the tremendous impact CT scanning has had, particularly in oncologic areas. In the same paragraph, he expresses concern as to the cost and ultimate impact of magnetic resonance imaging (MRI). He suggests that regional MRI installations could be served by existing computers, connected by modems so that each clinician could view and interpret his own images. Unfortunately, this is a most unrealistic and impractical consideration. Although images might be transmitted with the aid of microwave technology, radiologic operator interaction is essential in the design of the study and manipulation of the data, to a far greater degree than is the case with CT scanning.

"The development of MRI scanners has virtually entirely been the result of industrial R&D dollars. Very few federal dollars have supported this process until recently. We feel the investment will be returned with more accurate and specific diagnostic yield, as has been the case with CT. The additional increment of diagnostic information which MRI will provide is not yet known and we urge that patience and thoughtful analysis be allowed for the ongoing evaluative process.

"Finally, it should be understood that although elaborate imaging tools such as CT and MRI equipment are usually utilized as examples of runaway medical costs, the amount of the total health care budget devoted to medical imaging is approximately three percent. If we eliminated medical imaging and reallocated the funds to other areas, as suggested in part by Dr. Holland, the impact on the total health care budget would be nominal yet the medical losses, awesome."

SOCIETY OF SURGICAL ONCOLOGY PLANS SYMPOSIUM ON GRANTSMANSHIP MAY 13

"How to Write and Review Oncology Research and Training Grants: A Grantsmanship Symposium for Surgical Oncologists" will be held May 13 at the Grand Hyatt Hotel in New York, from 2-5 p.m. The symposium is being sponsored by the Government Relations and Clinical Research Committee of the Society of Surgical Oncology.

Charles Balch, chief of surgical oncology at the Univ. of Alabama Comprehensive Cancer Center, will be the moderator. The agenda includes:

--NCI research and training programs involving surgical oncology, Bruce Chabner, director of the Div. of Cancer Treatment.

—American Cancer Society research and training programs involving surgical oncology, Gerald Murphy, ACS president.

—Reasons why research grants are not fundable, William McLaughlin, director of government and agency relationships, Memorial Sloan-Kettering Cancer Center.

—Principles of writing a research grant, John Niederhuber, chief of surgical oncology, Univ. of Michigan.

—Surgical research in cancer cooperative groups, Robert Wittes, director, Cancer Therapy Evaluation Program, NCI, and Balch.

—Investigator initiated (RO1), program project (PO1) and planning grants (P20), Chabner and Niederhuber.

—Training grants in surgical oncology (RO8, R25), Barney Lepovetsky, chief, Cancer Training Branch, NCI, and Arthur Boddie, professor of surgery, M.D. Anderson Hospital & Tumor Institute.

—The grant review process: study sections and

site visits, Dennis Cain, chief, Grants Review Branch, NCI, and Murphy.

NCI REISSUES CCRU RFA, ANNOUNCES OUTSTANDING INVESTIGATOR GRANTS

NCI has reissued its RFA for Cancer Control Research Units and has formally announced its new Outstanding Investigator Grant with the fervent expectation that the latter, the result of suggestions made by scientists to the President's Cancer Panel, will produce a more successful response than the CCRU did its first time around.

OIG's inception came when Chairman Armand Hammer started taking the Panel around the country to hear what the scientific community thought of the Cancer Program, NIH grant policies, and related subjects. What they heard were requests for more stable support, over longer periods, for the top investigators—"support people, not projects." Bernard Fisher and Harold Amos started pulling it together, and Amos—in the last of his multitude of contributions over 12 years as a member of the Panel and National Cancer Advisory Board—submitted a draft which the NCAB sent back for revisions. NCI staff took it from there, with the result described below. Present Panel members John Montgomery and William Longmire, along with Hammer, approved the general outline last December, and the NCAB gave its OK in February.

Main features of OIG are that it will fund outstanding investigators with seven year, competitively renewable, awards; replace existing NIH support they may have and thus not require additional funds for the grants pool; and will be reviewed initially by a national panel by mail, with further screening by the NCI Executive Committee and concurrence of the NCAB.

Cancer Control Research Units were supposed to be the centerpiece of NCI's redirected efforts in cancer control, with the shift in emphasis from demonstration to research. The problem was that, in the first round, only one application, that of the Univ. of Washington, scored well enough to be funded. CCRUs are supposed to be "centers of excellence" for cancer control research, but much to the chagrin of NCI executives, they found that most applicants did not have the base of ongoing cancer control research to make up a center.

"Centers of excellence can't be built overnight," Joseph Cullen, deputy director of the Div. of Cancer Prevention & Control, said this week. "But they will come."

A related effort, the Cancer Control Science Program, also was a disappointment. This program was developed as a compromise, when the old cancer control core grants were phased out. Cancer centers had been using that mechanism to support various outreach efforts which were classed more as service programs than research. The CCRU concept being developed as the successor to the core grants was seen by most centers exectives and by some NCI staff to be too restrictive to allow very many centers into the competition, a perception more accurate than they had thought, as it turned out.

CCSP was established to give centers with a certain amount of cancer control research activity the opportunity to seek support through a core like mechanism. It was advertised through an RFA, and generated a substantial number of applications, but only three were funded—UCLA, Illinois Cancer Council, and Fox Chase Cancer Center.

NCI executives have decided that CCSP might do better if it is handled as a program project activity and have announced that no further CCSP RFAs will be issued. Potential applicants are advised to develop program project applications.

"Our philosophy is that this is really a PO1 activity," Cullen said. "They must revolve around a central theme, and not come in with just three or more unrelated cancer control projects. They have to have some science if they want to get cancer control dollars."

There are four CCSP applications currently under review at NCI. They are the last that will be treated under the old concept; henceforth, CCSP applications must meet the requirements for program projects.

There are no CCRU applications in review at present.

Those interested in pursuing the CCSP-program project route should obtain copies of "Guidelines for Cancer Control" from the Cancer Control Applications Branch, DCPC, NCI, Blair Bldg Rm 1A07, Bethesda, Md. 20205; and also, "Guidelines for the NCI Program Project Grant" from the Grants Review Branch, Div. of Extramural Activities, NCI, 2115 E. Jefferson St., Rm 401, Rockville, Md. 20852.

The success of CCRUs, CCSPs, and indeed the ambitious latter day Cancer Control Program with its emphasis on research probably depends on the viability of the individual investigator initiated cancer control grant mechanism. Those are the R18 grants, which are reviewed within NCI, by the Cancer Control Grants Review Committee. In a major policy shift, one which has been made but not yet announced, future individual project cancer control grant applications which deal with phase 1, 2, or 3 studies as defined by DCPC will be treated as RO1s and will be sent to the NIH Div. of Research Grants for review by DRG study sections. Phase 4 and 5 studies will continue to be treated as R18s.

Another cancer control initiative which did not generate the response expected were the program

announcements for studies on smokeless tobacco and nontobacco smoking product use by children and adolescents and on tobacco use by blue collar workers.

"We weren't getting anything from the program announcements," Program Director Thomas Glynn said. DCPC staff has decided to ask the division's Board of Scientific Counselors for concept approval of reissuing the announcements as RFAs, which would have more defined approaches and involve setting aside specific amounts of money to fund any subsequent grants.

RFA 84-CA-08
Title: Cancer Control Research Units
Application receipt date: Dec. 3, 1984; letter of intent, July 2, 1984

The Div. of Cancer Prevention & Control of NCI invites grant applications from investigators for the support of Cancer Control Research Units. This RFA is a reissue of the CCRU RFA previously announced.

The goal of this RFA is to establish CCRUs which will plan and implement focused research studies aimed at major cancer control problems. Cancer Control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results. The research will address cancer control interventions with potential for reducing cancer incidence, morbidity, and/or mortality, and for generalizability to larger populations. The CCRU will be a long term resource for research and training for NCI's Cancer Control Program.

The proposed CCRU should have one or more clearly identified themes or programs, each consisting of an integrated group of projects from cancer control research phases 2 through 5. The general areas of DCPC's cancer control research are described in Cancer Control Program Guidelines issued last year and available from DCPC.

The required components of the CCRU will include:

*A rationale for the CCRU in terms of the cancer control themes and problems which will be investigated.

*A CCRU director with research and administrative experience.

*A multidisciplinary cancer control research team of qualified investigators, and an underlying research base.

*At least three high quality research projects which are approved with the CCRU application, of which two must be defined population studies.

*Organizational, administrative and institutional procedures, commitments and support.

Optional components of a CCRU are:

*Limited developmental or research projects, including applied epidemiology studies.

*Shared resource cores which are integral to two or more projects.

The CCRU will be encouraged to establish cancer control research training programs, including field involvement and applications. At this time, however, there will be no funds specifically earmarked for training within the CCRU grant, and potential applicants are encouraged to seek peer reviewed support through the NCI training grant mechanisms. After the CCRU grants are awarded and underway, spinoffs such as training programs may develop.

Applicants are strongly encouraged to submit a letter of intent and consult with NCI program staff before submitting an application because of the need for a clear understanding of cancer control research issues and the P50 guidelines, and to facilitate planning for the review of applications.

Nonprofit and for profit institutions within the U.S. are eligible to apply for project periods of up to five years. Funds have been set aside for the fiscal year 1985 to fund the initial year's awards. It is anticipated that a maximum of five awards will be made as a result of this RFA, subject to availability of funds.

Copies of the complete RFA and the 1983 Cancer Control Program Guidelines (NIH Publication 84-2659, Feb., 1984) may be obtained from Carlos Caban, PhD, Program Director, Cancer Control Applications Branch, DCPC, NCI, Blair Bldg Rm 1A01, Bethesda, Md. 20205, phone 301-427-8735.

Announcement
The NCI Outstanding Investigator Grant
Application Receipt Date: July 15; letter of intent receipt date, May 1

NCI announces the availability of the Outstanding Investigator Grant for the purpose of providing long term support to experienced investigators with outstanding records of research productivity. The initiation of this grant is intended to encourage investigators to embark on projects of unusual potential in cancer research. Emphasis will be placed on evidence of recent substantive contributions, i.e., seminal ideas and innovative approaches to resistant problems.

A. Candidate. Applications may be made by domestic institutions on behalf of investigators who have recently demonstrated outstanding research productivity for at least five years. There are no age restrictions. Only U.S. citizens, nationals, or permanent residents may be presented as candidates for this grant.

B. Letter of intent. Prospective applicants are strongly encouraged to submit a one to two page letter of intent, accompanied by a curriculum vitae and bibliography. This will enable NCI to plan the review and advise applicants regarding their eligibility for consideration. Letters should provide a brief statement of the investigator's accomplishments, plus a brief general statement of the project(s) expected to be undertaken with the OIG support. Though application for a Public Health Service grant may be submitted without prior notification, such letters would be appreciated.

Candidates considered to be ineligible based on the stated criteria and the letter of intent will be so informed by the director of the Div. of Extramural Activities of NCI. A prospective candidate considered eligible will be so advised and invited

to submit an application for a PHS grant (PHS 398).

The OIG is nontransferable and is awarded for a maximum period of seven years. The grant is not a lifetime award but is renewable. Application for competitive renewal should be submitted at the end of the fifth year according to the guidelines for the initial award.

The actual dollar award will reflect specifically the investigator's current and projected research needs evaluated by the initial reviewers, and reviewed by the NCI Executive Committee. The award will provide that fraction of the investigator's salary that approximates the total proportion of salary awarded through current grants, but not to exceed 75 percent. This limit may be waived under exceptional conditions such as evidence of institutional provision of unusual levels of support of other types.

Funds will be provided for the support of technical staff, research staff and graduate students, but not for other academic faculty or institute equivalents. Salaries of other principal investigators may not be included. Other expenses, as would be included in individual project grants, are legitimate costs.

It is required that the OIG principal investigator will commit at least 75 percent of his/her time and effort to the research supported by this instrument.

Candidates for this award may concurrently apply for additional NIH research grant or research contract support for the balance of his/her time and effort, provided the requirement that the candidate institution provide 25 percent salary support has been waived. Renegotiation of all concurrent NIH funds upon acceptance of this grant is required.

Candidates for this award may concurrently apply for training grants, construction grants and capital equipment grants.

Review. Applications submitted in response to this announcement will be assigned to an appropriate subset of a nationwide panel of recognized cancer investigators for review. The summary statements from this initial review group will be submitted by the exectuve secretary (DEA staff member) to the NCI Executive Committee to prepare its funding recommendations for the National Cancer Advisory Board. The NCAB will recommend awards to the NCI director for final action.

Reviewers will consider the following factors in evaluating the scientific merit of each response to this announcement:

1. What has been the impact of the applicant's work on the field of biomedical research?

a. Is his/her research cited often and as incentives for others' research efforts?

b. Has the applicant developed new experimental approaches crucial to the progress of his/her area of research?

c. Has he/she contributed to the collection of important reliable data?

d. In what way is the applicant's work seminal in nature?

e. Has the applicant productively exploited his/her own breakthroughs and/or those of others?

f. Has the applicant demonstrated imagination, energy, and sensitivity to the potential of serendipitous findings?

2. What will be the significance of the investigator's continued work in the field described above?

a. Does the proposed work break new ground or continue previous work?

b. Are the questions posed of significant interest and importance to cancer research?

c. Will this work provide impetus for others working in related areas?

3. Is there a strong likelihood that the investigator will continue at the frontiers of research?

Evaluation of the capabilities of the applicant. Comment on the way in which the applicant has achieved his/her present stature in the field. Speak both to the individual accomplishments and to collaborative interactions. Has the applicant made significant contributions in the areas of teaching and research training and/or clinical research? Comment on the applicant's communicative, pedagogic, and organization skills.

Institutional and administrative relationships. Does the applicant have adequate administrative support? Have the applicant investigator and his/her institution presented a workable plan for phase out of the applicant's current research support and conversion of staff and facilities to support by the OIG? Are there any problems anticipated? Will there be any particular benefits or disadvantages for the institution?

Application for this award should be made on form PHS 398 (Rev. 5/82) in accordance with instructions in this announcement. These applications are available in the business or contracts offices of most academic or research institutions or from the Div. of Research Grants, NIH, Bethesda, Md. 20205.

The research proposal must be cancer related as defined by the DRG grant application referral guidelines. Its prose portion should not exceed five typewritten single spaced pages.

A letter indicating clear and continuing institional commitment to the applicant must be submitted.

The original and six copies of the application should be submitted to DRG, NIH, as directed in the instructions of the grant application.

Inquiries related to further information, application development or letter of intent should be directed to Mrs. Barbara Bynum, Director, DEA, NCI, Bldg. 31 Rm 10A03, Bethesda, Md. 20205, phone 301-496-5147.

The Cancer Letter _Editor Jerry D. Boyd

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