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Breast Cancer Action Plan Calls For More Federal Coordination, Patient Participation

The National Action Plan on Breast Cancer developed as a result of last December's conference calls for federal coordination of breast cancer research and education, patient and consumer participation in cancer control, multidisciplinary and translational research and research training, funding for biological materials banks, wider availability of clinical trials, and expansion of prevention and control and psychosocial research.

The plan was developed following a conference convened by HHS Secretary Donna Shalala as a result of lobbying by the National Breast Cancer Coalition (**The Cancer Letter**, Jan. 7).

Other recommendations in the plan include increased participation by breast cancer advocacy groups in health policy decisions, the creation of a breast cancer study section in NIH, and development of safeguards to protect the rights of patients with the breast cancer susceptibility gene.

The introduction describes the plan as a "blueprint, highlighting opportunities to advance and apply knowledge about the causes, diagnosis, prevention, treatment, and ultimate eradication of breast cancer.... It is an operational strategy, setting into motion a dynamic process of sustained collaboration among many involved groups."

HHS officials said the plan was expected to be presented to President Clinton before April 1. A draft of the document was obtained by **The Cancer Letter**.

(Continued to page 2)

In Brief

Baker Leaves Wayne State To Take Job As Deputy Director, UM Cancer Center

LAURENCE BAKER has been appointed deputy director of the Univ. of Michigan Comprehensive Cancer Center and associate chief for the Div. of Hematology-Oncology at Univ. of Michigan Medical Center. For the past seven years, Baker has been director of the Wayne State Univ. Meyer L. Prentis Comprehensive Cancer Center. **Max Wicha** is director of the UM cancer center. Baker said he hoped to attract a number of clinicians to UM "who will focus their efforts on diagnosing and treating the more common cancers such as breast, colon and lung, and work within existing UM research teams." He will also serve as associate director for clinical research at the cancer center. . . . **RAPHAEL POLLOCK** has been named chairman of the Dept. of Surgical Oncology at the Univ. of Texas M.D. Anderson Cancer Center. Pollock, former deputy chairman of research in the surgical oncology department, joined the center in 1984.

Action Plan: More Research, Training, Communication

(Continued from page 1)

Following are excerpts from the Proceedings, Secretary's Conference to Establish a National Action Plan on Breast Cancer:

I. Health Care

Effective health care delivery is critical to reducing morbidity and mortality from breast cancer. In turn, the health care delivery system depends on the effective dissemination of information about breast health and breast care. Responsibility for breast health services is shared by a wide range of participants including consumers, providers, patients, and educators, as well as industry, the media, and the research community.

A. Improve access to and utilization of breast health services.

•Mandate public health agencies at all levels to provide all women with essential breast health services through service as system providers, coalition builders, data collectors, quality assurance professionals, public educators, health care provider educators, and community organizers.

•Act immediately to establish breast health services as a priority in all relevant programs funded by the federal government. Foster partnerships between federal agencies and the private sector.

•Summarize, disseminate, and implement proven strategies for improving access to and use of breast health care, such as providing vouchers for transportation...and using mobile systems.

•Encourage a pyramid system of health care delivery in which physicians lead a collaborative team that gives qualified nurses, other health care professionals, community outreach workers, advocacy groups, and support groups a prominent role in providing care.

•Use community-based organizations and outreach workers as lay advisors, patient advocates, disseminators, and interpreters of breast health information.

•Require federally-funded hospitals and health care centers to screen all women who enter the health care delivery system, and for whom guidelines recommend regular mammography screening, as soon as possible if they have not already received such services, and provide necessary and appropriate follow-up.

•Make clinical breast exams a part of every general physical examination conducted by qualified health care providers.

B. Improve coordination and information management among providers, patients, consumers, organizations, scientists, the media, and other involved groups to disseminate information on breast health and breast health services.

•Use the full range of electronic media, print media, consumer-oriented publications, and interactive multimedia approaches to disseminate research findings to scientists and the public and to inform health care providers and consumers about new scientific knowledge....

•Coordinate breast health educational programs among federal, private, and voluntary agencies to minimize redundancies and deficiencies in programs and conflicts in messages. Include consumers in the process.

•Provide incentives for employers and schools to participate in comprehensive, on-site breast health programs.

•Develop mechanisms for the centralized collection and distribution of existing and available consumer-oriented information on breast cancer....

C. Increase participation of underserved and at-risk populations in breast cancer programs related to risk factors, early detection, diagnosis, treatment.

•Involve organizations and individuals that have direct access to and a unique understanding of under-represented and high-risk population groups....

•Develop and disseminate information on breast health care tailored to cultural, educational, and psychosocial characteristics of women and their families.

•Increase the number and use of culturally-sensitive, large-scale programs among minorities, such as NCI's Cancer Information Service and Centers for Disease Control and Prevention (CDC) community programs....

•Provide for funding of mobile mammography units to increase access to screening among rural and working women.

•Establish community-based comprehensive school health programs to reach young women....

•Provide financial and technical support to local community-based programs that target low-utilization groups to assist in program evaluation and expansion, and to coordinate with program planners.

D. Ensure that research results relevant to breast cancer reach community health care providers, patients, consumers, the elderly, and the general public in a timely fashion.

•Communicate clinical research results to the in-

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volved community, immediate family members, significant others, and clinical trial participants once valid results have been confirmed.

•Establish a registry of ongoing and published clinical trials that is accessible to the public.

•Disseminate and make widely available information on breast cancer research in forms suitable for different audiences (e.g., consumers, providers, and payers)....

E. Establish public and private partnerships to enhance breast health education.

•Use multiorganization panels, programs, and forums to extend the scope, impact, and credibility of breast health education programs. Involve consumers at all levels in this effort...

II. Research

Research on the causes and cures of breast cancer is informed by and relies on a substantial foundation of work on basic cellular mechanisms and on other diseases. This foundation is multidisciplinary and is supported by all Federal agencies, institutions, and organizations that support and conduct research. New knowledge about the causes, diagnosis, prevention, and treatment of breast cancer is derived from many approaches and is accelerated through communication about promising areas of exploration and discovery. The following section addresses key objectives in basic, clinical, and epidemiologic research on breast cancer including (1) ensuring that such research addresses the most promising areas of opportunity; (2) sustaining the growth of investigator-initiated studies; (3) attracting, training, and retaining a qualified and diverse body of research investigators; and (4) overcoming barriers to the conduct of research related to breast cancer. The rapid translation of knowledge gained from such research into clinical practice is critical to ensuring that there are practical benefits for patients.

A. Support collaborative multidisciplinary research related to breast cancer.

•Identify and foster promising new areas of basic research through interagency, interdisciplinary, and private- and public-sector collaboration.

•Facilitate collaboration among basic, clinical, behavioral, epidemiologic, and health services scientists across disciplines; among affected consumers; and among university, clinical cooperative group, federal, and industrial investigators.

•Organize and support multidisciplinary research and collaborative efforts, using a wide range of mechanisms which maximize individual and group efforts. Adapt and/or expand innovative models such as the SPORE mechanism. Increase the amount of discretionary funds provided through the SPORE program and develop methods to provide similar discretionary funds outside the SPORE program.

B. Establish comprehensive patient data registries and materials banks as research tools.

•Convene a group consisting of clinicians, basic and clinical research scientists, industrial representatives, representatives of the health care industry, consumers, patients, and federal agency representatives to develop and define requirements for national resource banks for biological materials relevant to breast cancer. The materials banks should: 1) continuously collect and make available paraffin embedded and fresh frozen samples of malignant and nonmalignant tissues as well as other specimens—such as serum, urine, and DNA—from women at risk, women diagnosed as having breast cancer, and unaffected women, as requested; 2) ensure access to and the availability of specimens to diverse investigators through a peer review mechanism; and 3) provide data regarding the source of the specimens, such as patients' family medical history, occupational and epidemiologic information, and clinical results. Reports and plans should be submitted to the HHS Secretary on the establishment of these banks with initiation targeted for fiscal year 1995.

•Establish new, comprehensive registries of patient data that are centralized and easily accessible....

C. Increase opportunities for research training in fields related to breast cancer.

•Expand and provide diverse opportunities for interdisciplinary research training through such programs as the National Research Service Award, clinical investigator career development awards, and Minority Investigator Administrative Supplements.

•Support researchers and other professionals who wish to spend time in cross-disciplinary sabbaticals in research related to breast cancer.

•Revise the research training guidelines to allow support for 2 additional years of training for postdoctoral fellows who agree to pursue research related to breast cancer.

•Provide for debt forgiveness for physicians, nurses, and others (e.g., doctoral candidates) who have completed 2 years of research training and who agree to devote a minimum of 2 years to research related to breast cancer.

•Support re-entry programs for scientists who have spent periods of time away from research....

D. Expand the scope and breadth of biomedical and behavioral research activities related to breast cancer.

•Continue support for and increase the number of unsolicited meritorious investigator-initiated research grants.

•Support health services research, the development of outcome data, and studies that can determine racial/ethnic and subgroup differences.

•Increase support for research on alternative medicine and therapies.

•Extend throughout the federal government opportunities for support of investigator-initiated research on

breast cancer. For example, continue support for the Dept. of Defense breast cancer research program administered by the Army under the strategy recommended by the Institute of Medicine. This program has attracted 2,400 new proposals for breast cancer research, many from investigators who were not previously involved in breast cancer research.

•Conduct studies of the relationships among nutrition, exercise, and endogenous/exogenous hormone levels. Explore the following topics: the improved measurement of hormones at the tissue level; hormone metabolism; and differences across age groups.

•Conduct investigations of environmental influences on breast cancer and on the influences of compounds that have been shown to possess estrogenic properties on the etiology and incidence of breast cancer. Enlist representatives in public and private partnerships from industry, regulatory authorities, the scientific community, and consumers in identifying strategies of research aimed at the reduction of carcinogenic exposures, and in assessing and identifying appropriate control strategies, including setting standards, labelling, controlling, and phasing out.

•Conduct clinical research on the hormonal treatment of menopausal symptoms that result from breast cancer treatment, including research on controlling the health effects of early menopause in young women being treated for breast cancer.

•Support behavioral studies on the experiences of persons living with breast cancer, particularly their strengths and coping mechanisms as well as their stresses. Support behavioral research relating to treatment effectiveness; study the role of psychological factors in survival.

•Investigate psychosocial barriers to participation in breast cancer research studies, such as professional staff's and patients' attitudes and cultural and lifestyle factors, as well as identify strategies to overcome these barriers....

E. Provide adequate resources and mechanisms to speed the translation from the laboratory to the clinic of new therapeutic opportunities.

•Increase efforts to speed the translation of basic research findings into clinical applications wherever possible. Develop partnerships with industry employing such models as the NIH Cooperative Research and Development Programs Agreement. Review the reasonable pricing clause in relation to CRADAs, as they impact the flow of industrial funds into clinical research and, thus, affect collaborations.

•Address the issue of liability as an impediment to industrial participation in clinical studies.

•Convene a task force on translational research related to breast cancer to identify promising new areas of basic research and actions necessary for successful translation. and to identify responsibilities for recommended actions.

•Extend the "orphan drug act" to new breast cancer therapies and technologies.

F. Conduct basic, translational, clinical, and health services research to improve breast cancer detection, treatment, and monitoring.

•Establish a breast cancer study section with consumer representation focused on translational research studies.

•Identify, study, and use biomarkers for detection and/or prognostic indicators for breast cancer. For example:

Conduct translational research and use centralized multidisciplinary decision-making to rapidly define and bring promising biomarkers and prognostic indicators into clinical trials.

Conduct research to provide an understanding of the development of breast cancer in the majority of women who have no known risk factors. Employ these new detection biomarkers to define groups at risk for participation in new screening trials.

Target and expand both translational and clinical trials of new therapeutic opportunities including novel chemotherapeutic and hormonal agents, vaccines, gene therapy, anti-angiogenesis and antimetastatic strategies, and anti-growth factor approaches.

Define subsets of patients by potential for recurrence of breast cancer and select therapeutic approaches based on prognostic indicators developed from translational and clinical research.

Confine the use of putative biomarkers for detection and prognostic indicators to the translational and clinical research settings until their utility has been scientifically proven to apply to decisions regarding standard care.

•Increase research on molecular genetics targeted at defining breast cancer susceptibility gene(s). For example:

Develop sensitive, specific, and inexpensive tests for the gene(s).

Conduct prospective research regarding the psychosocial, quality of life, and ethical ramifications of genetic testing as such gene(s) are identified.

Conduct basic and translational research using existing and planned data banks and tissue, fluid, and DNA banks from carriers and relatives of carriers to detect new biomarkers and predictors for the development of breast cancer. Extend this research to members of the general population who do not have a genetic history of breast cancer.

•Develop better methods of breast cancer detection. For example:

Develop a system to ensure communication between those who refer patients for detection procedures and those who provide the final diagnosis.

Support research to determine appropriate interventions for women at high risk of breast cancer.

•Conduct clinical research on early detection of breast cancer, including continued analysis of follow-up

data from screening trials done to date. Clarify the efficacy of mammography screening for women ages 40 to 49 and women over 75 years of age.

G. Make clinical trials more widely available to women with breast cancer and women who are at risk for breast cancer.

•Conduct research to determine optimal methods and/or incentives (1) to facilitate widespread enrollment in clinical trials and (2) to improve compliance once enrolled. Determine ways to incorporate safeguards to ensure the anonymity/confidentiality of women enrolled in breast cancer studies.

•Establish a mechanism of outreach to ensure that all women have access, within a reasonable geographic area, to centers conducting approved clinical research. Include outreach to areas geographically distant from research centers so that all women choosing to participate in the most promising clinical trials can do so more easily. Include the Medicare and Medicaid populations.

•Redefine quality of care to include participation in a peer-reviewed and approved clinical research trial. Develop a mechanism to offer preferential coverage for therapies and diagnostic methods offered through clinical trials or for those proven effective in peer-reviewed and approved clinical trials....

•Involve consumers, especially from populations historically under-represented in clinical trials, in the design, planning, and evaluation of clinical investigations.

H. Support research on the prevention and causes of breast cancer.

•Target and expand basic and clinical studies of key prevention opportunities, including prevention research (exploratory studies as well as studies based on large-scale populations), specific studies of prevention by hormonal modulation, and chemoprevention.

•Increase funding for primary prevention research, including multi-site and/or large-scale population-based trials.

I. Extend the scope, depth, and applications of quality of life and psychosocial research related to breast cancer.

•Conduct research on end-stage disease including psychosocial factors and questions of quality of life, supportive care, when to stop care, and how to deal realistically with incipient death.

•Support studies on consumer decision-making and the influences that affect women's use of breast health care services....

•Incorporate questions related to psychosocial factors and quality of life issues prospectively in treatment and follow-up studies.

•Design behavioral research to develop, test and incorporate psychosocial interventions based on socioeconomic variables and psychosocial needs (e.g., race, culture, location, income, and stage of life).

J. Support culturally-sensitive researchers and research programs related to breast cancer.

•Expand support for studies on breast cancer in special populations (e.g., minorities, young women, older women, women in low socioeconomic status groups, and lesbians).

III. Policy

Many issues related to breast cancer require policy decisions to mandate necessary changes. Policies of government agencies are one key focus, but policy changes in all the organizations having a role in breast health are also important. The following policy actions are proposed to facilitate changes in approaches to breast cancer.

A. Implement a comprehensive plan to address the needs of individuals carrying breast cancer susceptibility gene(s).

•Implement safeguards and standards to prevent uncontrolled use of these new genetic testing technologies.

•Develop and enact legislation to ensure the confidentiality of the patient's genotype.

•Create a task force on safeguards and standards with participation from patients and their advocates, geneticists, physicians, consumers, as well as genetic counselors.

B. Increase participation of breast cancer advocacy groups in health policy decision-making.

•Involve advocacy groups and women with breast cancer in setting research priorities, in evaluation, and in patient education. Ensure consumer input at all levels in the development of public health programs, research studies, and clinical trials.

•Exempt the Public Health Service from Office of Management and Budget regulations regarding consumer research to allow ready use of proven social marketing techniques in breast cancer research and education. Use these techniques to determine consumer perspectives.

•Include as part of health care reform proposals mechanisms to obtain consumer feedback on health care delivery for patients with breast cancer and make this information available to consumers. Invite breast cancer advocacy organizations to monitor and report on breast cancer health care.

•Include as part of health care reform provision for: universal access to care and universal coverage (including necessary specialized care), elimination of coverage gaps and restrictions based on pre-existing conditions, costs and treatments arising from participation in peer-reviewed clinical trials, and mammography screening.

C. Eliminate unnecessary confusion about breast health issues.

•Develop scientifically valid national guidelines about prevention, detection, diagnosis, and treatment of breast cancer....

D. Make breast health management, diagnosis, treatment, and follow-up care comprehensive, compassionate, widely-available, and of high quality.

•Initiate intra-governmental and inter-governmental agency coordination of breast cancer research in conjunction with patient and provider education and the provision of patient care.

•Work through state licensure agencies and professional national certifying and accrediting organizations to mandate competence in evaluating signs and symptoms related to breast health.

•Improve mammography systems through the Mammography Quality Standards Act (MQSA).

•Implement final standards of medical quality assurance for mammography. Finalize and implement the regulations for MQSA, recently issued by FDA....

•Provide incentives for development of educational programs for health care providers to incorporate learning objectives and curricula modules on breast health and cancer management.

•Define a range of comprehensive psychosocial services that encompass all the needs of women at risk for breast cancer as well as those women with the disease....

•Expedite review and approval of new drugs and diagnostic tests, devices and technologies related to breast cancer.

•Ensure reimbursement for all costs for patients enrolled in peer-reviewed clinical trials on research related to prevention, screening, diagnosis, and treatment of breast cancer....

E. Develop new and stable sources of funding for health-related research and public health activities.

•Work cooperatively to identify new revenue sources.

F. Develop a mechanism to coordinate the implementation of action steps identified in the Proceedings of the Secretary's Conference to Establish a National Action Plan on Breast Cancer

•Initiate intra- and inter-governmental agency coordination of breast cancer activities, including relevant research, education, and health care delivery activities.

•Establish a national task force that meets periodically to evaluate progress and identify new opportunities in each of the three major areas--health care delivery, research, and policy outlined in the plan.

Tamoxifen Benefits Outweigh Risks, NSABP Study Finds

Breast cancer patients who take tamoxifen have an increased risk of developing endometrial cancer, but the benefits of the drug greatly outweigh the risks, according to data from the National Surgical Adjuvant Breast & Bowel Project study B-14.

The study is to appear in the April 6 issue of the Journal of the National Cancer Institute. NCI officials lifted an embargo on the results early, saying they were concerned that "incomplete data" had appeared in news reports.

Earlier this year, NCI advised the cooperative groups to rewrite informed consent forms for tamoxifen studies, following the deaths of four of the B-14 patients who had contracted endometrial cancer as a result of taking tamoxifen (**The Cancer Letter**, Feb. 25).

B-14, the largest randomized study of tamoxifen, involving more than 4,000 women, found that women who took tamoxifen daily for at least five years had about the same risk of developing endometrial cancer as postmenopausal women taking estrogen. The risk was about one or two cases per 1,000 women per year.

That is two to three times greater than the rate for women with breast cancer not treated with tamoxifen.

Lower Risk Of Breast Cancer Recurrence

However, women who took tamoxifen in the study had a much lower risk of recurrence of breast cancer than those who did not take the drug, reported Bernard Fisher, NSABP chairman, at the Univ. of Pittsburgh.

"The cumulative rate/1,000 of breast cancer recurrence was reduced from 227.8 in the placebo group to 123.5 in the randomized, tamoxifen-treated group; the cumulative rate of cancer in the opposite breast was reduced from 40.5 to 23.5 respectively, in the two groups," Fisher writes. "Thus, there was a benefit in that there were 121.3 fewer breast-related events per 1,000 women. On the other hand, the cumulative rate of endometrial cancer was increased: there were 6.3 events per 1,000 women."

Nevertheless, Fisher writes, "The benefit from tamoxifen is substantially greater than the incidence of endometrial cancer currently being reported; consequently, tamoxifen should continue to be used in the treatment of breast cancer."

There were 25 reported cases of endometrial cancer, including two in the control group and 23 among the women getting tamoxifen. The rate of endometrial cancers in the control group was "unusually low," Fisher and his colleagues write. Using data from the Surveillance, Epidemiology & End Results program, predictions were that nearly 7 endometrial cancers would occur.

Fisher acknowledges that the data have implications for the NSABP's Breast Cancer Prevention Trial testing tamoxifen in healthy women at high risk of breast cancer. However, an analysis using the B-14 endometrial cancer rate compared to

the actual projected risk of breast cancer in the first 8,300 BCPT women enrolled shows that "the risk-benefit analysis for the BCPT continues to favor a benefit." Thus, the prevention trial should continue as planned, Fisher concludes.

In an editorial in the same issue, Michael Friedman, director of NCI's Cancer Therapy Evaluation Program, called for the pursuit of a "broad research agenda," including larger studies to determine whether tamoxifen-induced tumors are more aggressive than naturally-occurring tumors, and whether some patients are more at risk than others.

Poisson's Data Do Not Change Findings

The report includes an "editor's note" acknowledging that the study included information from a Canadian researcher found to have submitted falsified data to a number of NSABP trials. Roger Poisson, of St. Luc Hospital in Montreal, was accused of scientific misconduct by the NIH Office of Research Integrity last year (**The Cancer Letter**, March 18). ORI said it identified 115 instances of data fabrication by Poisson, 35 of which were associated with patients enrolled on study B-14. Altogether, 223 St. Luc's patients were enrolled in B-14.

Fisher said Poisson's data do not alter the findings of the tamoxifen study. "Irrespective of the data provided by St. Luc's, the conclusions remain the same in this paper," he writes.

RFPs Available

RFP NCI-CP-05646-02

Title: Support Services for Studies of Emergent Cancer Issues
Deadline: Approximately May 2

NCI intends to recompete its master agreements in search of additional qualified offerors able to provide support services on emergent cancer issues. MA holders already in the pool need not respond. Contractors selected may be solicited to provide managerial, data collection, and data processing support for epidemiological studies to be designed and executed alone or in collaboration with other research organizations. Tasks may include: study planning and liaison activities, data collection forms design, development of data collection manuals, data abstracting and coding, identification, location and interviewing of study subjects, exposure assessment, quality control, and submission of computerized data and associated reports or deliverables.

Contract specialist: Michael Loewe, RCB NCI, Executive Plaza South Rm 620, Bethesda, MD 20892. Tel. 301/496-8611.

RFP NCI-CM-57207-30

Title: Detailed Drug Evaluation Of Treatment Strategies For Chemotherapeutic Agents
Deadline: Approximately May 20

The Developmental Therapeutics Program of NCI's Div. of Cancer Treatment is seeking a contractor to evaluate compounds for anticancer activity in experimental in vivo tumor models. Studies will focus on agents identified by the program's disease-oriented in vitro drug screen and will employ human tumors growing in immune-deficient (e.g. athymic, SCID) mice. Experiments will be designed and conducted to optimize drug activity and evaluate the drug's therapeutic potential. Some in vivo studies may involve murine tumors growing in pathogen-free immune-competent rodents, and some cell culture support will be required for propagation of selected human tumors.

Pharmaceutical and chemical companies will be excluded from the competition. The organization must be willing to sign a confidentiality of information statement. One incrementally funded contract will be awarded for three years, with two one-year options.

Contract specialist: Elsa Carlton, Treatment Contracts Section, Research Contracts Branch, OAM, NCI, Executive Plaza South, Rm 603, 9000 Rockville Pike, Bethesda, MD 20892, Tel. 301/496-8620.

RFP NCI-CM-47037-09

Title: Minority Adolescent HIV Research; Model For Community-Based Treatment And Prevention
Deadline: Approximately May 27

The Pediatric Branch, Clinical Oncology Program, in NCI's Div. of Cancer Treatment is seeking organizations with the capabilities and facilities to participate in the development of a comprehensive program to study HIV infection in the minority adolescent and pediatric population. The purpose of this contract is to identify, refer, and enroll adolescents into clinical research trials of the Pediatric Branch. This will be achieved through the establishment of comprehensive, coordinated care for HIV-infected adolescents between a community based facility in the District of Columbia and the clinical research programs of the Pediatric Branch, NCI, NIH. The contractor shall provide a minimum of 6 inpatient rooms which provide associated care services in a licensed hospital facility that has been accredited by the Joint Committee for Accreditation of Health Organizations.

Contract specialist: Mary Landi O'Leary, RCB Executive Plaza South Rm 603, Bethesda, MD 20892, Tel. 301/496-8620.

NCI Contract Award

Title: Study of precancerous gastric lesions in relation to stomach cancer in China

Contractor: Beijing Institute for Cancer Research, $151,727.

RFA Available

RFA CA-94-010

Title: **Clinical/Metabolic Studies In Nutrition And Breast Cancer Prevention**

Letter of Intent Receipt Date: April 12

Application Receipt Date: June 9

NCI's Div. of Cancer Prevention and Control invites Interactive Research Project Grants to encourage formal interdisciplinary collaborations through the coordinated submission of related research project applications that share a common research focus relevant to the development and conduct of clinical/metabolic studies for nutrition and breast cancer prevention research and do not require extensive shared physical resources or core functions. A minimum of two independent investigators with related research objectives will be encouraged to submit individual research project grant applications that share a common research focus.

Domestic and foreign organizations are eligible. Approximately $2.5 million in total costs per year for up to four years will be committed. Six to nine awards.

Representative areas of particular interest focus on many basic issues of biological functions and modulating actions of dietary patterns and nutrients that need to be investigated directly in human studies. Another area of interest is the application of innovative research approaches to development and evaluation of specific methodologies for use in human studies to elucidate the mechanisms of action and quantify the role of diet and dietary components in breast cancer prevention and control.

Inquiries: Dr. Carolyn Clifford, DCPC, NCI, Executive Plaza North, Suite 212, Bethesda, MD 20892-6130, Tel: 301/496-8573, FAX: 301/402-0553.

Program Announcements

PAR-94-048

Title: **Small Grants For Therapeutic Clinical Trials Of Malignancies**

Application Receipt Dates: June 1, October 1, February 1

NCI's Div. of Cancer Treatment announces a program to encourage submission of small grant applications for new pilot, phase I, or phase II therapeutic clinical trials of malignancies that take advantage of recent laboratory developments. New and experienced investigators in relevant fields and disciplines (clinical, surgical, and radiation oncology) may apply for small grants to test new treatment strategies or do pilot studies.

Applications may be submitted by foreign and domestic organizations. The NIH small grants (R03) mechanism provides maximum of $50,000 direct costs per year for short-term (up to 2 years) research projects.

The aim of this initiative is to support pilot, phase I, or phase II therapeutic clinical trials of malignancies to move new treatment strategies more rapidly from the laboratory into the clinic. Clinical studies must involve human subjects and be therapeutic in design. The clinical studies must be based on a strong rationale and preclinical data should support the underlying hypotheses. New clinical therapeutic trials employing drugs, biologics, radiation, or surgery whether used as a single agent/modality or in combination are appropriate.

Laboratory studies may also be proposed to conduct pharmacokinetic, pharmacodynamic, and other important correlative studies in the cancer patients receiving therapy. The laboratory studies should be in support of the clinical trial, such that their conduct leads to a greater understanding of the relationship between drug administration and biological changes in patients. Applications will be reviewed by a review group in NCI's Div. of Extramural Activities.

Inquiries: Diane Bronzert or Roy Wu, DCT, NCI, Executive Plaza North Rm 734, Bethesda, MD 20892, Tel: 301/496-8866, FAX: 301/480-4663.

PA-94-050

Title: **Exploratory Grants To Stimulate Correlative Laboratory Studies and Innovative Clinical Trials**

Application Receipt Dates: June 1, Oct. 1, Feb. 1

NCI's Div. of Cancer Treatment invites research grant applications for tightly focused innovative laboratory studies that are related to clinical trials and/or for innovative clinical trials that take advantage of new developments in the laboratory. Applications may be submitted by foreign and domestic, for-profit and non-profit organizations. Applicants may request up to $100,000 per year in direct costs, not including indirect costs for collaborating institutions, if any. Total project period may not exceed two years.

The goal of this initiative is to promote translational and clinical research that may lead to improved treatment results and clinical outcomes. Two types of studies will be supported: 1) development of new therapeutic clinical trials or 2) new correlative studies relevant to clinical trials. Applications should be focused on integrating clinical goals with laboratory research areas.

This PA envisions funding new therapeutic clinical trials that move new treatment strategies more rapidly from the laboratory into the clinic. These clinical studies must involve human subjects, be designed to ultimately improve cancer treatment, and be based on a strong rationale. Furthermore, the underlying hypothesis should be supported by preclinical data.

The second research goal is funding new correlative laboratory studies that are relevant to therapeutic clinical trials. The therapeutic correlates must have a future clinical application such as development of new treatment strategies or identification of patient subsets for specific treatment therapies.

Inquiries: Dr. Roy Wu or Diane Bronzert, DCT, NCI, Executive Plaza North Rm 734, Bethesda, MD 20892, Tel. 301/496-8866, FAX 301/480-4663.