THE CANCER LETTER

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Illinois Cancer Center Closes Following Veto Of State Funds; Was First Consortium Center

The Illinois Cancer Center, the first consortium cancer center to receive NCI recognition, closed last week following a five-month effort to wind down its operations since Illinois Gov. Jim Edgar unexpectedly vetoed state funding for the center last summer.

Since 1985, the state provided the center $1 million to $1.5 million annually to implement the Illinois State Cancer Plan, which is modeled

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In Brief

FASEB Recommends $11.75 Billion NIH Budget; Natcher Wins House Appropriations Chairmanship

NIH BUDGET for fiscal 1994 should be $11.75 billion, according to a report released by the Federation of American Societies for Experimental Biology (FASEB). The proposed amount represents a 13.4 percent increase over the FY93 appropriation and would support at least 6,800 new and competing grants, FASEB said. The recommendation was drafted and approved by two representatives from each of the eight FASEB societies during a conference last month. Copies of the report are available from FASEB, phone 301/530-7075. . . . **REP. WILLIAM NATCHER** (D-KY) won the chairmanship of the House Appropriations Committee this week when House members voted to replace Rep. Jamie Whitten (D-MS), who had a stroke earlier this year. . . . **AMERICAN CANCER SOCIETY** awarded Medals of Honor recently to: **Joseph Bertino**, for contributions in clinical research; **Bert Vogelstein**, for revolutionizing the understanding of genetic mutations; and **Robert Stempel**, former chairman and CEO of General Motors Corp., in recognition of GM Cancer Research Foundation's contributions to cancer researchers. The Society presented its Humanitarian Award to **Harold Freeman**, chairman of the President's Cancer Panel, for his "unwavering dedication to the improvement of cancer control, and for genuine accomplishment in human welfare and social reform." Distinguished service awards were presented to **Kathleen Foley, Tish Knobf,** and **Henry Lynch.** Voluntary leadership awards went to **Warren Knauer, Jeannette Silber,** and **Lila Rae Johnson.** . . . **NEW SPORE** concept in gastrointestinal cancers recently approved by NCI advisors (**The Cancer Letter**, Dec. 4), has been changed by the NCI Executive Committee to state that the RFA will support one or two SPORE grants for a total of $1.5 million, rather than two grants for $750,000 each. The RFA also will say that if high quality applications are not fundable in FY93, they will be considered for funding in FY94.

Illinois Cancer Center Shut Down As Governor Crosses Out Funding

(Continued from page 1)
on NCI's "Year 2000" goals for reducing cancer incidence and mortality.

Illinois has faced severe budgetary shortfalls in recent years caused by the recession and declining federal funding. However, ICC officials and supporters were taken by surprise last July, when Edgar used his line-item veto authority to cut the $1.5 million in state funding for the center.

"There was no warning, and no comment after the fact," ICC president and director Shirley Lansky said to **The Cancer Letter.** "Like all line-item vetoes, it was very final."

Edgar's office has not responded to phone calls from **The Cancer Letter** seeking comment on the veto.

A Unique Cancer Center

The Illinois Cancer Center had no beds, no attending physicians, no nurses. It treated no patients, and operated no laboratories. With 55 employees in office space filled with computers in downtown Chicago, the ICC looked more like a research services firm that helped clients compete for government contracts.

That is partly what ICC did.

Founded in 1974 as a non-profit consortium, the center (called until last year the Illinois Cancer Council) initiated and coordinated the expertise of investigators and physicians at the center in conjunction with major medical schools and hospitals in Illinois to conduct cancer clinical and prevention research.

The consortium was composed of the seven Illinois medical schools, the Illinois Institute of Technology, the Univ. of Illinois School of Public Health, Fermi and Argonne National Laboratories, the Illinois State Medical Society, the Illinois Hospital Assn., the Illinois Dept. of Public Health, and the Chicago Health Department.

ICC officials and supporters said the consortium was a success, as measured by:

▶**Patient access to investigational therapy, cancer education:** The Illinois State Cancer Plan, implemented with the state funding to ICC, supported phase 2 clinical trials protocols and data management for Illinois oncologists; epidemiology studies for mortality, incidence and risk factors; cancer education for patients, families, and health professionals; cancer awareness and early detection programs for special populations; nutrition and antismoking programs for targeted audiences.

The consortium operated three regional offices--in Decatur, Rockford and Calumet City--to provide physicians and residents outside the Chicago area greater access to clinical trials and cancer information.

Over 150 oncologists and thousands of cancer patients participated in NCI-sponsored clinical trials through the ICC. More than 800 health professionals interacted in ICC programs. The center served as a research base for five NCI-designated Community Clinical Oncology Programs, and was a member of the Gynecologic Oncology Group and the National Surgical Adjuvant Breast & Bowel Project.

▶**Scientific recognition:** NCI renewed the ICC's grant as a consortium cancer center three times. ICC had three of the original six NCI Cancer Control Science Programs, large program project grants awarded in the mid-1980s. One of these is still operating. Investigators associated with the ICC regularly presented their research at scientific meetings; 10 ICC abstracts are to be presented at the American Society of Clinical Oncology annual meeting next May.

▶**Financial results:** The ICC brought $25 million worth of federal grants and contracts to the state over the past five to six years alone, according to one estimate, Lansky said. The consortium also held, for 15 years, the contract from NCI to operate the Cancer Information Service for Illinois.

'A Tremendous Loss'

"The ICC offered a number of unique programs, including a clinical trials program that made new treatments available throughout the state, and a well organized epidemiology program," Richard Schilsky, director of the Univ. of Chicago Cancer Research Center, said to **The Cancer Letter.**

"The residents of Illinois have lost a valuable resource," Schilsky added. "The ICC had certain strengths that none of the other institutions in the

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area had. It is a loss."

"Every year we entered hundreds of patients on NCI investigational drug studies," said Al Benson, director of ICC's clinical trials division. "For many of our community physicians this is a tremendous loss. These physicians are trying to regroup now. Some protocols can be obtained from the NCI cooperative groups, but because the ICC was regional, physicians felt they had better access, and felt comfortable in this environment."

For example, ICC brought together 11 institutions to apply for participation in the NCI-sponsored National Breast Cancer Prevention Trial of tamoxifen, run by the NSABP. The ICC's proposal was accepted, and so far the consortium has entered 100 women in the trial, Benson said.

In 1988, the center pulled together expertise from its consortium members to successfully compete for an NCI master agreement to conduct chemoprevention research.

Alone, these institutions might not have applied for these programs, Benson said.

"What the state has lost is millions of dollars of federal funds, an expansive phase 2 clinical trials program, the Cancer Information Service--it is a huge, huge loss," Benson said.

"The state cancer plan died a rapid death as of July," Lansky said.

Never Sought State Funds

Ironically, ICC never sought state funding. The consortium operated without state support for 11 years after its founding by the leaders of three major medical centers: John Ultmann, Univ. of Chicago; John Brewer, Northwestern; and Sam Taylor III, Rush-Presbyterian-St. Luke's. The American Cancer Society housed the consortium for the first few months in ACS office space.

Taylor served as acting director until Jan Steiner was named the consortium's first director. Steiner left in 1983. Lansky was the interim director and then was selected to succeed Steiner as director.

Prior to 1985, the ICC was primarily a cancer control program with clinical trials, Lansky said. ICC participated in many of the cooperative groups.

"We were driven by the ability to keep those grants and contracts," Lansky said.

ICC was a force behind Illinois getting a state tumor registry, which pleased the legislature, Lansky said. "After they had seen what we were capable of doing, members of the state legislature came to us and asked us to develop a state cancer plan," she said.

In a 1985 editorial, the "Chicago Tribune" urged the legislature to provide ICC nearly $1 million to implement the state cancer plan, which the legislature did.

"The cancer plan gave us the ability to do pilot studies that could go on to get grants and lead to development of programs throughout the state," Lansky said. "The program that grew the most was the clinical trials program. We had 500 physicians participating. For many of them it was their singular opportunity, and they did very well with it."

The state came through with funding for the cancer plan every year without incident. Then, in 1991, newly elected Republican Gov. Edgar cut the funding for the state cancer plan--and thus the ICC--from the state health department's budget.

The funds were restored through overwhelming bipartisan support from the state legislature.

This year, Lansky said, "It was very hard to read the signals. The governor's office was difficult if not impossible to get through to."

Since the veto came at the end of the budget year, the ICC had little time to find other sources of funding. Seeking private funding also was a delicate political matter.

"Being a consortium, we were in competition with our consortium members for private funding," Lansky said. "That was always a problem." A foundation the center established previously to raise funds had "limited success," she said.

The $1.5 million "ended up being a huge amount of money when it came to getting any funds," Lansky said. "None of the universities were willing or able to come in with that kind of money."

The ICC was up for renewal of its $835,000 NCI Cancer Center Support Grant (core grant) this year. A site visit was scheduled for September.

The consortium had asked the office of Rep. John Porter (D-IL) to write a letter of support to NCI. Porter's office got all but one member of the Illinois Congressional delegation to sign a letter to NCI Director Samuel Broder in support of the ICC application.

"The center is an excellent example of a public/private partnership successfully working to reduce cancer morbidity and mortality in the region," the delegation's June 26 letter to Broder said. "Perhaps most important, the ICC provides effective technology transfer to move research into the field to directly benefit current and potential cancer patients. Through the state cancer plan and the NCI-sponsored Cancer Information Service, the ICC provides Illinois residents access to the most updated cancer treatment therapies."

At the time, Porter's office, like the ICC, did not

suspect that state funding for the consortium might be threatened. "We were shocked when they got cut out of the budget," a spokesman for the congressman said.

After the July veto, the center's hopes for renewal of the core grant were shattered. "One criteria for the core grant is having institutional support--in our case that was the state funding," Lansky said. "If that's not there, you don't have the basis for a core grant. We couldn't work around that."

ICC informed NCI that it was withdrawing its application, and the site visit was cancelled.

No Assurance Of Funding

After several long discussions, the ICC board decided the consortium could not continue without the state funding--and without the NCI core grant.

The legislature held an override session in the fall, but the consortium could not survive that long, Lansky said. Even if the consortium had been able to function, and if the money had been restored, the future was uncertain.

"There was no assurance that a line-item veto wouldn't happen again," Lansky said.

The ICC officially closed its doors Nov. 30, and planned to auction computer equipment and office furniture this week--"18 years worth of stuff," Lansky said.

When the decision was made to shut down, the goal was to transfer as many of the consortium's grants and contracts to the member institutions.

"I tried to salvage as many programs as possible," Lansky said. "NCI was very cooperative and agreed to transfer as many grants and contracts to consortial member institutions where the principal investigator had an academic appointment, or got an appointment."

Benson, a professor of medicine at Northwestern Univ. and director of the adult oncology program at Northwestern's Robert Lurie Cancer Center, took much of the ICC clinical trials work to Northwestern. Benson said he plans to collect all the data available on ICC sponsored trials, some of which are almost completed. "That's going to be a lot of work with just a small staff," he said.

The 11 institutions that are participating in the tamoxifen trial have formed a group to continue that effort, Benson said. The chemoprevention contract is being carried out by Northwestern, Loyola, and Univ. of Chicago.

Kathy Mallin, who headed the ICC epidemiology division, took one large contract with her to the Univ. of Illinois School of Public Health, where she has had an appointment.

Marcy List, who headed the ICC cancer control division, was appointed associate director for cancer control of the Univ. of Chicago Cancer Research Center, and was appointed to the faculty of the Dept. of Medicine. She is one of the investigators for an NCI program project grant--a CCSP--examining treatment and rehabilitation in head and neck cancer patients. List also brings to the university an NCI contract to develop methods for teaching persons with low literacy about cancer.

Under a recompetition that will organize the Cancer Information Service into regional offices, the Illinois CIS will be combined into a region that includes Kansas, Missouri, and Nebraska. ICC had applied for the contract to run the regional office--a 10-year contract worth $15 million--but the competition took place following the governor's veto. Lansky said she tried to convince NCI that the ICC's CIS office could be moved to one of the consortium institutions, but the proposal did not fare well in the competition.

The CIS contract for the region was awarded to the Univ. of Kansas.

ICC Director Lansky will continue as a part-time professor of pediatrics and psychiatry at the Univ. of Illinois Medical Center.

"I made the decision when this happened that I absolutely would not do anything else until [the ICC shut-down] was finalized," Lansky said. "It was a wise decision. It has taken a lot of time and effort. We had good help from the board members, and we had to bring in consultants."

"The saddest part is always the personal part," Lansky added. Some staff had worked for 10 or 15 years for the ICC. "They are highly skilled and were faced with going out into a bad economy and trying to find another job."

Though there is sadness and loss, Lansky said she is not embittered.

"I cannot go out in an angry manner. I still live in this state, I still work at the state university," she said. "And I truly don't have any other information [from the governor's office regarding the veto]. So anything else is conjecture."

'Failure Of Political Leadership'

Benson does not hide his outrage.

He believes the governor did not understand ICC's mission, but, if he did understand it, then he chose the worst way possible to withdraw state funding.

"What would have been appropriate was to sit down and work on compromises or other ways of funding the program," Benson said. "It is a failure of political leadership. The governor did a very destructive act with no understanding of the consequences."

Illinois is never high on lists of states receiving federal funds, Benson said. "And here was a group that was effectively bringing money in to the state."

"We're all feeling depressed and tired," Benson added. "It has been a horrible half-year."

Lessons For Future Consortia?

NCI funds only one other consortium cancer center through a core grant. The Drew-Meharry-Morehouse Consortium Cancer Center in Los Angeles coordinates the expertise of three major institutions.

According to those associated with the ICC, the lesson for institutions that hope to form consortial cancer centers is: get stable and reliable support.

"ICC was in the unique position of having a lot of support from the state," Schilsky said. "That was thought of as being a good thing, and it allowed them to expand. But the problem is, government funding is unstable, whether you are talking about an NIH grant or a line item in the state budget."

"The ICC model was a fantastic model that I wish could have been adopted in other areas," said John Ultmann, an ICC founder and former director of the Univ. of Chicago Cancer Research Center. "We did things that none of the individual hospitals could have done. We managed to cover a state that has many resources at north end and fewer resources at south end."

However, said Ultmann, the model's main problem was that it was a true consortium--an administrative structure not based at any particular institution, and lacking the philanthropic draw of a medical center complete with patients. It was the type of activity only a state government could support.

"It's a loss to the state," Ultmann said. "It is very sad."

New Head Of Alternative Medicine At NIH Vows To 'Talk Bluntly'

An argument can be made that Joseph Jacobs has stepped into the most politically charged job NIH has to offer.

Jacobs, 46, is the new director of the Office for the Study of Alternative Medical Practices.

Even the name of the office suggests controversy: it used to be called the Office for the Study of Unconventional Medical Practices, but then the practitioners got upset, arguing that unconventional is a pejorative term.

Now, the name has changed, but the American Cancer Society, among others, is upset, arguing that the word "alternative" implies that naturopathy is as good as chemotherapy (**The Cancer Letter**, Nov. 20).

To make things even more complicated, Congress is certain to be keeping an eye on Jacobs's job performance. The office was created in the most controversial way Congress can set policy: after being lobbied by a former colleague, Sen. Tom Harkin (D-IA) included $2 million into the NIH FY92 appropriations bill.

It wasn't an easy program to get off the ground. There were hot issues, hot-headed speeches, hot-tempered advisors.

"I feel that the office should have been called the Office for the Study of the Healing Arts," Jacobs said to **The Cancer Letter.** But whatever the name, the office would allow NIH to acknowledge that biology is only one aspect of medical care.

'A Kind Of Healing Milieu'

"I am not carrying the banner for any modality or treatment," Jacobs said. "The idea is how can we look at alternative therapies in terms of the care of people.

"It's arrogant to dismiss something out of hand, and this office has to give NIH a way to relax its guard to be able to look at these modalities.

"There is a kind of healing milieu that we have to look at," he said. "That's a dimension of the NIH that has always been there, but has not been seen by a lot of people."

Jacobs is a Yale-trained MD and a Wharton MBA, is a member of the St. Regis Mohawk Tribe in upstate New York, a former physician with the Indian Health Service and former president of the Assn. of American Indian Physicians.

When he was growing up, his mother took him to traditional as well as mainstream medical practitioners, Jacobs said. Later, at Yale, Jacobs considered specializing in pediatric oncology. The specialty intrigued him because it required the physician to support patients and their families in terms of their spiritual and emotional needs, Jacobs said.

As a pediatrician with the Indian Health Service, Jacobs developed a system for tracking Navajo infants at risk for developmental disability. Later, at Wharton, he studied appropriate medical technology for third world settings. After a stint as a medical director in research and program development at Aetna Life Insurance Co., he returned to the government. Most recently he worked for the National AIDS Program Office as director of policy program analysis.

His predecessor, Stephen Groft, whose job was to get the program off the ground, will return to the NIH Office of Rare Diseases.

At this point, however, Groft, Jacobs and Jay Moskowitz, the NIH Associate Director for Science

Policy and Legislation, are putting together an advisory panel to the office. The panel will include 21 to 23 members. These members will be bound by ethics rules and will be rotated every one to four years.

If the previous meetings of ad hoc panels of advisors are an indication, Jacobs's office will have to deal with the most volatile advisory board at NIH.

'Leave Ego Feathers At The Door'

"My job is to talk bluntly to everybody," Jacobs said. "I don't want to tolerate political rhetoric, not within the scientific context. When they deal with this office, they will have to leave their ego feathers at the door."

Jacobs's other hope is to work closer with the groups that have criticized his office, including the American Cancer Society. "I think it's important for organizations like ACS, rather than being critical of this office, to participate with us in how we look at other alternatives."

Last fiscal year, the office transferred about $1 million, about half its budget, to NCI, which is supporting several studies of unconventional medical practices. This year, NCI is unlikely to receive funds for such studies, NIH sources said.

According to Jacobs, his office will spend about $1 million on salaries and program expenses, give out $500,000 to fund 10 extramural grants and spend the rest on programs that are likely to include the consolidation of the literature base on unconventional therapies at the National Library of Medicine.

Correction

The Nov. 20 issue of **The Cancer Letter** incorrectly cited the conflict of interest regulations applicable to the advisors to the NIH Office for the Study of Alternative Therapy.

Last June, members of the ad hoc panel were brought in as "professional service contractors" and in that capacity were under no obligation to file conflict of interest statements, NIH sources said.

At the September meeting, the participants were brought in by an NIH contractor who handled the logistics support for the meeting. That, too, made the disclosure unnecessary, sources said.

The advisory committee to the office, when its is formed, will be subject to the conflict of interest rules.

Final Cancer Letter Of 1992, Next Issue Dated Jan. 1, 1993

This issue of **The Cancer Letter**, Volume 18, Number 48, is the final issue of 1992. The next issue, Volume 19, Number 1, will be dated Jan. 1, 1993.

Best wishes for the holiday season and New Year.

NCI Relaxes Core Grant Support For Clinical Trials Research

NCI's Cancer Centers Program has issued a policy statement designed to better define the type of clinical trials research that can be supported by centers using the Cancer Center Support Grant (core grant).

The program also has finalized a list of funding organizations whose grants NCI considers peer reviewed and thus eligible for access to the shared resources of the core grant.

The policy statement and organizations list will be discussed at the Dec. 14 meeting of the National Cancer Advisory Board's Subcommittee on Cancer Centers. NCI's Centers, Training & Resources Program considers the policy statement a strong move to support clinical trials research funding, program staff said to **The Cancer Letter.** The guidelines previously were not clear about what clinical research could be supported, and thus, tended to be restrictive.

Following is the text of the policy statement:

The Support of Clinical Trials Research With CCSG Funds. This statement is issued to NCI clinical and comprehensive cancer centers to help clarify various issues associated with the support of clinical trials research using CCSG funds. Summarized below are some of the current positions of NCI related to CCSG support of clinical trials research in general and specifically to the CCSG support of a clinical trials core operation.

In general, NCI continues to encourage the development of shared resources dedicated primarily to the support of clinical research. These shared resources (e.g., biostatistics, protocol management, pharmacology) are intended to provide core support to ongoing, externally peer reviewed research (most of which is funded) and to ongoing institutional protocols evaluated and monitored by a cancer center "process" which has been approved by an external peer review group. However, within the continuum of clinical trials research from pilot/phase 1 studies to phase 3 studies, the CCSG should serve a unique function and not duplicate or disproportionately augment clinical trials research for which there are available competitive grant, cooperative agreement, and contract funding opportunities. The CCSG can be used in a unique way to support innovative pilot studies involving institutional protocols because these kinds of studies cannot be suitably developed for submission as grant applications to traditional funding organizations and are critical for determining which translational research opportunities should be more intensely pursued. In fact, the pilot study concept is one of the new elements included in the 1992 CCSG Guidelines that allows cancer centers to explore innovative ideas.

With the above in mind, the Cancer Centers Program has developed the following positions:

Specific position with regard to a clinical trials core operation: This policy is in effect as of Dec. 1, 1992, and relates to the use and peer review of CCSG funds in support of a clinical trials core operation in which research nurses and

data managers are directly involved in the conduct of the clinical trials research of a cancer center. This policy does not apply to research nurses and data managers who are paid from the CCSG as part of shared resources and have oversight, quality control, and training functions which broadly benefit clinical trials research, i.e., are not directly involved in the conduct of specific research protocols. Research nurses and data managers dedicated to these broader functions have always been appropriately funded by the CCSG.

It is the intent of the Cancer Centers Program to recognize the need of cancer centers to conduct pilot studies that test new, innovative ideas, as well as provide some flexibility to accommodate other clinical trials research needs in the center. It also represents a continued effort on the part of NCI to stimulate the submission of R01 applications to NIH. The general guidelines for supporting this type of clinical trials activity using the CCSG are as follows:

▸Allowable costs: An NCI clinical or comprehensive center can request up to three FTEs for data managers and research nurses (the mix being left to the discretion of the center) as part of a CCSG application. These positions will comprise a stable "core" component of a larger clinical trials research operation. They may consist of three full time staff, or multiple part time staff which constitute three FTEs.

▸Use of data managers and research nurses:

1. The primary justification for these positions is part of a CCSG application should focus on the need to conduct smaller, innovative, multidisciplinary, hypothesis-driven scientific (as opposed to strictly empirical) studies of a pilot/phase 1 nature.

All pilot studies that use these positions and any other shared resources of the CCSG (e.g., biostatistics) must receive some form of acceptable outside peer review (e.g., CTEP) or be evaluated, approved and monitored by the Clinical Protocol Review and Monitoring Process sponsored by the cancer center. This "Process" will be reviewed and approved by an external peer review group as noted in the 1992 CCSG Guidelines.

2. With the primary emphasis noted in 1 above, the center can use these positions in a flexible manner to accommodate other scientific needs and priorities of the center funded through acceptable peer review sources (e.g., R01, contract, cooperative groups).

▸Peer review of clinical trials research operation: Continued CCSG support for a clinical trials research operation as noted above will depend on a favorable peer review that evaluates both the acceptability of the institution's "Process" for reviewing and monitoring clinical research protocols and the overall quality and productivity of the clinical trials core operation.

The cancer center's "Process" will be evaluated using the criteria generally delineated in the "Guidelines for Cancer Center Support Grants." Other measures of the quality and productivity of the institution's pilot studies and how they contribute effectively to the overall clinical trials research program will be made separately approximately six months to a year before the review of a cancer center's competing renewal CCSG application. A panel of peer experts primarily derived from the extramural research community will be convened to evaluate institutional clinical trial activities of the center that have used CCSG resources (i.e., RNs and data managers as described above and shared resources) during the last grant period. This evaluation will be in the form of a report and supplied to the applicant prior to the site visit and to the site visit team and CCSRC for their use in peer reviewing all core shared clinical research resources (e.g., clinical trials research core, biostatistics shared resource, protocol management shared resource) supportive of the center's non-industrial, institutional protocols. The panel will examine the following:

1. Audits of pilot/phase 1 cancer center protocols using therapeutic agents, for which CTEP holds the IND (audits provided by CTEP to the panel).

2. Requirement to demonstrate a "good faith effort" to submit R01 grant applications to NIH based on the results of pilot/phase 1 studies supported by the CCSG.

3. Any successful movement of cancer center pilot studies to larger peer reviewed studies supported by R01s, P01s, cooperative groups, etc.

4. The novelty of the approach of these smaller clinical trials.

5. The scientific basis of these studies (i.e., hypothesis-driven versus strictly empirical).

6. Evidence for multidisciplinary input into these studies (e.g., surgical oncology, medical oncology, radiation oncology, etc.).

7. Publications in peer reviewed journals.

The cancer center will be responsible for providing information that addresses the above criteria for all pilot studies which have used CCSG resources in the last grant period. The details of the information to be provided (e.g., probably no more than one page of information per trial) and the process of evaluation will be developed at a later time.

The general relationship of approved cancer center clinical protocols to the CCSG. Clinical protocols approved by each cancer center's internal evaluation and monitoring "Process" become an important part of the center's research base. Since this "Process" is peer reviewed, there is reasonable assurance that all protocols approved by this system are of high quality. Consequently, these approved cancer center clinical protocols may relate in the following ways to the CCSG:

1. They may have equivalent access to any shared resources (e.g., protocol management, biostatistics) that generally support external peer reviewed, funded clinical research.

2. They may be listed as users of clinical shared resources as part of the budget justification of these resources in a CCSG application.

3. They may contribute to "Programs" as defined by the CCSG Guidelines. In some cases, the quantity, quality, and innovativeness of the active and completed protocols of the center combined with the strong track records of multiple clinical researchers in the center, as evidenced by the consistent publication records in clinical trials research in "peer reviewed journals," may serve as a basis for meeting part of the minimum requirement for a "Program" of three peer-reviewed project equivalents.

Areas which the Cancer Centers Program will not support at this time with the CCSG:

--The cost of the cancer center's process for designing, developing, and refining institutional protocols. Ideas that were incorporated into experimental designs are the responsibility of the scientists and the institutions that employ the scientists. These are the very ideas that should eventually be presented as competitive applications to funding organizations. At this time, NCI does not believe it should go beyond supporting the

pilot project concept, providing greater flexibility to biostatistics cores in the prospective design of trials, and providing .5 FTE to assist the center in managing its internal quality control "Process."

--Activities associated with trials requiring long term follow up. These are associated with larger, confirmatory clinical trials and resources for this purpose should be provided as an inherent part of a funded study.

--Outreach functions requiring support for the conduct of research or the collection of data outside the boundaries of the primary institution. While NCI encourages all clinical and comprehensive centers to conduct research that relates to the needs of its population base, this is not a cost effective way to use existing CCSG resources and these activities usually are associated with accruing large numbers of patients to phase 2 and phase 3 trials.

--Studies done for the specific benefit of industry. These would include activities associated with the submission of an IND to the FDA, industry sponsored or approved clinical trials in which industry holds the IND, and any activities associated with the submission of an NDA to the FDA. This does not include studies with agents in which industry hold the IND but donates the drug, allowing the cancer center to have full responsibility for the design and conduct of the research; however, under all such center agreements with industry, there should be no actual or apparent conflict of interest in using federal funds for this purpose.

Note: The above exclusions do not imply that people and facilities must be different, only that there be a clear distinction in the use of CCSG funds for those costs that are allowable under the policy and CCSG Guidelines in general.

List of Funding Organizations

Following is the new list of funding organizations whose projects NCI will consider peer reviewed for the purpose of the CCSG, in addition to grants, contracts and cooperative agreements from NIH:

National office of the American Cancer Society

National Science Foundation

Environmental Protection Agency

Central office of the Veterans Administration (excluding local/regional awards and "block" grants)

American Institute for Cancer Research

Univ. of California Tobacco-Related Disease Research Program (includes research project awards only)

National Institute for Occupational Safety and Health

Agency for Health Care Policy and Research

Food & Drug Administration

Howard Hughes Foundation (as long as these grants are reported by a grant number, a project title, and a dollar level and that there is no scientific overlap with other supported projects of the recipient investigator)

American Foundation for AIDS Research

Susan G. Komen Breast Cancer Foundation

Nebraska Cancer and Smoking Disease Research Program

Texas Advanced Research Program/Advanced Technology Program

Cancer Research Foundation of America

Univ. of California-Wide AIDS Research Program.

The Cancer Centers Program also said it recognizes that "many high quality, cancer-relevant research projects are funded by other organizations such as the Dept. of Energy, Dept. of Defense, Dept. of Agriculture, Centers for Disease Control, state health departments, etc.

"While funding from these organizations should not represent the major component of a cancer center's research base, the Cancer Centers Program wishes to provide all centers the option of carefully defending selected projects of special importance to the center for full access to CCSG resources. With this intent in mind, multiyear projects, which are equivalent in size and scientific complexity to an NIH R01 research project and funded by other organizations not listed specifically above, can be considered for eligibility if approved by peer reviewers as part of the initial review of a competing CCSG application."

The following criteria should be used by peer reviewers to evaluate funded projects on a case by case basis, NCI said:

1. Project is a multiyear project equivalent in size and scientific complexity to an NIH R01.

2. The project is clearly cancer relevant.

3. The investigator has a clear, current track record of productivity in the field as judged by scientific publications in peer reviewed journals.

4. If a newly funded project, it is clearly within the proven experience and expertise of the investigators as judged in (3) above.

5. If a continuing funded project, it clearly has a convincing track record of high quality scientific productivity as judged by publications in peer reviewed research journals.

NINDS Awards Brain Tumor Grants

The National Institute of Neurological Disorders & Stroke at NIH has awarded three-year exploratory grants to eight centers to develop brain tumor research programs. Later, the centers will compete for funding to establish permanent regional brain tumor research centers.

The grants went to: Univ. of Alabama at Birmingham Comprehensive Cancer Center, New York Univ., Brigham & Women's Hospital, Univ. of Michigan, Univ. of California at San Francisco, Children's Hospital of Philadelphia, Univ. of Cincinnati, and Ohio State Univ.