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Congress Insists On No Downward Negotiations; NCI May Drop 200 To 300 Grants In FY 1991

NCI will have to drop 200 to 300 grants this year because Congress has stood firm in its belief that arbitrary across the board funding cuts in approved grants ("downward negotiations") are unnecessary. The House and Senate conference agreement on the FY 1991 budget took the

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In Brief

Million, Donaldson Head ASTRO; James Weese Moves To Presbyterian; Ginder Replaces Kennedy

RODNEY MILLION, Univ. of Florida College of Medicine, is the new president of the American Society for Therapeutic Radiology & Oncology. Other new officers named at the society's recent annual meeting: president elect, **Sarah Donaldson;** secretary, **Frank Wilson;** treasurer, **Robert White;** chairman, **Carl Bogardus;** immediate past chairman, **Stanley Order.** . . . **JAMES WEESE** has been appointed founding director of the Presbyterian Medical Center of Philadelphia's Comprehensive Cancer Center. He will also serve as chief of surgical oncology and associate director of the surgery department. Weese, a pioneer in surgical treatment of previously inoperable tumors such as those of the pancreas and liver, was chairman of surgical oncology at Fox Chase Cancer Center. . . . **GORDON GINDER,** who has been professor of medicine at the Univ. of Iowa, is the chairman of the Div. of Medical Oncology at the Univ. of Minnesota. He replaces **B.J. Kennedy,** a pioneer in the development of medical oncology as a subspecialty. Kennedy will continue as Masonic Professor of Oncology at the university. . . . **SUSAN BAIRD** has been named director of nursing at Fox Chase Cancer Center. Baird, who has served as editor of the Oncology Nursing Society journal "Oncology Nursing Forum" since 1979, came to Fox Chase from Univ. of Pennsylvania School of Nursing, where she was a research associate. . . . **THOMAS JOHNSTON,** retired organic chemist from Southern Research Institute who was instrumental in developing effective anticancer and antiradiation drugs, died last month at age 71. He helped develop BCNU and CCNU, which are manufactured by Bristol-Myers-Squibb Co., as well as clomosone, which has progressed through preclinical trials. He also developed antiradiation drugs for the Walter Reed Research & Development Command. . . . **ROBERT KOCH** Foundation awarded the Robert Koch Prize to Lloyd Old, director of the Ludwig Institute for Cancer Research, and the Robert Koch Gold Medal to Ernst Wynder, president of the American Health Foundation at a ceremony this week in Bonn, Germany.

Congress: No Arbitrary Grant Cuts; NCI May Lose 200 To 300 Grants

(Continued from page 1)

House position that the NIH amount of $8.3 billion is "sufficient to fund grants at the levels approved by the Institutes with no arbitrary downward negotiation of awards."

NCI could not release estimates of exactly how the elimination of downward negotiations will affect the FY 1991 budget by **The Cancer Letter's** presstime this week, since the estimates are still being worked out by NIH.

However, NCI Director Samuel Broder told the Div. of Cancer Prevention & Control Board of Scientific Counselors recently that if downward negotiations were not allowed, NCI would lose 200 to 300 grants. He said the institute planned to make some "counter-proposals" to avoid the cuts.

The major problem is how to implement the House and Senate recommendations. The House specified that NIH fund 6,000 new and competing grants this year, while the Senate requested 5,600. But grants were to be given increases no higher than the biomedical inflator, an index that is somewhat higher than inflation, and no downward negotiations.

Broder pointed out the predicament when he told the board, "We do downward negotiations so we can fund more grant applications."

The conference agreement also said NIH must submit to Congress an estimate of the cost of implementing the four-year financial management plan outlined by the House, which would eliminate downward negotiations, limit the average length of grants to 4 years, and require study sections to consider the "inherent value" of grant applications, among other provisions. The HHS secretary was directed to submit an estimate of the 1992-1995 cost of implementing the plan within 30 days of the bill's enactment.

"While the Committees on Appropriations are willing to discuss modifications to this plan as part of their review of the 1992 budget, they are agreed that this funding schedule provides the stability, predictability and minimum levels of planned growth which the NIH needs at this time."

An NIH committee was formed to react to the House plan.

The $25 million increase in funding for cancer prevention and control outlined by the Senate Appropriations Committee did not survive in the conference agreement, but NCI sources told **The Cancer Letter** this week that there will be some increase for prevention and control.

The conferees did specify that NCI must spend $250,000 for a "major study of the use of tamoxifen as a prevention of breast cancer." NCI is already funding such a study.

The conferees also appropriated $100.575 million to the Office of the Director of NIH, and agreed that $20 million of that amount will be available as a director's reserve for high priority needs. That amount is in addition to funds potentially available under another provision that gives the director the authority to transfer 1 percent of funds from any NIH account to any other account.

The conferees urged the director to expand support for supercomputing in the extramural research program. In addition, they let stand a Senate recommendation providing $15 million for extramural construction grants.

The conferees provided $1.3 billion for the CDC budget, $320.5 million more than the House request and $4.5 million less than the Senate request.

In the Medicare legislation passed in the waning days of the session, a provision was included requiring Medicare to pay for mammography screening.

Congress also passed the Health Objectives 2000 Act, which will provide $300 million in FY 1991 and an additional $25 million each year thereafter to FY 1995 to state public health agencies to achieve the Year 2000 National Health Objectives.

The bill directs the agencies to implement prevention activities in 21 areas including smoking, alcohol use, nutrition, physical fitness, mental health, environmental health hazards, HIV infection and maternal and infant health. The bill was introduced by Sen. Tom Harkin (D-IA).

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Core Grant Guideline Changes Would Increase Base To $1.5 Million

Revisions in guidelines for cancer center support (core) grants have been proposed by the staff of the Centers, Training, & Resources Program in the Div. of Cancer Biology, Diagnosis, & Centers, changes which double the size of the research base required for eligibility andwhich add a category of funding for planning by comprehensive centers.

A draft of those and other changes, which Cancer Centers Branch Chief Margaret Holmes said are intended to "clarify the guidelines and strengthen and clarify review criteria" was presented to the division's Board of Scientific Counselors and will be distributed to cancer centers.

Some of the changes had been proposed by center representatives at the workshop held last June prior to the annual meeting of the Assn. of American Cancer Institutes.

Summaries of the changes follow:

Eligibility for submission of CCSG applications

Current guidelines: Institutions must have at least $750,000 total direct costs in peer reviewed research and/or research training grants and contracts. These are limited to 100% of NCI research grants and contracts; 100% of American Cancer Society grants; 25% of National Science Foundation grants; and 25% of grants from other NIH institutes.

Proposed change: A minimum base of $1.5 million annual direct costs in peer reviewed cancer research support will be required. This may include 100% of all peer reviewed grants and contracts from NCI; and 100% of research grants from ACS, other NIH institutes, ADAMHA (Alcohol, Drug Abuse, & Mental Health Administration), NSF, and the Leukemia Society of America if they comply with the NCI referral guidelines.

Holmes pointed out that the $750,000 base was established 10 years ago, "when that amount of money meant something." Since then, the average size of grants has increased to the point where $750,000 could cover as few as two or three.

Essential characteristics of a cancer center

To the four existing characteristics--authority of the center director (space allocation, appointments, etc.), organizational capability and facilities, interdisciplinary coordination, institutional commitment--a fifth has been proposed, a focus on cancer research.

"This essential characteristic means that a cancer center must have a clearly identifiable focus on cancer research at the basic and/or clinical level," the draft explains. Holmes added, "This may have been an implied requirement, but was never explicit."

Planning and evaluation

Current guidelines allow for costs of planning and evaluation of research programs and activities, including costs of an external advisory committee, ad hoc scientific and technical consultants, and consulting firms providing needed expertise and/or technical assistance in planning and evaluation.

Proposed change: To add as an allowable planning activity limited to comprehensive cancer centers costs of sponsoring planning meetings that specifically address the problems of cancer in the community the center serves. Costs may not exceed $15,000 a year.

Justification for limiting this to comprehensive centers is that community outreach is one of the specific activities required for recognition as comprehensive.

Innovative institutional clinical trial protocols

Present guidelines: only peer reviewed, funded research grants and research contracts from NCI, NIH, ACS, and NSF are eligible to receive support and benefits of the shared resources of the cancer center. Clinical trial research projects that may be supported with the clinically oriented shared resources include those from the national cooperative groups, protocols using IND drugs, and/or those supported by RO1s and PO1s. Institutional protocols are not eligible because they do not receive peer review except for "mini" peer review of innovative institutional clinical trial protocols carried out prior to site visits. Those approved are eligible to benefit from shared resources supported by the core grant.

Proposed change: Review will be conducted of both the system the center has in place for assuring scientific quality of new institutional protocols and the subsequent quality assurance system to be used throughout the conduct of the protocol. The system's completeness and quality will be reviewed, and sampling of protocols approved and some that have failed will be reviewed to assess the quality of the system's review. If the system is favorably reviewed, then any institutional protocol approved by the institutional committee may use the shared resources.

Staff investigators

Current guidelines: Support of individual staff investigator salaries are permitted according to a specific formula. If a principal investigator of an RO1 grant requests a level of effort on the grant but does not request full salary support for that level, then the percentage of approved but unfunded effort may be paid from the core grant. The amount requested for staff investigator salaries may not exceed 10% of the total direct cost in new applications, nor, in renewal

applications, 25% of the last year of the current grant or the current level of staff investigator support plus 10% of the ceiling, whichever is lower. The staff investigator salary budget request is not reviewed by the core grant review committee, on the rationale that the staff investigators' grants have already been peer reviewed once.

Proposed changes:

1. This category will now be peer reviewed by the site visitors and the CCSG review committee. The peer review committee will have the option of disapproving support for specific investigators and/or reducing the percent effort supported by the core grant.

2. In all cases, the selected investigators should be justified in the application with respect to their importance as key investigators to the center. An individual investigator's eligibility for staff investigator salary support may be based on NIH grants only. However, staff investigators who are not funded for their research by NCI should be justified relative to their contribution to cancer.

3. The core grant will limit the amount that may be requested in a renewal application to an amount not exceeding 20% of the total direct costs of the renewal application. However, in terms of absolute dollars, the amount that may be requested is higher than the old guidelines would permit due to the 50% increase allowed for the overall renewal request.

Senior leadership positions

Current guidelines: Partial salary support is allowed for specific senior leadership positions including the center director, deputy director, and associate directors for basic, clinical, and cancer control research and research education.

Proposed change: Salary support would be permitted for an associate director for community affairs, or for special populations, or for minority population programs. This need not be at the associate director level but could be a senior position reporting to the AD for cancer prevention and control research. This will be limited to comprehensive cancer centers.

Developmental funds

Current guidelines: Developmental funds are limited to newly recruited investigators, interim research support, and development of new shared resources.

Proposed change: This would make established investigators eligible for developmental funds, for pilot projects and feasibility studies preparatory to the development of a larger project designed to attract independent support. Such seed support may be awarded to either new or established investigators.

Shared resource payback systems

Current guidelines: Leave it to center directors to make cost allocations, and prohibit reviewers from deciding whether costs requested should be provided by other grants or contracts.

Proposed change: Center directors would be encouraged to use payback systems wherever feasible. Although reviewers still would be prohibited from making judgments on appropriateness of specific shared resource costs requested, they will be asked to comment on the appropriateness of a decision not to have a payback system, and if one is in place, whether it is well managed.

NCI To Offer Planning Grants For New Centers, Consortia

In an effort to encourage development of cancer centers in areas and among populations which do not have ready access to them now, NCI will offer a new program of planning grants designed to help institutions establish new cancer centers.

The Div. of Cancer Biology, Diagnosis, & Centers Board of Scientific Counselors has approved the concept of planning and development grants for prospective centers for underserved geographic areas and underserved populations. A total of $750,000 will be set aside for first year funding of three or four grants. The project period will be for three years and may be competitively reviewed for an additional three years.

"The NCI leadership made the decision that these planning grants will be funded with new money, and will not come out of the (cancer center) core grant pool," Brian Kimes, director of the Centers, Training, & Resources Program, told the board.

Board Chairman Vittorio Defendi commented that in the 1970s, institutions with cancer center planning grants sometimes used that money to hire consulting firms to help in the development process.

"That's not precluded now," said Alan Schreier, who will be program director for the planning grants. "But we won't promote it."

"The question is whether centers can succeed in a certain substrate," Board member Ross McIntyre said. "Puerto Rico and Howard (University) had grants which are now gone. Possibly they could have been helped with planning grants, but the problems went far beyond planning."

In answer to board member Margaret Kripke's question on why institutions would need six years for planning, Schreier said that some may need that much time to develop their research bases.

To qualify for core grants, centers must have a minimum of $750,000 in peer reviewed cancer related

research and/or training grants. "It seems unlikely that someone who would require six years would be competitive for a core grant," Kripke said.

"It's clear that areas like San Francisco have the research base," Kimes said. "All they need is the decision to work together. I know of four or five places, where they are attracting people, but need some time to build up their research bases. In our judgment, some of the planning grants were shut down too early, particularly in the smaller areas. There are some larger institutions which are not thinking of planning grants, they're thinking core grants now."

The board approved the concept unanimously. The description of the concept follows:

Planning and development grants for prospective cancer centers and consortium cancer centers for underserved geographic areas and underserved populations.

The purpose of this program initiative is to announce the availability of planning and development grant funds to assist cancer research institutions in the organization and planning for new traditional cancer centers or consortium cancer centers. These prospective cancer centers must either be in geographically underserved areas of the U.S., or must specifically target minorities or other underserved populations in any region of the U.S. Traditionally, cancer centers are major hubs of cancer research excellence which function as regional resources for the most up to date cancer diagnosis, treatment, and prevention activities and as sources of authoritative cancer information for both the public and health professionals. The legislative mandates of the cancer centers program require that the benefits of cancer centers be made available to as wide a population base as possible.

The mission of the cancer centers program of NCI is to further the goals of the National Cancer Program by supporting basic cancer research, treatment research, cancer prevention and control research, and by encouraging community outreach activities. NCI reaches these goals by designating and supporting, through a competitive peer review process, multidisciplinary centers of excellence in cancer research throughout the country.

NCI provides support and designates cancer centers through competitively awarded cancer center support grants and consortium cancer center support grants. These grants provide the infrastructure of core to support peer reviewed research on the cause, prevention, diagnosis, and treatment of cancer. They also provide support to senior leaders of the institution as well as provide developmental monies for recruitment of new investigators and initiation of new shared resources. Thus, these grants help to create a stable research environment with resources to help develop innovative approaches to cancer research.

Current NCI designated centers vary greatly in size and breadth, from small specialized research centers to large complex comprehensive and consortium centers. They often develop initially from existing areas of strength within the parent institutions.

In addition, consortium cancer centers focus primarily on cancer control research and clinical trial investigations. Consortiums also interact with state and local public health agencies to promote the application of recent research findings to public health problems.

To form a center of excellence and to be eligible for NCI designation, an institution or institutions must demonstrate a minimum base of peer reviewed research and the organizational infrastructure necessary for the operation of a successful center or consortium.

Rationale for this initiative: The funded NCI designated cancer centers and consortium cancer centers are not evenly distributed around the country. The majority of centers are located either on the two coasts or around the Great Lakes. In part, this distribution reflects both the U.S. population density and the locations of medical research centers. Nonetheless, a review of institutions holding NCI grants reveals the presence of many excellent medical institutions outside of these areas which have significant peer reviewed cancer research support.

With appropriate encouragement, some of these institutions could develop cancer centers and eventually become eligible and competitive for a cancer center or consortium cancer center core grant. In order to carry out the congressional mandate to promote the geographic distribution of cancer centers, Cancer Centers Branch program staff proposes this RFA for planning and development grants as one mechanism for encouraging such institutions.

Detailed planning and development is crucial to the success of a new cancer center or consortium cancer center. Since a new center must be an entity that has its own distinct administrative identity and a measure of autonomy before it can successfully apply for a center grant, it may need to be 'created' within the parent institution through a process of sometimes complex negotiations.

The center director, for example, must be given sufficient authority through control of funds, space, and appointments to effectively lead the center. The goals of a new center must be clearly defined. Space and personnel must be dedicated to the center. The center must have distinct interdisciplinary research programs.

These programs may need to be developed and members recruited from the parent institutions. In addition, specific central research resources must be identified for inclusion or development as part of the center. Finally, the parent institution must give both enthusiastic and tangible support to the new center.

The planning process requires a significant investment of institutional resources, and this fact alone has probably prevented many institutions from exploring the possibility of forming new cancer centers or consortium cancer centers.

This RFA will provide funds to qualified institutions to develop cancer centers or consortium cancer centers in underserved areas.

The planning grant may cover a portion of the salaries of the principal investigator, a small staff, and other administrative expenses as well as the cost of appropriate consultants.

New Grants For Soybean Studies OK'd; Other Concepts Approved

Advisors to NCI's Div. of Cancer Prevention & Control gave concept approval to a new grant that would provide $2.7 million for studies of anticarcinogens in soybeans.

Four three-year awards are expected to be made under the program, which will attempt to quantify levels of anticarcinogens in soybeans and soy products and examine their absorption, metabolism and physiology in humans.

The new RFA concept was one of more than $17.7 million worth of competitive grant and contract

concepts approved by the DCPC Board of Scientific Counselors at a recent meeting, including the recompetition of a computing support contract for the division, worth $11.68 million over five years.

Following are excerpts of the concept statements:

Analyses, metabolism and physiology of anticarcinogens in soybeans. Concept for a new RFA, estimated total $2.7 million over three years; four awards. Populations consuming predominantly plant based diets, for whom legumes represent a significant protein source, have lower rates of several cancers than populations that rely heavily on animal products. One legume, soybeans via a variety of soy products (tofu, miso, tempeh, soymilk, soynuts, yuba and soy sauce) is commonly consumed throughout much of East Asia, where breast and colon cancer rates are particularly low in comparison to Western countries.

Experimental data indicate that soybean rich diets inhibit a number of chemically induced cancers. Soybeans contain several classes of anticarcinogens including isoflavones, protease inhibitors, phytosterols, saponins and inositol hexaphosphate. However, basic research in humans on the absorption, metabolism, tissue distribution and analyses of these compounds in soybeans is lacking. These data are critical to assessing the potential impact of soybeans on cancer prevention and will aid greatly in future investigations of other legumes.

The focus of this research is to determine levels of anticarcinogens in soybeans and soy products and to examine their absorption, metabolism and physiology in humans. Limited in vitro work is permitted but only if these efforts are an essential prelude to human studies. Only those components of soybeans/soy products with demonstrated anticancer potential and that are present in soybeans/soy products at substantially high levels relative to other foods should be considered for investigation. Such components include but are not limited to isoflavones, protease inhibitors, plant sterols, saponins and inositol hexaphosphate. It is essential that the validity and reliability of all analytical procedures used in anticarcinogen assays be established and that all methodology include quality control procedures. In cases where methodology is inadequate or lacking, new methods can be developed.

All applicants will be required to justify anticarcinogen selection. Selection should be based on the evidence indicating the potential for a given compound to decrease cancer risk. Applicants are also required to justify the specific area of research proposed. That is, work can be conducted in one or both major categories, i.e., 1) analyses and/or 2) metabolism and any subcategory therein. Justification should be based on the existing gaps in our knowledge and the importance of filling those gaps to establishing the role of soybeans/soy products and/or compounds in soybeans or soy products in the dietary prevention of cancer.

Areas of investigation:

1) Soybean and soy product analyses--Anticarcinogens in soybeans and soy products are to be analyzed. Total as well as individual anticarcinogens (total isoflavones as well as individual isoflavones, diadzein, genistein, etc.) should be quantified. Factors potentially effecting anticarcinogen levels/activity that should be considered for investigation include but are not limited to: a) form--different forms of the same anticarcinogen, eg., conjugated versus unconjugated; b) stability--effects of storage, cooking and other food processing techniques; c) variation--comparisons among different brands of similar soy products and/or among varieties of soybeans and among different batches or lot numbers of the same soy product.

2) Absorption, metabolism and tissue distribution--Areas considered appropriate for investigation include but are not limited to: a) anticarcinogen levels--in blood, urine, feces and/or bile in response to known levels of anticarcinogen intake. When feasible, this should be examined using both whole foods as well as individual carcinogens or isolated soybean fractions; b) factors affecting absorption and metabolism--examples include diet composition, form of anticarcinogen and intestinal microflora; c) tissue distribution and turnover--may include the use of isotypically labeled forms of the anticarcinogens.

Mark Messina of the Diet & Cancer Branch and program director for the RFA, said the study represents "a small amount of money that may give us some answers. We need this basic research information."

DCPC Board member David Alberts asked Messina why the studies could not begin directly in humans. "How would we know which foods to use? The basic research is an important step," Messina said.

Board Chairman Edward Bresnick questioned the concept's methodology, and noted that there would be "tremendous variation" in humans of absorption of the soybean anticarcinogens. "I wouldn't care about tissue distribution at this stage," Bresnick said. "I would do the blood levels." Bresnick suggested that the board approve the concept "in principle" and allow a subcommittee to fine-tune the proposal. With that caveat, the board approved the concept unanimously.

Biomedical computing support for cancer control. Recompetition of a contract held by Information Management Services Inc., to end September 1992. Estimated total $11,678,530 over five years; one award. The purpose of this concept is to continue to provide comprehensive computer systems analysis, programming, data management, data analysis, reporting and documentation services for projects primarily or secondarily conducted by the Surveillance Program.

DCPC supports a wide range of scientific projects. All utilize computers for data management and analysis. Many include primary or collaborative involvement of the Surveillance Program staff. Primary projects include maintenance and data analysis of the SEER Program and Medicare cancer cost analysis; secondary ones include collaboration on the Black/White Cancer Survival Study and the Giant Foods Study.

The current contract is managed by the task order mechanism. DCPC staff specify the nature of the work to be done. The contractor estimates the amount of resources required and completes it. Currently 18 task orders are active. The nature of the work comprises five general categories:

1. Statistical programming (about 45 percent of the effort). For typical projects such as the Cancer Statistics Review, a standard statistical package such as SAS is used to generate statistics and a PC graphics package is used to produce graphs. Some data manipulation is done to recode variables, clean up data sets, and produce analysis files, but data entry is minimal.

2. Data management (15 percent). Data entry, editing and file creation work is done for some human nutrition and clinical trials projects and data validation and file consolidation are performed for other projects such as SEER Operations. The efforts may involve the use of a generalized package such as SAS, specific edit programs written in COBOL, or personal computer entry

programs written in dBase.

3. System development (30 percent). Typical projects such as SEER/PC aim to develop portable programs for generating specialized cancer statistics such as relative survival analyses. The typical programming language used is C and the goal is portability to a variety of computer environments.

4. Documentation (5 percent). Two subtasks, SEER Manuals and Disease (Neoplasm) Classification are primarily documentation efforts.

5. Administrative overhead and delivery services (5 percent). The administrative overhead consists of task order processing and preparing planned and completed work reports. Delivery of computer printouts and other material between the central NIH computing facility, division offices and the contractor offices is a service included in the current contract.

In addition to the five categories, several other supporting activities or acquisitions are included in the current contract: 1) printing of reports and production of slides, 2) purchase of hardware or software to support special requirements of an individual project or to reduce the programming effort required, 3) travel expenses for contract staff for field support or other activities related to a project, 4) consultant subcontracts to apply special expertise to as task when the requirement is short term or not a routine computer programming or systems analysis skill, 5) some miscellaneous expenses related to special projects, such as the payment of 800 number fees for bulletin board systems for SEER and the National Black Leadership Initiative.

Brenda Edwards, associate director of the Surveillance Program, said the FY 1990 cost of the computing support contract is $1.64 million, and the concept for the recompetition proposes to increase that for FY 1992 to $2.11 million. Edwards said the reason for the increase is that "we can't count on the current contractor's rates applying in the future." The costs were figured using current average rates among similar contracts within NIH. "If I go on the market, there's no guarantee I'll get the same rates" as the current contractor's, she said.

Bresnick noted that the amount represents a maximum, but he asked whether developing a computer support unit on campus would be more efficient.

"We don't have too many options," DCPC Director Peter Greenwald said. He said the program has been "very closely analyzed" and found to be the most efficient way to perform the necessary work.

The concept was unanimously approved.

Obtaining cost of cancer data from health maintenance organization records. This is a concept for a new RFP, estimated total amount cost $1.51 million over three years, two to three awards anticipated.

Data on the cost of cancer is an important informational resource to NCI and other government agencies as a tool of health services research and an aid to health policy analysis. Cost savings analysis performed by NCI on NCI funded cancer prevention and treatment innovations require data on pre and post-innovation costs, often by site and stage of disease. NCI is often asked by policy makers to provide estimates of the total cost of cancer to society. Treatment costs of cancer by site, along with incidence rates, are necessary in determining an accurate estimate of one component of this cost. The benefit cost analysis of any policy which affects cancer incidence through broad preventative measures, such as a change in tobacco taxes or nutritional labeling, requires these data.

Unfortunately, available data are very dated and of questionable reliability. Estimates of hospital based cost of cancer treatment by site and stage are usually based on projections from the Third National Cancer Survey. These data were collected during the years 1969-1971. Since that time the treatment procedures and technology for many cancers have changed dramatically, and the proportion of costs attributable to hospital based services has decreased relative to outpatient services.

More recent studies have estimated the costs of both hospital based and outpatient services using a variety of sources, such as insurance reimbursement records and Medicare data files. The cost of cancer data to be acquired by this project have a number of attractive characteristics: reliable classification of cancer site and stage, complete ascertainment of all costs, ability to distinguish between costs, expenditures and charges, inability to distinguish between cancer-related and non-cancer-related costs, long term followup periods and large sample sizes.

An NCI sponsored workshop on the cost of cancer held in June 1989 recommended that NCI should collect cost of cancer data, maintain an on-going, cross-sectional sample for some of the more prevalent cancer sites, conduct pilot studies to cost out recommended or standard treatment, and conduct a workshop on quality of life issues. A number of ongoing and planned efforts of the Applied Research Branch are designed to address these recommendations.

To assess the cost and feasibility of using HMO records as a data source, a pilot study was initiated in July 1989, conducted by the Kaiser Foundation Research Institute. The study showed it is feasible to obtain detailed data on procedure utilization and costs through chart review of HMO medical records and computerized HMO records.

Under this proposed RFP, the following sites would be studied: cancer of the colon, breast, lung, bladder, prostate and lymphomas. Since determinants of cost may differ between closed panel and open panel HMOs, it is proposed that at least one HMO of each organizational type be included in this project.

Data on the cost of cancer will be collected from the financial and medical records of health maintenance organizations which have a sufficiently large cancer patient population to make the acquisition of reliable cost estimates feasible and which have a reliable method for establishing the site and stage of cancer at time of diagnosis. Two awards are anticipated.

A regression model will be used to estimate the relationship between data items available in the HMO computerized record system and the cost data determined from chart abstractions of primary medical records. Once the parameters of this model have been determined it will be possible to generate estimates of cancer cost using only data from the computerized record system. After the initial study based on six cancer sites has established the cost estimation model, it will be desirable to continue to conduct periodic chart review studies in order to check the validity of the model against new sites or to update it for changing determinants of costs. It is anticipated that a case-control sample of non-cancer patients may also be used to validate the method of attributing costs to cancer in the cancer patient sample.

In order to obtain estimates of the lifetime cost of cancer treatment within a reasonable time period, three samples will be selected for each cancer site or stage of interest. A sample of

recently diagnosed patients will be used to determine initial costs by tracing cost from date of diagnosis; a sample of recently deceased patients will be used to determine terminal care costs by tracing cost during the last year of life; a sample of patients midway between the initial and terminal period will be used to determine continuing care costs.

Because HMO records include a unique personal identification number for each patient, it will also be possible to follow-back records to distinguish between screen detected and non-screen detected cases and to determine if subsequent costs are related to this.

Sample size for data obtained from HMO records should be as large as possible. Given the desirability of sampling each site for initial, continuing and terminal cost, a sample of 200 charts per cancer site would probably prove useful. Sample size estimates will be further refined during the course of the actual study.

Edwards, also program manager for this study, said the Kaiser pilot study was successful in showing the advantages of using HMO data on outcomes and cost. The board unanimously approved the concept.

Support contract for the Public Health Agency Initiative. Recompetition. Estimated total $1.85 million over five years; one award. The objective of this contract is to provide technical and logistical support for efforts by the Cancer Control Applications Branch to obtain an increase in the quantity and quality of cancer prevention and control activities in state and local health departments.

The CCAB, with the assistance of outside experts, has identified a series of actions that should be taken to obtain an increase in the quantity and quality of cancer prevention and control by health departments. These actions are based on the premise that there will not be an infusion of NCI funds to support direct cancer control services to the public.

The NCI program consists principally of: 1) the provision of direct technical assistance, 2) stimulation of adoption of cancer prevention and control interventions, 3) information exchange, 4) capacity building and technical development activities. This project requires a contractor to provide direct support to NCI staff in order to develop and implement health agency initiatives in a timely and efficient manner. The contractor will provide technical and logistical support to include:

--Staffing working groups to identify the elements of successful prevention and control programs in health agencies, formulation of guidelines and materials to support the adoption of such programs, and marketing and distributing of the resulting initiatives.

--Organizing national and regional conferences and workshops to promote utilization of state of the art cancer control.

--Developing and delivering training programs in cancer prevention and control for public health agency staff.

--Acting as a focal point for information gathering, compilation and distribution of information on existing cancer control programs in health agencies, including maintenance of a legislative data base.

--Preparing special reports and other documentation as needed.

--Identifying high quality consultant expertise available to public health agencies and brokering it as needed.

Lawrence Bergner of the Cancer Control Applications Branch said the last year of the current contract will cost $293,000, and the concept is requesting $350,000 for FY 1992, the first year of the recompetition due to inflation and increased activity under the contract.

The board approved the concept unanimously.

The board also gave concept approval for continuation of the Assn. of State and Territorial Health Officials Tobacco Prevention & Control Contact Network, which coordinates antitobacco efforts among state health departments. The board committed up to $150,000 for the interagency agreement with the Office on Smoking or Health of the Centers for Disease Control, and the National Heart, Lung & Blood Institute.

IOM Panel Urges More Funding For Training, Construction

A larger share of available funds for biomedical research should be invested in training young scientists and improving research facilities, an Institute of Medicine committee said in a recent report.

Training and facilities have been neglected for a decade while Congress and NIH gave the highest priority to funding new and competing research grants each year, according to the committee's report, "Funding Health Sciences Research: A Strategy to Restore Balance." The committee was made up of 18 representatives of health sciences, academic research, economics and government.

The committee developed "allocation strategies" it said could be applied to four different budget scenarios in the 1990s--no growth beyond inflation, 2 percent annual real growth, 4 percent growth and higher than 4 percent growth.

About $12 million (0.2 percent) per year should be added to training programs with a goal of reaching 5.75 percent of the extramural research budget by 1995 and 6.75 percent by the year 2000. In FY 1990, 4.76 percent of the extramural NIH budget went to training. Allocations for construction, now 0.25 percent of the extramural budget, should be increased each year to 0.5 percent by 1995 and remain there through the decade, the report said.

"What we propose won't divert many funds away from research projects," said Floyd Bloom, Scripps Clinic, who was committee chairman. "But it will make a difference in training and facilities over the decade."

Copies of the report, "Funding Health Sciences Research," are available from the National Academy Press, 2101 Constitution Ave. NW, Washington, D.C. 20418, phone 202/334-3133 or 1-800-624-6242.