# THE CANCER LETTER

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# Tell NCI About Science, Not Funding Mechanisms, Broder Says To Society

How can an advocacy group get the attention of NCI officials without antagonizing them?

Last week, speaking to the Leukemia Society of America, NCI Director Samuel Broder volunteered the answer: <u>Do</u> tell the Institute about the scientific opportunities. <u>Don't</u> tell it which grant mechanism to use. And <u>don't</u> go to Congress to create new mechanisms.

"We should avoid an excessive compartmentalization or an overfixation on organ-specific research," Broder said.

Later in the speech, Broder said leukemia research should be funded (Continued to page 2)

In Brief

# Hopkins Wins SPORE In Gastrointestinal Cancers; Nurses Group Calls For Proposals

JOHNS HOPKINS Medical Institutions received a \$4.4 million award from NCI for the gastrointestinal Specialized Program of Research Excellence. Hopkins was the only institution to receive the award. The Hopkins oncology center last year received two SPORE grants for lung and prostate cancer studies. Principal investigator on the GI SPORE is Stanley Hamilton. . . . AMERICAN NURSES Foundation has initiated a call for proposals for its 1994 Nursing Research Grant Awards. The program is designed to support beginning nurse researchers. Experienced nurse researchers entering new fields also are eligible to apply. Application deadline is May 1. For information, contact ANF, 600 Maryland Ave. SW, Washington, DC 20024, Tel. 202/554-4444. . . . KATHRYN BEMMANN was named president of the American Medical Women's Assn. during the organization's annual meeting recently. Elected president-elect was Diana Dell, Duke Univ. . . . NIH APPROPRIATIONS should be \$11.9 billion, according to a consensus conference of the Federation of American Societies for Experimental Biology. This would represent an increase of \$978 million over the FY 94 appropriation. FASEB recommended that \$6.5 billion be used to support nearly 25,000 research grants, a 5 percent increase over the current year's level. The recommended budget increase, FASEB said, "will enable NIH to address the problem associated with two renewal cycles coming to maturity in one year. Because many awards made in 1990 and 1991 will complete their funding cycle in 1994, there will be an increase in the number of competing renewal applications for 1995."

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# **Broder To Leukemia Society: Tell Us The Scientific Priorities**

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through existing mechanisms. "Tell us the scientific opportunities that exist," he said. "It's my impression that talking doesn't cure any diseases and administrative mechanisms frequently fail to do so as well."

At a time when advocacy groups are becoming increasingly prone to tell NCI how to spend its money, Broder's remarks to the leukemia society amounted to a call for trust, undertanding and, perhaps, mercy. "This is the same talk I'm giving to all groups that want to hear my cloying speeches," he said.

Though no promises were made, Broder said NCI will consider developing a Request for Applications for program project (P01) grants in leukemia, lymphoproliferative disease and multiple myeloma. This would allow the Institute to set aside funds for research grants for these diseases. P01 applications are reviewed by ad hoc study sections rather than by the regular NIH study sections.

Broder said NCI did not intend to create leukemia and lymphoma centers that were advocated by the leukemia society, but had every intention of funding excellent science. He invited the society to submit a report to him listing scientific priorities. Leukemia society representatives said they agreed with Broder on avoiding organ-specific research mandates.

The leukemia society suggested the language on leukemia centers that appeared in the Senate Appropriations Committee report, said Ronald McCaffrey, vice chairman for medical and scientific affairs for the society. The provision did not make it into the final appropriations measure.

The word "center" was not meant as NCI defines

# THE CANCER LETTER

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it: a cancer center with a core grant or a Specialized Program of Research Excellence, McCaffrey said to The Cancer Letter. "We used the word 'center' to cover what we meant as a group, a program, a network, a critical mass of people with equipment and ideas," he said.

In testimony to the House Appropriations Committee last spring, the leukemia society joined other organizations asking for a \$340 million increase in the NCI budget. Congress should not specify how the money should be spent, the society said.

"I don't think we would want a SPORE, because that doesn't give you the lean, mean fighting machine that you want," McCaffrey said. In its report to Broder, the society might suggest jointly funding with NCI an RFA for leukemia research that would allow several institutions to work together, similar to the National Cooperative Drug Discovery Groups, he said.

In a related development, Broder said NCI is developing a concept for a new Request for Applications for R01 grants designed to provide funding for first-time clinical grant applications (see story, page 3).

### 'There Is A Unity To Cancer'

"Many concepts that we now take for granted, including the concept of the cureability of disseminated cancer, derive from leukemia research," Broder said. "The efforts of the men and women involved in leukemia research in the late '60s and early '70s...radically changed our entire perspective of cancer and made it possible to develop the National Cancer Program in its current form.

"We need to take stock and to be honest with ourselves where progress is limited and where we can expect very few returns based on current knowledge," he said. "It is very wrong to concede defeat to pessimism or to therapeutic nihilism, but by the same token, it is equally wrong to issue promissory notes about progress where we cannot redeem such promissory notes.

"It is also important that we do not permit our enthusiasm for the level of progress already made, and for the challenges we have in fact already overcome, to create a sense of optimism that is not informed by the facts at hand."

Broder said the best research ideas come from investigators.

"The most important commitment we can make is to reaffirm our passion for a strong agenda of basic and clinical research in which investigators define problems and then are given the means to solve these problems, based on peer review," he said. "I think it is very important for us to avoid limiting the models investigators use as they seek to solve problems. In our modern era, scientists who are interested in various aspects of cancer, including leukemia, must be given the freedom to study the models that they, as scientists, see fit for the problem at hand. The exact model must be chosen by scientists and not by a central governmental authority and least of all, by a budget officer.

"In the same spirit, recognize that we should avoid an excessive compartmentalization or an over-fixation on organ-specific research," he said. "There's a unity to cancer, and that applies to leukemia. The earliest leukemia pioneers believed in this unity and they accomplished great things by this belief."

#### **Invited Grant Applications**

Responding to questions from the audience of mostly scientists and clinicians, Broder said the NIH R01 grant is a viable method for funding both laboratory and clinical research.

"Anybody, anywhere, has the right to send in an application with that person's best ideas and to have it seriously considered for review by a peer group, not by some central government bureaucrat," he said.

However, some researchers think the R01 is not suitable for clinical research, Broder said. "That is clearly not the case," he said. "The R01 mechanism can be adapted to clinical research. We seem not to be using it much in that way."

Broder invited R01 applications from clinical researchers, as well as interactive R01s (coordinated submission of three related R01s), and program project (P01) applications.

"There's no substitute for flooding us with applications," Broder said. "I can recite the problems all you have had with ET2 [Experimental Therapeutics 2 study section]. But we can deal with those issues if we have lots of applications."

The Institute receives about 75 clinical R01 grant applications out of a total of about 3,000 R01 submissions per year, Broder said. About 10 to 15 percent of these grants are funded.

"We are funding 8 or 9 clinical applications per year," Broder said. "We need to have a larger base of applications."

The leukemia society's McCaffrey, chief of medical oncology at Boston Univ. Medical Center,

said organ-specific funding is not the society's goal.

"We don't want you to feel this group is compartmentalized and looking for money for leukemia and only leukemia research," he said during the discussion with Broder. "What we want now is a new beginning, so that leukemia can provide insight to all cancers."

To the investigators in the room, McCaffrey said, "We need to take Sam at his word on awards. We need a new paradigm. We're stuck. We've been stuck for three or four years. At this meeting we have identified about a dozen scientific areas which will lead us to the new paradigm."

#### **Rational For Centers**

Though it is clear that NCI will not fund leukemia centers in the current fiscal year, the rationale for such centers is powerful, conference participant Emil (Jay) Freireich, professor of hematology and oncology at M.D. Anderson Cancer Center, said to The Cancer Letter.

The types of treatment necessary to get high cure rates are technical and expensive, Freireich said. "If we are going to say that clinical care costs more than HMOs and PPOs, then we should identify the places with expertise, where it will cost more, and where there is a benefit to science and the community for spending the money," he said. "All of the center programs have been successful."

Freireich said he would recommend the Leukemia Society to set aside funds for planning grants for such centers.

# **Clinical RFA Under Discussion**

NCI's Div. of Cancer Treatment is preparing a concept for a new Request for Applications for clinical cancer research.

The concept will go before the DCT Board of Scientific Counselors at its meeting Feb. 14-15. If approved, the RFA will seek R01 grant applications from investigators who have never applied for a grant for clinical research.

NCI Director Samuel Broder discussed the proposed RFA last week. In the eligibility for the RFA, he said, "We'll have so few restrictions that you'll need a microscope to find them."

Continuing his often-repeated complaint that NCI receives too few clinical research grant applications, Broder said, "If you don't apply, you won't be considered, and yes, you probably won't be funded."

## RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Address requests for NCI RFPs to the individual named, Executive Plaza South room number shown, NCI, Bethesda, MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville, MD.

#### RFP NCI-CB-46207-82

Title: Immunological blood sample preparation and assays

Deadline: Not specified

NCI is soliciting proposals from offerors with the capability to provide immunological testing support services in the cancer vaccine field. Testing will be of patient and/or non-human primate blood. The assays required will include: isolation and freezing of peripheral blood mononuclear cells, lymphoproliferation assays, cytolkine assays, T cell phenotyping, cytotoxic T cell assays, and assays for antigen, antibody, and antigenantibody complexes. This is a new requirement. Some limited testing has been provided through the use of purchase orders.

The first recombinant anti-cancer vaccine developed by NCI has already begun Phase 1 clinical trials. There are other recombinant anti-cancer vaccines that will also be tested in non-human primates and in clinical trials. Common to all these trials and preclinical testing is the fact that active specific immunotherapy approaches are based on the potentiation of the cellular and/or the humoral immune response by active immunization, the induction of cellular and/or humoral responses, and the subsequent role of the antitumor activity. This information is critical to evaluation of the vaccines. This necessitates a comprehensive and uniform evaluation of the immunological responses, since many of these studies will be carried out at different institutions and companies.

The government will supply patient and/or nonhuman primate blood to the contractor for analysis. These samples will be identified by code to ensure patient confidentiality and blinded analysis. Blood analyses are separated into the following tests: 1) isolation and freezing of peripheral blood mononuclear cells; 2) including: immunoresponse assays lymphoproliferation assays, 2b) culture supernatant harvets, 2c) cytokine assays (IL-2, IL-6, IFN-gamma, TNF-alpha); 3) T cell phenotyping (CD3, CD4, CD8, CD4/C); 4) cytotoxic cell assays including; 4a) generation of EBV immortalized B cell lines, 4b) preparation of target cells, 4c) preparation of effector cells, 4d) cytotoxic assays; 5) serologic assays including: 5a) separation of serum from blood samples, 5b) antitumor associated antigen immunoglobulin response, 5c) serum tumor associated antigen levels, 5d) immune complex determination. The NCI project officer will order the assays to be performed on each individual sample. The orders, therefore, may be only one assay of all of the above, per individual sample. It is anticipated that the proposed contract will be for a five-year period of performance.

Contract specialist: Michelle Scala, RCB Executive Plaza South Rm 638, Tel. 301/402-4509, FAX 301/402-4513.

#### RFP NCI-CM-57208-74

Title: Phase I clinical trials of anticancer agents

Deadline: Not specified

NCI's Cancer Therapy Evaluation Program, Div. of Cancer Treatment, is seeking organizations with the capabilities and facilities to provide Phase I clinical trials of investigational new agents. Specifically, the organizations will perform studies to: a) define the acute toxicities of new anticancer agents in patients with advanced cancer; b) re-define the acute toxicities and pharmacokinetics of existing anticancer agents administered in combination with colony stimulating factors and other toxicity ameliorating agents that may facilitate the exploration of more effective doses and schedules; c) provide information on the pharmacologic characteristics of selected antitumor agents; d) define treatment regimens for evaluation of antitumor activity in Phase II trials; e) establish appropriate Phase II doses in special patient populations, such as those with impaired end-organ function or with heavy pretreatment, geriatric populations, and to explore pharmacokinetic and pharmacodynamic differences based on gender. race, or ethnic group; f) obtain preliminary information on pharmacokinetic/pharmacodynamic correlations that can then be extended in Phase II trials; and g) incorporate ancillary basic laboratory studies, when possible and appropriate, to enhance our understanding of the biochemical and/or biological mechanisms of drug actions. The Contractor will accrue at least 50 contract credits per year to at least three active Phase I trials per year for five years. Pharmacokinetics and/or correlative laboratory studies will be a standard feature of these studies. All patients for these studies must be treated at the offeror's own institution. Offerors who submit proposals must demonstrate the accrual of at least 50 evaluable adult cancer patients to IRB approved Phase I cancer treatment protocol studies conducted at the offeror's institution during calendar year 1993.

The proposed acquisition is a recompetition of six existing contracts currently held by: Univ. of Chicago, Johns Hopkins Univ., Univ. of Maryland, Mayo Foundation, Univ. of Texas Health Science Center, Univ.

of Wisconsin. It is anticipated that six awards will be made and that the resulting contracts will be awarded on an incrementally funded basis for a period of 66 months.

Contract specialist: Odessa Henderson, RCB Executive Plaza South Rm 603, Tel. 301/496-8620.

## RFAs Available

RFA CA-94-003

Title: Tissue and biological fluids banks of hivrelated malignancies

Letter of Intent Receipt Date: April 15 Application Receipt Date: May 17

NCI's Cancer Therapy Evaluation Program, Div. of Cancer Treatment, invites applications from consortia of institutions for cooperative agreements to design and develop banks of tissue and biological fluids and clinical data from patients with HIV-associated malignancies. The purpose of the proposed awards is to stimulate cooperative efforts to identify and improve access to tumor tissue, biological specimens and associated clinical outcome data that could then be utilized for research by the research community at-large on the pathogenesis of HIV-associated malignancies and development of more effective therapies. Seed money can be requested for proposed pilot studies utilizing these materials.

Domestic and Canadian for-profit and non-profit organizations, public and private, are eligible to apply. Foreign institutions other than Canadian are not eligible to apply or be a collaborating institution. Canadian institutions are included because many of them are members of the NCI-Sponsored Clinical Trials Cooperative Groups and the NIAID-Sponsored AIDS Clinical Treatment Units. Applications must be from a consortium of no less than two institutions, which can include, but are not limited to, the NCI-Sponsored Clinical Trials Cooperative Groups, the NIAID-Sponsored AIDS Clinical Treatment Units, or a coalition of Cancer Centers. New and experienced investigators are encouraged to apply. Applications from minority individuals and women are encouraged.

The funding instrument will be the cooperative agreement (U01). Size of awards will vary. The total project period may not exceed four years. Anticipated award date is Sept. 30. Approximately \$2 million in total costs per year for four years will be committed. It is anticipated that three to four awards for the Tissue and Biological Fluids Banks of HIV-Related Malignancies will be made. Up to 10 percent of the

total costs, or \$50,000 per year for three years (whichever number is smaller, and to start in year two of the cooperative agreement) can be requested for pilot studies.

The purpose of the proposed awards is to stimulate cooperative efforts to design and develop Tissue and Biological Fluids Banks of HIV-associated malignancies with associated clinical and outcome data. The banks would provide critical resources to the research community at-large for research studies to gain insight into the pathogenesis of the malignancies that arise in HIV-infected individuals.

Formation of a consortium of institutions is encouraged to maximize specimen accession. All applicants must provide evidence of availability and access to patient specimens, and each Consortium (made up of a minimum of two institutions) must have an Operations Office that is capable of providing the necessary coordination of specimen collection, data management, and storage of specimens at a central location. Banked specimens may consist of fixed or frozen tumor tissue and biological fluids. Investigators must address coordination of quality control among collaborating institutions and consortia with regard to collection, shipment and storage of specimens.

The awardees will provide to the research community at-large tissue and biological fluids of high quality from patients with HIV-associated malignancies for high priority research studies. This task will be accomplished through the workings of two committees, the Steering Committee and the Research Evaluation and Decision Panel.

Of the funds provided by this RFA, at least 90 percent of the total costs proposed in each application must be directed to the actual banking (accession of tissues and biological fluids, facilities, laboratory personnel, clinical data collection and linkage to specimens) and up to 10 percent of the total costs, or \$50,000 per year for three years (whichever number is smaller, to start in year 2 of the cooperative agreement) can be requested for pilot studies. Pilot studies should be designed to obtain sufficient data to form the foundation for future R01 research grant applications. The pilot studies should also help identify new research areas where additional investigations should be pursued. Examples of such studies could include, but are not limited to, the following: prospectively comparing the response to therapy in patients with different molecular characteristics, determining the cytokine expression that might be etiologically involved in the development of the malignancies seen in HIV infection, and the effect on such expression by therapy; evaluating the interaction of other factors with HIV in malignancies, and the effects of therapy on those factors; assessing the impact of therapy both on viral burden and on tumor response, and designing assays for in vitro or in vivo animal models for testing of pharmacologic compounds in HIV-associated malignancies, that could be tested in the context of a clinical trial.

The letter of intent is to be sent to: Dr. Roy Wu, Div. of Cancer Treatment, NCI, Executive Plaza North Rm 734, Tel. 301/496-8866, FAX 301/480-4663.

Address requests for the RFA to: Dr. Ellen Feigal, Div. of Cancer Treatment, NCI, Executive Plaza North Suite 741, Tel. 301/496-2522, FAX 301/402-0557.

#### RFA ES-94-004

Title: Timing of environmental exposures in breast cancer

Letter of Intent Receipt Date: March 8 Application Receipt Date: April 8

Research on environmentally related causes of breast cancer and its prevention is a priority of the National Institute of Environmental Health Sciences. The goal of this RFA is to stimulate research on the role of environmental factors in the etiology of breast cancer. Of particular interest are aspects related to the timing of the exposures to harmful environmental agents and the subsequent cellular and genetic changes that may lead to breast cancer. Another equally important area of research is to develop a better understanding of what effects environmental agents have on the normal growth and development of mammary gland tissues. In vitro and in vivo studies that further our understanding of the influence of environmental factors on sex steroid hormones, growth factors, and receptors in cellular and genetic process are encouraged.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations. This RFA will use the NIH individual research grant (R01) and FIRST (R29) award. The total project period for R01 applications may not exceed four years; R29 applications must be for five years. The estimated funds (total costs) available for the first year of support for the entire program is \$1.5 million. The expected range of number of awards is five to six.

This research program is designed to stimulate experimental work in three important areas to enhance our understanding of environmental influences on normal breast development and breast cancer. These are to understand the cellular and genetic effects of environmental agents on the normal growth and development of the mammary gland, to study the role of environmental factors in the development of breast cancer, and to explore the role of timing of these agents during critical developmental periods as it pertains to future risk of abnormal development and carcinogenesis. Research into how exposures during these periods effect the latency of the disease is also desirable. It should be noted that research that explores the cellular, genetic and hormonal aspects of normal and abnormal breast development, without regard to the role of environmental factors will not be considered responsive to this RFA.

The letter of intent is to be sent to: Ethel B. Jackson, Div. of Extramural Research and Training, National Institute of Environmental Health Sciences, PO Box 12233, Research Triangle Park, NC 27709, Tel. 919/541-7826, FAX 919/541-2503.

Direct inquiries regarding programmatic issues and requests for the RFA to: Gwen W. Collman, Div. of Extramural Research and Training, at the same address, Tel. 919/541-4980.

#### RFA RR-94-003

Title: Extramural research facilities construction projects

Letter of Intent Receipt Date: Feb. 18 Application Receipt Date: April 8

The National Center for Research Resources is authorized under Sections 481A and 481B of the Public Health Service Act to "make grants to public and nonprofit private entities to expand, remodel, renovate or alter existing research facilities or construct new research facilities" for biomedical and behavioral research and research training. The Appropriations Act for the Dept. of Health and Human Services for Fiscal Year 1994 provides \$7 million for extramural facilities construction grants, to be awarded competitively.

Applications for construction grants that were submitted previously to NIH must recompete under this RFA.

Domestic, non-Federal, public and private nonprofit institutions, organizations, and associations that conduct or support biomedical/behavioral research are eligible to apply. An institution of emerging excellence must have been so designated under Section 739 of the PHS Act and received a PHS Centers of Excellence grant award in FY 1993 to be eligible to apply. Regional Primate Research Centers are also eligible to apply. An institution may submit only one application in response to this announcement.

The award mechanism will be the construction grant award (C06). Matching funds from non-Federal sources will be required. The FY 1994 appropriation provides \$7 million for this initiative, with up to 25 percent of these funds targeted for institutions of emerging excellence. Up to 50 percent of the necessary and allowable costs of a project may be awarded, or 40 percent of costs proportionate to use in a multipurpose facility, not to exceed \$2 million. Because the nature and scope of the activities proposed in response to this RFA may vary, it is anticipated that four to ten awards at different levels will be made. Prior to grant award, the applicant must provide an assurance of required matching funds and that additional funds will be secured to meet any projected costs in excess of the award amount. Requests of less than \$500,000 will not be accepted. No indirect costs or continuation costs will be awarded.

The letter of intent is to be addressed to: Dr. Charles L. Coulter, Research Facilities Improvement Program, National Center for Research Resources, Westwood Building, Room 8A15, Bethesda, MD 20892, Tel. 301/594-7952.

# Program Announcements

PA-94-027

Title: Educational intervention research on cancer risk reduction for high-risk youth

NCI invites applications for studies to develop, evaluate, and disseminate effective cancer risk reduction methods and materials for high-risk youth. This population is here defined as children or adolescents aged 1 to 18 years who are from low socioeconomic status households or communities. Applications may be submitted by foreign and domestic, non-profit and for-profit organizations. Grant mechanisms include Research Project Grants (R01); and FIRST (R29) awards.

For the purposes of this PA, the following serves as a working definition of high-risk youth: children or adolescents aged 1 to 18 years who are living in low socioeconomic status households or communities. The exact dollar amount of this status is usually determined locally, but may be derived through average income by census tract, high unemployment

by census tract, family eligibility for medicaid, eligibility for school breakfast programs or lunch supplements, or as defined in each local jurisdiction.

This PA has two major research objectives related to the high-risk youth population: 1) to develop and conduct educational interventions to reduce cancer risks associated with tobacco use, poor dietary choices, alcohol use, and early, unprotected sexual activity among high-risk youth; and 2) to design and conduct randomized controlled studies among a representative sample of high-risk youth to determine the knowledge, attitude, and behavioral effects of these educational interventions.

Behaviors related to these risk conditions may lead to cancer in several sites. Tobacco use is associated with cancers of the lung, lip, mouth, tongue, pharynx, larynx, esophagus, bladder, kidney, prostate, pancreas, and uterine cervix. More than a third of all cancers in this country may be related to excessive fat consumption and inadequate fiber consumption. Alcohol consumption increases the risk of cancers of the mouth, pharynx, larynx, and esophagus, particularly when combined with smoking. Unprotected sexual activity has been linked to Burkitt's lymphoma (Epstein-Barr virus), cancer of the uterine cervix (herpes simplex type 2 and human papilloma virus), liver cancer (hepatitis B virus), as well as non-Hodgkin's lymphoma and other cancers associated with the AIDS virus.

Interventions should be based on appropriate behavioral, developmental, and educational scientific theories. They should also be built on the results of previous strategies shown to be efficacious in changing risk factors related to knowledge, attitudes, and behaviors, especially in populations of adolescents. Intervention sites may include community health centers, the juvenile justice system, community youth organizations, or schools. Investigators will be required to give full details of how they intend to accomplish their evaluation, and explain how they will recruit and track what is likely to be a hard-toreach population. Interventions should use a variety of culturally sensitive approaches rather than a single approach, and should be adapted to the special needs of high-risk youth to provide them with skills to make their own decisions to refrain from unhealthy behaviors in spite of peer, advertising, and other pressures endemic to their social environment.

Projects will consist of intervening and measuring change in a sample drawn from a population of 1 to 18 year olds shown to be of low socioeconomic or

other high-risk status by the investigator. Projects will usually include pilot testing survey instruments and techniques for feasibility and acceptability, validating instruments, assessing participation and adherence rates, and adapting materials to cultural sensitivities. Investigators may develop their own, or select from or adapt existing materials or strategies that have been shown to be effective in reducing cancer risks.

Inquiries: Dr. D. Michael Anderson, Div. of Cancer Prevention and Control, NCI, Executive Plaza North Rm 232, Bethesda, MD 20892-4200, Tel. 301/496-8584.

#### PA-94-025

Title: Postdoctoral training in alternative medicine Application Receipt Dates: April 5, Aug. 5, Dec. 5

The Office of Alternative Medicine is planning to fund, through the various Institutes at NIH, individual postdoctoral training awards for FY 94 using the National Research Service Award mechanism. The purpose is to provide a cadre of investigators capable of conducting systematic studies on safety, efficacy, cost-effectiveness, or mechanisms of action of unconventional methods for treating major diseases and promoting well-being. This training is expected to attract postdoctoral candidates who are in the early stages of their careers. They will have obtained expertise in conventional research methodology and some familiarity with/or interest in alternative medical procedures. Prospective trainees will be expected to form an alliance with established researchers to provide a mutual learning experience.

This program announcement on alternative medicine is an abbreviation of a larger, NIH-wide PA on NRSA Individual Postdoctoral Fellows, which should be requested from the contact person listed.

Individuals must be citizens or noncitizen US nationals, or permanent residents. Prior to beginning the award the applicant must have received a PhD, MD, DO, DDS, DVM, OD, DPM, ScD, EngD, Dr. PH, DNS, DPharm, DSW, or Psy. or equivalent doctoral degree from an accredited domestic or foreign institution.

Before submitting a fellowship application, the applicant must arrange for appointment to an appropriate, accredited university, hospital, or other institution with facilities including staff for postdoctoral training. This may include institutions that train in areas outside conventional medicine such as acupuncture or chiropractic. The candidate should be accepted by a sponsor who will actively supervise

the training. The sponsor should have research experience in clinical medicine and/or basic preclinical research along with an involvement in the evaluation of alternative medicine. Thus, the sponsor should be qualified to supervise in the application of rigorous study design to the assessment of individual alternative therapies. Because of the novelty of some procedures, it is recognized that the sponsor may not have reached the level of "senior" investigator in a particular field of alternative medicine.

Applicants proposing training at their doctorate institution or at the institution where they have been training for more than a year must document thoroughly the opportunity for new training experiences that would increase their scientific background relating to alternative medicine.

Individuals may request up to 3 years of aggregate NRSA support at the postdoctoral level. The stipend level for the first year of NRSA support is determined by the number of years of relevant postdoctoral experience at the time the award is issued. The range of support is from \$18,600 (less than I full year of experience) to \$32,300 (7 or more years of experience). Relevant experience includes research experience, teaching, internship, residency, and clinical duties.

It is expected that four to six awards in Alternative Medicine will be made in FY 1994.

Unconventional practices include medical interventions that are not widely taught at medical schools or are not generally available at hospitals within the US. For the most part, such treatments are not reimbursable by third party (insurance companies) payers. Examples of areas of interest include, but are not limited to: acupuncture; homeopathy; structural manipulation including chiropractic/massage; visual imagery, relaxation techniques, meditation, herbal therapies, or diet and life style. The Office is especially interested in alternative procedures in the treatment of life threatening diseases, e.g., women's breast cancer or AIDS-HIV and the subsequent impact on either/and: a) course of disease; b) wellness/quality of life/ prevention; c) statistical/population disease trends d) basic biological systems. However, any particular health problem such as arthritis, depression, drug or alcohol addiction, or heart disease is acceptable.

Inquiries: Dr. John Spencer, Office of Alternative Medicine, NIH, 6120 Executive Blvd, Suite 450, Rockville, MD 20892-9904, Tel. 301/402-4333, FAX 301/402-4741.