THE CANCER LETTER

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NCI Objects To Fisher As Scientific Director Of NSABP, Threatens To Cut Off Funding

NCI said it would cut off funding to the Univ. of Pittsburgh for the National Surgical Adjuvant Breast & Bowel Project unless the cooperative group changes its scientific leadership.

In a May 2 letter to the university, NCI objected to an NSABP restructuring plan which created the position of scientific director, to be held by Bernard Fisher.

Last March, NCI ordered the university to remove Fisher as principal investigator and chairman of the NSABP.

Last week, the NSABP's interim principal investigator, Ronald

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In Brief

Senate Cancer Coalition Hearing On Tamoxifen Planned For May 11; Bresnick Leads AACR

SENATE CANCER COALITION has scheduled a hearing on tamoxifen and the Breast Cancer Prevention Trial for May 11, 9 a.m. in the Dirksen Senate Office Building, Room 562. The coalition is co-chaired by Sen. Diane Feinstein and Sen. Connie Mack. . . . **EDWARD BRESNICK**, director of the Norris Cotton Cancer Center at Dartmouth Hitchcock Medical Center, succeeded **Margaret Kripke** as president of the American Association for Cancer Research at the group's annual meeting in San Francisco last month. **Joseph Bertino**, of the Sloan-Kettering Institute for Cancer Research, was elected president-elect. **Bayard Clarkson**, member of Memorial Sloan-Kettering Cancer Center, was elected treasurer, succeeding **Thomas King**. Four new members of the AACR Board of Directors are: **Webster Cavenee**, **Philip Hanawalt**, **Stanley Korsmeyer**, and **Thea Tlsty**. . . . **AACR AWARDS:** Eight scientists received prestigious awards at the the American Association for Cancer Research annual meeting last month in San Francisco. **Marc Lippman**, director of the Vincent T. Lombardi Cancer Research Center, received the Richard and Hinda Rosenthal Foundation Award. **Igor Roninson**, Univ. of Illinois, received the Cornelius P. Rhoads Memorial Award. **Mary-Claire King**, Univ. of California, Berkeley, received the GHA Clowes Memorial Award. **Mansukh Wani** and **Monroe Wall**, both of the Research Triangle Institute, received the Bruce F. Cain Memorial Award. **Brian Henderson**, president of the Salk Institute, received the American Cancer Society Award for Research Excellence in Cancer

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NCI To Pittsburgh: Fisher, Redmond Can't Lead NSABP

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Herberman, sent NCI a draft plan for restructuring the cooperative group.

The plan included a proposal to retain Fisher as the group's scientific director, while removing him from an administrative role.

The same plan included the NSABP's assurance that it is working on the reanalysis of several studies that included fraudulent data from St. Luc Hospital in Montreal.

An appendix to the plan listed studies that had been submitted for publication in scientific journals years after the NSABP learned about the fraud committeed by St. Luc surgeon Roger Poisson.

The plan resulted in two separate reactions from federal health officials:

- First, the NIH Office of Research Integrity last week ordered the Univ. of Pittsburgh to initiate a formal inquiry into possible scientific misconduct by Fisher and NSABP biostatistician Carol Redmond (see story, page 3).
- Second, this week, NCI said the Institute would not comment on the restructuring plan until its concerns about NSABP's scientific leadership were addressed.

The letter contained an indirect reference to Fisher and Redmond. "The NSABP draft plan includes personnel who appear to have been involved either as co-authors or in supervisory roles in the submission for publication of papers containing fradulent or falsified data," Lyn Bacon, NCI deputy grants management officer, wrote in a May 2 letter to Michael Crouch, director of the university's Office of Research.

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"The knowing submission of such data could raise grave concerns about the integrity and judgment of those involved," Bacon wrote.

"An acceptable NSABP leadership structure is of primary concern and a prerequisite to the NCI's consideration of any reorganization plan," she wrote. "The NSABP must assure the NCI that the proposed leadership is of the highest integrity and fully knowledgeable of the principles of science and the NCI directives regarding scientific misconduct.

"The participation...of personnel involved in the submission of the papers in question will not be acceptable."

NCI will comment on the NSABP plan after this issue is resolved, Bacon wrote.

"It may be difficult or impossible for the NCI to provide continued funding...unless these matters are resolved to the NCI's satisfaction," the letter concluded.

In an interview with **The Cancer Letter**, Herberman asked NCI for clarification of the letter. "They are somewhat vague about whether Dr. Fisher and Dr. Redmond can have any role," Herberman said.

"We feel both Dr. Fisher and Dr. Redmond made very valuable contributions to the group, to the science and the protocols," Herberman said. "We would sorely miss them, and we hope we could retain them in an advisory role."

Herberman also asked NCI to comment on other parts of the reorganization plan while the discussion over scientific leadership continues.

"I am concerned that this is just going to delay things," he said.

Fisher's Role In The New NSABP?

In his presentation of the NSABP restructuring plan to advisors to NCI's Div. of Cancer Treatment last week, Herberman said Fisher had agreed to serve as the cooperative group's scientific director.

However, NCI officials opposed placing Fisher in that role.

"I think that needs some additional discussion," Bruce Chabner, DCT director, said at the meeting.

Herberman's plan for NSABP described the scientific director as playing "a central role in the development of clinical protocols.

"Dr. Fisher has outstanding expertise and a unique perspective to serve in this capacity," the plan states. "He will interact regularly and extensively with the chairman, Executive Committee and the disease and

stage-specific committees, to provide advice and direction in formulating and implementing innovative and important clinical trials.

"This role will provide another important mechanism for maintaining continuity with the previous role of Dr. Fisher in the group and for revitalizing the interest and enthusiastic participation of the membership who have developed strong ties and loyalty to Dr. Fisher," the plan said.

NCI's approval of the restructuring plan is required for NSABP to resume accrual to its clinical trials. NCI ordered the group to halt accrual at the end of March as a result of the problems the Institute discovered in the group's auditing procedures.

Early Recompetition Of Grant?

Chabner recommended that NCI recompete the grant that supports the NSABP ahead of schedule.

In the most recent competition, in 1992, Univ. of Pittsburgh won a cooperative agreement for the NSABP headquarters. The cooperative agreement, worth $6.8 million a year, expires in 1997.

"Given the magnitude of the problems and the restructuring that would be necessary, I would favor an early recompetition of the grant," Chabner said to the DCT board.

"The grant should not be an inheritance for the current leadership of the NSABP," Chabner said. "A means should be created whereby there is true competition for the right to lead the $20 million agenda of trials."

An earlier recompetition would provide NSABP with a "permanent leadership and a new scientific leadership," Chabner said.

The board took no action on Chabner's recommendation, as several board members said NSABP's new leadership deserves a chance to restructure the cooperative group. Several sources said to **The Cancer Letter** that the issue is expected to come up again at the board's next meeting.

NCI Doubts About Auditing System

Chabner said NCI is concerned that NSABP is yet to institute an effective auditing system.

NSABP's plan to implement group-wide a site visit system similar to one that has been used for the Breast Cancer Prevention Trial was insufficient, Chabner said. "The reports we have seen with the prevention trial do not give me great confidence," he said at the meeting last week.

An alternative would be to use contractors to conduct audits, Chabner said. This would allow NSABP to resume accrual to its trials while developing a permanent auditing system.

Fisher, Redmond Are Subject Of Misconduct Investigation

The Univ. of Pittsburgh was ordered to initiate a formal inquiry into possible scientific misconduct by Bernard Fisher, former chairman of the National Surgical Adjuvant Breast & Bowel Project, and Carol Redmond, the cooperative group's chief biostatistician.

The letter demanding the investigation, issued by the NIH Office of Research Integrity last week, cited materials in the draft plan for restructuring NSABP.

"It has come to the attention of the ORI that a draft plan for revamping NSABP... contains an allegation of possible scientific misconduct," Dorothy Macfarlane, medical officer for ORI, wrote in a letter to the Univ. of Pittsburgh. "The specific allegation is that data from St. Luc Hospital which were known to be falsified and fabricated were included in publications of the NSABP."

"The publication of data known to be false may represent scientific misconduct," Macfarlane wrote in a confidential letter dated April 26 and addressed to Jerome Rosenberg, research integrity officer at the university. A copy of the letter was obtained by **The Cancer Letter**.

The plan for restructuring NSABP was submitted to NCI by Ronald Herberman, the cooperative group's acting chairman, last week.

According to confidential materials obtained by **The Cancer Letter**, Fisher and NSABP were in a position to know about the problems with the St. Luc data as early as February 1991, but apparently did not seek to notify the majority of journal editors of the problems until March 30, 1994.

"Evidence exists that Dr. Fisher and his colleagues were fully aware about their obligations to notify journals about the falsification of data in the study population," Marvin Kalt, NCI's misconduct policy officer, wrote in a confidential letter to Macfarlane, dated April 28.

Nonetheless, Fisher continued to submit papers that contained "one or more cases that were known to him to be falsified by Dr. Poisson," Kalt wrote. "Such data were not voluntarily expunged, and

apparently no adequate explanation or caveat was originally appended to these submissions."

Kalt's letter cited two papers submitted for publication by NSABP:

—"The Role of Thymidylate Synthase Expression in Prognosis Outcome to Adjuvant Chemotherapy in Patients with Rectal Cancer," submitted to the Journal of Clinical Oncology, but later withdrawn. According to Kalt's letter, the staff of the NCI Div. of Cancer Treatment who were listed as co-authors were not told that falsified records were included. After DCT questioned NSABP on the matter, the cooperative group acknowledged the presence of tainted data, and the paper was withdrawn, Kalt wrote.

—"Endometrial Cancer in Tamoxifen-Treated Breast Cancer Patients: Findings from NSABP B-14," published in the Journal of the National Cancer Institute, issue 86, pp. 527-537. The paper, in which Fisher is listed as the first author, was officially noted as being received on Jan. 18, 1994, but an acknowledgment of the St. Luc data was added in proof, after questions had been raised by the journal, Kalt wrote.

"These facts raise substantive issues materially different than simple failure to reanalyze data in an expeditious fashion," Kalt wrote.

ORI gave the university the deadline of May 11 to outline its plans for the investigation.

Regulations would require the university to form an inquiry committee that would determine whether a full investigation is warranted. The committee was given the deadline of June 27 to complete its recommendations.

NSABP Reorganization Plan Proposes Complete Overhaul

Key objectives of the NSABP reorganization plan are to correct the administrative and reporting problems in the group's headquarters, NSABP interim principal investigator Ronald Herberman said to an NCI advisory group last week.

Speaking before the Div. of Cancer Treatment Board of Scientific Counselors, Herberman said the main elements of the plan are to:

- Begin a high-quality audit process.
- Restore the confidence of NCI and the public in the NSABP.
- Maintain a leadership role for Bernard Fisher in the scientific direction, not the administrative responsibilities for the NSABP.
- Rapidly restore the functioning of NSABP.

"This group has clearly made important contributions to treatment of breast and bowel cancer in the past, and the membership is very eager to get started again," Herberman said at the meeting.

NSABP formed an oversight committee that will serve during the transition period to provide advice and review plans for reorganization. It will cease to exist or will be replaced by an advisory committee. Clara Bloomfield, chairman of the DCT Board of Scientific Counselors, had served on the oversight committee, but announced last week that she would resign because of possible conflict of interest. The committee met to approve the reorganization plan last month.

Following are the major changes in the group's structure, as proposed in the reorganization plan submitted to NCI last week:

- An Executive Committee will be the group's main governing body. Meeting at least twice a year, the committee will elect the group chairman and group statistician. A search committee will recommend candidates for the top positions, and the Executive Committee will select the new leaders this fall.
- A Constitution and Bylaws Committee, chaired by David Hyams, was formed to develop a proposal for revised bylaws, to be sent to all NSABP principal investigators by May 15. The goal is to complete this process before the group's June meeting.
- The group established a new position of executive officer. Donald Trump, deputy director of the Pittsburgh Cancer Institute, serves as interim executive director. The executive officer is to be appointed by the group chairman.
- A Data and Safety Monitoring Committee was established and its membership approved by NCI. It will meet three times this year. Thereafter, meetings will be held every six months. The committee is independent from NSABP headquarters, Herberman said.
- Separate disease committees will be established in breast and bowel cancers. Each will have subcommittees on prevention and treatment. This will broaden the role of NSABP members in development of clinical trials.
- Patient advocates will be involved in decision-making. The oversight committee includes two lay advocates, Dorothy Raizman, a Pittsburgh attorney,

and Amy Langer, executive director of the National Alliance of Breast Cancer Organizations.

The Data and Safety Monitoring Committee includes Kay Dickersin, of the Univ. of Maryland, a breast cancer advocate and survivor with an expertise in clinical trials and epidemiology.

In addition, NSABP has consulted Craig Henderson, principal investigator of a Breast Cancer SPORE at Univ. of California, San Francisco, and Kathy Albain, chairman of the Southwest Oncology Group's Committee on Women's Health. Henderson and Albain have worked to involve patients in their organizations.

A detailed plan for patient involvement will be presented to NSABP members at the group's June meeting, Herberman said.

"A central objective in this plan will be to establish an ongoing partnership between patients and their physicians, to fully educate the patients about the clinical trial and their options and to also educate physicians about the concerns and needs of the patients," according to a draft of the NSABP plan.

On-Site Auditing Planned

An audit committee, chaired by an NSABP principal investigator and composed of group members, will be formed.

Walter Cronin, of the NSABP Biostatistical Center, was designated the contact for the on-site audit program.

Under the proposed audit procedures, group members will be involved in the on-site audits. NSABP headquarters and NCI will be notified within 24 hours of any "major deviation."

NSABP will submit a preliminary audit finding within 24 hours to NCI, and will transmit an audit summary report to the audited institution and NCI within seven days. The institution will have 20 days to respond to the report.

A final report will be sent to NCI and the audited institution within 30 days from the submission of the preliminary report.

"All sites are at risk to be audited annually and will be audited at least once every three years," the NSABP plan states.

The group's executive officer will be responsible for reviewing and assuring compliance to the audit guidelines.

The plan emphasized that NSABP will audit all sites that accrue patients, despite the significant logistical problems in auditing the many sites that accrue fewer than 10 patients per year.

"This challenge is acknowledged and plans for reorganization of audits and establishment of affiliate/center relationships are being developed," the plan said.

Also under evaluation is NSABP's method of funding its investigators. In the past, the funding level was determined by the level of patient accrual.

"Restructuring of funding guidelines will be developed which take into account scientific and administrative contribution to the functioning of the NSABP," the plan said.

"For example, institutional and investigator support can be related to participation in a leadership role in modality committees, audit or constitution and bylaws committees, authoring or presenting abstracts or papers." A committee to examine these approaches will be appointed, the plan said.

A membership committee will develop criteria for group membership. A system of main members and affiliates is being considered as a way of handing the hundreds of members who enter few patients on studies.

Innovative Procedures

Herberman also described the group's plan to implement "innovative procedures" for data checking that would involve the patients, particularly in questions of eligibility.

Consent forms could include the relevant dates or other information determining eligibility, and the patient would be asked to affirm the accuracy of the information.

"This type of system would have made it impossible for Dr. [Roger] Poisson to do what he did," Herberman said.

Currently, an audit provides one of the few opportunities for NSABP headquarters to offer feedback to with the investigators.

The system proposed by Herberman would initially rely on paper records, but would later be computerized.

Ultimately, the caregiver would transmit enrollment information to NSABP headquarters, and headquarters would respond immediately, requesting corrections or pointing out deficiencies.

A demonstration of the system will be provided to group members at the June meeting, Herberman said.

"We believe these are relatively simple feedback loops that can be put into place quite rapidly and could be made as user-friendly as possible so that participants would see this as a value-added rather than an additional burden placed upon them," Herberman said.

"Part of idea for these loops would be to make falsification or fraud much more difficult and more expensive," Herberman said.

Reanalysis and Resubmission of Papers

NSABP's Biostatistical Center is working on reanalysis of all trials that contained the fraudulent data from St. Luc Hospital in Montreal, where Poisson was an NSABP principal investigator.

"It must be emphasized that full compliance with this requirement encompasses some 15 years of NSABP data," the plan states. An appendix submitted with the plan listed all NSABP publications which included Poisson's data.

Fisher wrote to the editors of all journals that had published these papers since 1991, informing them of the fraudulent data. Manuscripts submitted or in press have been withdrawn, the plan said.

NSABP will submit manuscripts to NCI for information at the time of submission to journals Audits of a sample of charts from all institutions participating in a study would be completed prior to submission of a manuscript, the plan states.

NCI To Double Contract Funds For Clinical Trials Monitoring

Advisors to NCI's Div. of Cancer Treatment last week approved a plan to increase funding for clinical trials monitoring.

Under the plan, DCT will double its monitoring expenditures over the next year to support the new Clinical Trials Monitoring Branch. The branch was created in response to the revelations of fraud in the National Surgical Adjuvant Breast & Bowel Project, and NCI's delays in responding to the cooperative group's problems.

DCT will spend nearly $3.3 million, double the current $1.6 million the division spends annually on a support contract. The current contract holder is Theradex Systems Inc.

Michael Friedman, director of the Cancer Therapy Evaluation Program, asked the DCT Board of Scientific Counselors for approval to double the funding for the contract annually for the next four years.

Board members, reluctant to approve what would amount to shifting of funds from research, said they felt NCI was responding to a one-time crisis. The board approved a one-year addition of about $1.6 million to the contract, asking Friedman to return to the board in a year if additional funding is necessary.

"We all hate to see valuable research money going into non-scientific things, such as auditing, but it is scientific in the sense that it ensures the quality of the science," DCT Director Bruce Chabner said to the board. "We will have to find the money. Some will have to come out of the cooperative group budget and other money will have to be diverted from other sources."

There are four years remaining on the Theradex Systems contract. DCT staff said it is not clear whether funds would be added to the existing contract, or whether a new Request for Proposals would be issued.

According to a 1992 concept statement, the contract supports a clinical trials monitoring service. The service co-site visits 10 to 20 percent of cooperative group audits of their members or affiliates, conduct other audits of studies as required by FDA, and serves as a central data management resource for phase I and phase II studies (**The Cancer Letter**, July 10, 1992).

Doctor May Have Breached Patient Confidentiality: NCI

Los Angeles physician David Plotkin may have breached patient confidentiality by releasing patient files to a Chicago Tribune reporter, NCI officials said.

The materials, which NCI said were released without the consent or notification of the patients, formed the basis of a story by John Crewdson in the Tribune last Sunday.

The story said Plotkin's Memorial Cancer Foundation of Southern California had enrolled several patients who later proved ineligible for the lumpectomy study, included several others without their written consent and reported some deceased patients as living.

Days before the Tribune story appeared, Plotkin called NCI to request an independent audit of his data.

Though the audit is yet to be completed, the Institute's first action was to refer the case to the institutional review board of Brotman Medical Center, the Los Angeles hospital with which Plotkin's

foundation is affiliated.

"NCI took appropriate steps to notify the [IRB] of the apparent breach of confidentiality," the Institute said in a press release. "The IRB has responsibility for protecting the privacy of research subjects and for maintaining the confidentiality of data."

A spokesman for Plotkin said to **The Cancer Letter** that Crewdson was given access to the files after making a promise that patients would not be identified by name. Though the promise was kept, several physicians said it was virtually unheard of for a physician to release patient files to the press regardless of the ground rules.

The Tribune story was based on materials in the files of 18 of the 29 patients Plotkin had enrolled in the lumpectomy study. Over the years, Plotkin's foundation had enrolled 311 women in the National Surgical Adjuvant Breast & Bowel Project studies.

According to Plotkin's spokesman, Crewdson had confronted the physician with a copy of an unfavorable NSABP audit of the files of the patients enrolled in the group's trials.

Neither Plotkin nor NCI had been aware of the audit's findings, said Lawrence Weinberg, a public relations consultant hired by the physician last week.

"The reporter in question threatened [Plotkin] with an unfavorable story based on a document [Plotkin] had in fact never seen," Weinberg said to **The Cancer Letter**.

"Because Dr. Plotkin had confidence in the honesty and integrity of his research, he first secured the reporter's guarantee of patient confidentiality, and then showed him some of the files in question," Weinberg said.

Weinberg acknowledged that the records contained errors. "This is no Montreal," he said. "There is no fraud here. What [Plotkin] has is a group of clerical errors that are not going to threaten the integrity of B-06 results."

In Brief

(Continued from page1)

Epidemiology and Prevention. **Carol Greider,** Cold Spring Harbor Laboratory, received the Gertrude Elion Cancer Research Award. **G. Marie Swanson,** director, Michigan State Univ. Cancer Center, won the Jack White/LaSalle Leffall Jr. Award for Cancer Prevention and Control. . . . **CORRECTION: The Cancer Letter,** April 22 issue, incorrectly reported that consumer advocates are members of the Breast Cancer Prevention Trial's data and safety monitoring committee. In fact, NCI is seeking a consumer to serve on the committee, according to Barnett Kramer, of NCI's Div. of Cancer Prevention & Control. The trial's steering committee does include consumer representation, Kramer said.

RFPs Available

RFP NCI-CM-57220-37
Title: A Request For Proposal For Logistics And Conference Support
Deadline: Approximately July 14

The principal objectives of this project are to provide conference and property management support to the Office of the Director, Div. of Cancer Treatment. The contractor shall provide conference management and logistics support for conferences, symposia, and meetings of the DCT Board of Scientific Counselors. Logistics support activities include various technical and clerical tasks ranging from 1) report design and preparation, 2) routine typing, and 3) abstacting and formatting (including bibliography preparation and indexing) of papers and reports generated at scientific meetings. This acquistion is 100% set-aside for 8(a) small businesses.

Contract specialist: Patricia Lightner, Contract Specialist, Treatment Contracts Section, Research Contracts Branch, NCI, Executive Plaza South, Room 603, Bethesda, MD 20892, Tel. 301/496-8620.

RFP NCI-CN-45582-41
Title: Phase I Studies of New Chemopreventive Agents
Deadline: Approximately June 27

NCI's Div. of Cancer Prevention & Control, Chemoprevention Branch, in its annual requirement to seek new sources, is soliciting proposals for master agreement holders for this contract. Objective of these studies is to determine the parameters and characteristics of toxicity in humans, the safely delivered dose, and the basic clinical pharmacokinetics of agents emerging from the NCI chemoprevention agent development program so that phase III risk reduction trials can be designed.

Contracting officer: Susan Hoffman, RCB, Executive Plaza South Rm 635, Bethesda, MD 20892, Tel. 301/496-8603.

RFP NCI-CN-45001-05
Title: Preclinical Toxicology of Chemopreventive Agents
Deadline: Approximately June 30

NCI's Div. of Cancer Prevention & Control, Chemoprevention Branch, wishes to award master agreement contracts for this study. It is estimated that four to five master agreement orders will be issued per year.

Contract specialist: Gary Topper, PCCS, Executive Plaza South Suite 635, Bethesda, MD 20892, Tel. 301/496-8603.

RFAs Available

RFA CA-94-021
Title: **Cloning and Sequencing the BRCA1 Gene**
Application Receipt Date: June 14

NCI's Div. of Cancer Biology, Diagnosis & Centers invites the submission of research project grant applications for support to clone and sequence the BRCA1 gene. The aim of this RFA is to foster and stimulate collaborations among investigators who can expedite the process of cloning and sequencing the BRCA1 gene. It is expected that the achievement of this goal will lead to new research opportunities for prevention, screening, early detection, and treatment of breast and ovarian cancer, and perhaps other malignancies.

Applications may be submitted by domestic and foreign nonprofit and for-profit organizations. Applications can be from single or multiple institutions. Foreign institutions may also participate in laboratory or clinical programs through subcontract or consortium arrangements.

NIH R01 is the funding mechanism. Project period may not exceed two years. Total proposed direct costs for the first year may not exceed $1.4 million. This does not include indirect costs on a subcontract that appears as a direct cost by the applicant organization. Anticipated award date is Aug. 15. Approximately $2 million in total costs per year will be committed specifically to fund applications. At least one award will be made.

Inquiries: Dr. Cheryl Marks, DCBDC, NCI, Executive Plaza North Rm 505, Bethesda, MD 20892, Tel. 301/496-7028, Fax 301/402-1037.

RFA CA-94-014
Title: **Investigator Grants for Clinical Cancer Therapy Research**
Letter of Intent Receipt Date: Aug. 5
Application Receipt Date: Sept. 21

NCI's Cancer Therapy Evaluation Program and the Biological Response Modifiers Program, Div. of Cancer Treatment, invites research grant applications for the conduct of therapeutic clinical trials research employing new agents, concepts or strategies for the treatment of cancer. This initiative is aimed at drawing new clinical investigators into this area of research.

Applications may be submitted by domestic nonprofit or for-profit organizations. An important principle to remember is that the more extensive the prior independent research experience, regardless of funding source, the greater likelihood there will be diminished priority for award.

NIH R01 will be the funding mechanism. Total project period may not exceed four years. Total direct cost for the four-year period may not exceed $500,000. Direct cost in any budget period should not exceed $150,000. Anticipated award date is July 1995. NCI plans to reissue this RFA for funding in 1996 and 1997.

Approximately $1.5 million in total costs per year for four years will be committed. Eight awards will be made.

Inquiries: Dr. Toby Hecht, DCT, NCI, FCRF 1052, Rm 253, Bethesda, MD 20892, Tel. 301/846-1098, Fax 301/846-5429.

RFA OD-94-004
Title: **Exploratory Centers for Alternative Medicine Research**
Letter of Intent Receipt Date: May 9
Application Receipt Date: June 15

The Office of Alternative Medicine invites applications that describe a plan for providing technical, clinical, scientific assistance to alternative medicine clinicians/researchers as they develop their clinical databases.

Applications may be submitted by domestic for-profit and nonprofit organizations. The U24 mechanism will be used. Estimated funds available will be $1.8 million. Two or three awards will be made, for a period of four years.

Inquiries: John Spencer, OAM, NIH, 6120 Executive Blvd., Suite 450, Rockville, MD, 20892-9904, Tel. 301/402-4741.

RFA CA-94-020
Title: **Studies Of The Viral Etiology Of AIDS-Associated Malignancies**
Letter of Intent Receipt Date: June 17
Application Receipt Date: July 29

NCI invites investigator-initiated research grant applications for support of basic studies on the role of viruses and other biological agents in the etiology and biology of malignancies associated with AIDS, including, but not limited to, Kaposi's sarcoma and AIDS-related non-Hodgkin's lymphomas.

For-profit and non-profit organizations and institutions, governments and their agencies are eligible to apply. Foreign institutions and organizations are not eligible for the First Independent Research

Support and Transition (FIRST) Awards (R29). This RFA will use the individual research grant (R01) and the FIRST Award (R29). Total direct cost award for the five-year R29 grant period may not exceed $350,000 and the direct cost award in any R29 budget period should not exceed $100,000. The total project period for an application for an R01 award may not exceed five years. The earliest award date is February 1, 1995. Approximately $1,000,000 in total costs per year for up to five years will be committed to fund approximately five to six awards.

Inquiries: Dr. Kenneth Cremer, DCE, NCI, Executive Plaza North Rm 540, Bethesda, MD 20892, Tel: 301/496-6085.