THE CANCER LETTER

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DCPC Advisors Request New Study Section In Prevention And Control Of Chronic Disease

Advisors to NCI's Div. of Cancer Prevention & Control have asked NIH to establish a permanent study section for the review of grant applications in the prevention and control of chronic disease.

The study section that currently reviews most of these grant applications, Behavioral Medicine, lacks expertise in community-based cancer prevention and control research, the DCPC Board of Scientific Counselors said in a resolution and letter to NIH Director Bernadine Healy before she left office.

The resulting low funding rate discourages researchers to seek grant funds, the board said in its resolution. "This situation is slowing discovery in cancer control science and the dissemination of advances in cancer

(Continued to page 2)

In Brief

FASEB Letter Urges Support Of NIH, NSF; Kansas Recruits Experts From Washington State

THIRTY-SEVEN organizations representing research scientists, persons with disease, research institutions, biotechnology companies, and voluntary health organizations have sent a letter to **President Clinton** and Congress in support of basic biomedical research. The Federation of American Societies for Experimental Biology last week said the letter was meant to impress upon Congress and Clinton the importance of basic research and the need for expanding federal support for life sciences research. The letter urged enhanced support for NIH, the National Science Foundation, and other federal agencies for "untargeted, investigator-initiated basic research." . . . **STEPHEN COHEN**, medical oncologist and hematologist in San Antonio, TX, has been elected president of Physicians Who Care, a national organization of physicians who advocate patients' rights. The group is conducting a nationwide petition campaign "to educate the Clinton Administration and Congress that patients' rights and choice must be hallmarks of health care reform," Cohen said. . . . **UNIV. OF KANSAS** Cancer Center has recruited experts in homone-associated cancers, **Jonathan Li** and **Sara Li**, from Washington State Univ. Jonathan Li will direct the center's new Div. of Etiology and Prevention of Hormone-Associated Cancers, and will become a tenured professor at KU Medical Center. Sara Li will become a member of the cancer center and an associate professor. They will bring their current research projects and six researchers. The Freemasons of Kansas, who have donated more than $1.4 million to the center since 1974, made a contribution of $181,000 to the KU Medical Center this year.

DCPC Advisors Seek Study Section In Disease Prevention And Control

(Continued from page 1)

prevention and control to benefit the American public," the resolution said.

NCI and NIH Div. of Research Grants (DRG) staff are scheduled to meet this week to discuss the letter.

"I think we are making progress," DCPC Director Peter Greenwald said to **The Cancer Letter.** "DRG is being most helpful."

DRG may be considering forming a subcommittee of the Behavioral Medicine study section to review prevention and control applications, Greenwald said.

Board members contacted this week said their action to seek a new study section grew out of years of frustration with NIH peer review among cancer prevention and control researchers.

A presentation by DRG staff at the board's meeting last May served to solidify their resolve, board members said (**The Cancer Letter**, May 14). An analysis by DRG staff of DCPC grants submitted to Behavioral Medicine concluded that prevention and control investigators do not resubmit their applications as often as other researchers.

None of 41 DCPC grants submitted over the past year have been funded.

Board members said the problem is not the resubmission rate, but the study section's emphasis on psychology. The experimental design in that field is too rigid for most community-based prevention and control research, the board said.

In the letter to Healy, signed by board chairman Alfred Haynes, the board wrote, "Data provided by DRG staff confirmed our perceptions of specific problems we have observed in the peer review of cancer prevention and control grant applications, especially in reviews conducted by the Behavioral Medicine Review Committee. These include:

▶ "Chartered members of the Committee, which is comprised primarily of physicians and clinical psychologists, exhibit disciplinary bias against: applied population-based research; research that necessarily departs from the methods used in clinical or laboratory experiments; research where the unit of analysis is a group, institution or community rather than the individual; and research that involves greater costs than small-scale laboratory investigations.

▶ "Chartered members of the Committee have limited expertise in chronic disease epidemiology, sociology, anthropology, health education, or population-based behavioral change.

▶ "Chartered members of the Committee include no scientists with significant experience in community-based prevention or screening trials and related methodological issues, such as procedures for minimizing attrition and tracking mobile respondents over time.

▶ "Chartered members of the Committee include no scientists with significant expertise in translating biomarkers of cancer risk into clinical trials in the community.

▶ "Chartered members of the Committee do not evidence understanding of issues involved in designing and conducting research in populations of diverse ethnic and socioeconomic background at the community level.

▶ "Chartered members of the Committee do not demonstrate understanding of institutional and community dynamics affecting the design, delivery, evaluation, and dissemination of cancer prevention and control interventions to the general population.

"In the face of disciplinary bias exhibited by chartered members of the Committee, adding one or two ad hoc members to the Committee for the review of particular projects does not result in adequate peer review of these applications."

The board also said it was concerned that:

▶ DRG staff told the board that cancer investigators should apply for small grants. "This comment appears to reflect the view that DRG staff are more expert than extramural investigators in identifying the studies needed in cancer prevention and control. It also ignores the fact that individuals who have been principal investigators on R01 grants are not eligible for the small grant program."

▶ When the board discussed peer review of complex community trials designed to change behaviors in large populations, "DRG staff said that such research is too complex and should focus on just

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one behavior change at a time."

▶ DRG staff said DCPC had not sent names of individuals qualified to serve as ad hoc members of the study section, but DCPC had in fact submitted a list.

"By the end of this exchange, [the board] was disappointed by the defensiveness and insensitivity of DRG staff to our concerns," the letter continued. "Although we have attempted to work with DRG staff to help resolve these problems, they have yet to acknowledge the existence of any problems with the review process."

The board's resolution requests "a standing committee dedicated to the review of community-based cancer prevention and control research applications." The board also requested data from DRG for the board's October meeting on DCPC grants received and funded for the past three years.

The board's letter continued: "Population-based prevention and control methodologies cross disease-specific disciplines and are not limited to cancer. A standing committee to review chronic disease prevention and control applications would accelerate the translation to community trials of interventions based upon the emerging understanding of molecular mechanisms. Until such a committee is established, we also seek your assistance in implementing the following sequence of interim measures:

"1. When a Standing Committee is to review DCPC grant applications: 1) four or more reviewer reserve members from the list submitted by DCPC staff should be added to the Standing Committee, and 2) DCPC extramural staff should present to the Committee the substance and intent of relevant program announcements before their review commences.

"2. When the volume of DCPC grant applications for any review cycle is not sufficient to warrant constituting an ad hoc Review Committee, review should be deferred for up to two cycles so that they can be reviewed by an ad hoc Committee of peers, or a subsection of an existing committee.

"3. A separate Study Section on Community-Based Disease Prevention and Control should be established on an experimental basis for two years."

Capitol Notes

ACS Asks Senate To Raise Budget For CDC Cancer Prevention Program

The American Cancer Society asked the Senate Health and Human Resources Subcommittee on Aging to authorize the Centers of Disease Control and Prevention breast and cervical cancer prevention program at $200 million.

The House authorized the program at $135 million, and the program's current budget is $72.5 million.

According to ACS, the increase in funding would allow CDC to expand the program to all states. Currently, 36 states participate.

Along with asking for funds, ACS outlined the difficulties experienced by the states that have established breast and cervical cancer registries.

▶ According to CDC's new policy, states are no longer permitted to count donated diagnostic and treatment expenditures as part of the matching funds required for taking part in the program. State health departments provide matching funds on a 1:3 basis, either with finds or in-kind contributions.

"This makes the application process for new states or states wishing to expand their program very difficult, since they must still provide diagnostic and treatment services, but can no longer count them as part of the match," Vicky Rakowski, vice president, cancer control, of the ACS Michigan division, said at the Senate hearing.

"I would urge you to consider amending the statute to allow these contributions to count," Rakowski said.

▶ Another problem is created by a provision prohibiting state health departments from contracting with private sector mammography facilities, Rakowski said.

"It represents a problem with private facilities and private practice OB-GYN's who wish to participate; it limits access, and in turn, undermines the community health infrastructure," she said.

▶ CDC should change its policies to require that mammography services provided under the program comply with the standards that will become effective under the Mammography Quality Standards Act of 1992.

"The intent of MQSA was to establish one uniform national standard for all facilities performing mammography, thereby assuring high quality and avoiding duplicative, unnecessary regulation," Rakowski said. "We do not believe that state inspectors should have to comply with one standard under MQSA, another for CDC of Medicare, and another for an existing state law."

▶ CDC should reexamine the issue of reimbursement of diagnostic and treatment needs determined by the screening process, Rakowski said.

"We are concerned that the long-term approach in this program must examine the issue of payment for services rendered on the front line--that is, reimbursement for screening--without similar resources being made available for critical diagnostic and

treatment needs of women in the program," she said.

Federal funds cannot be used to pay for diagnosis and treatment of the indigent and uninsured, thereby requiring states to depend upon the "good will" contributions of the private sector, Rakowski said.

"A dependable treatment component is essential to the success of any screening program," she said. "While in most communities, this need is met voluntarily by the private sector, this restriction on the use of funds represents a significant barrier to participation for some communities."

Book Makes Case For Reform In Approach To Clinical Research

The study of "whole human beings" is languishing in the U.S. due to a shift in emphasis from patient-oriented research to research at the cellular and molecular level at U.S. medical schools and the National Institutes of Health, according to Edward Ahrens Jr., professor emeritus at Rockefeller Univ.

In a book that has caught the attention of clinical researchers, not in the least because of its startling title, [The Crisis in Clinical Research: Overcoming Institutional Obstacles, (Oxford Univ. Press, 1992)] Ahrens painstakingly documents this shift, outlines the reasons for it, and suggests a multitude of reforms, most of which are controversial.

"The three traditional missions of U.S. medical schools--teaching medical students, providing service to patients, and performing research at the frontier of knowledge--are now seriously out of balance," Ahrens prefaces the book.

A major stumbling block for those who would remedy the situation is terminology. "Basic" and "applied" research are terms that too often are used pejoratively in common parlance, Ahrens writes.

"A plea is made for restricting the term 'basic research' to those investigations undertaken in the spirit of uncertainty, where the exploratory nature of a study is implicit and its outcome is not predictable. What many call basic science departments in U.S. medical schools (such as biochemistry and molecular biology) are more appropriately named "pre-clinical departments" since basic research (undertaken in uncertainty) is just as much the purview of faculty members in the clinical as in the pre-clinical departments."

Ahrens divides clinical research into seven categories:

1. Studies of mechanisms in human disease
2. Studies of management of disease
3. In vitro studies on materials of human origin
4. Animal models of human health or disease
5. Field surveys
6. Development of new technologies
7. Assessment of health care delivery

Mechanistic patient-oriented studies should be termed "Basic patient-oriented research" while management of disease studies should be termed "Applied patient-oriented research," Ahrens writes.

Crisis provides more than enough data and opinion for clinical researchers to study and use in presentations. Here are a few:

▶ The percentage of NIH grant awards to MDs has fallen by 30 percent from 1970 to 1987. However, success rates within each group are nearly the same. Thus, "the widely held perception that MDs wrote less sophisticated and less worthy applications that PhDs is simply wrong." The difference is due to the fact that PhDs outnumber MDs three to one in filing applications.

▶ The funding gap between new grant applications and competing renewal applications continues to widen.

▶ Indirect costs of research awards have risen sevenfold from 1970 to 1988, while the direct costs have risen fourfold.

In the 1950s, Ahrens writes, NIH study section meetings were "intoxicatingly pleasant and instructive.... The funds available to applicants seemed endless, and it was gratifying to be part of a rapidly growing national research enterprise."

The funding squeeze that began in the 1960s changed everything. "As the supply of funds had decreased, demand has increased, and the tenor of peer review, formerly low-keyed and constructive, has become more strident. The atmosphere of study section meetings is less generally educational because its members are so highly specialized. And the basis for decision-making has swung decidedly toward a hard-nosed assessment of the likelihood of successful performance of research protocols and away from a hopeful evaluation of the innovative capabilities of applicants. Sad to say, it has become more and more difficult to recruit experienced working scientists to serve on NIH review committees."

However, the problems are deeper that the supply of money and reviewer recruitment, Ahrens writes. Scientists have been so successful at reproducing themselves that the demand for funds will far outstrip the money available, thus making the odds of gaining a career in research so low that young investigators will turn toward more certain careers. This is already happening in clinical research, many investigators say.

According to Ahrens, the solutions are as follows:

▶ **Training** the physician-scientist: Training opportunities for research-minded MDs do exist, but MDs must be persuaded to undertake careers in patient-oriented research.

Ahrens proposes a "post-postgraduate" program as a pilot study in one medical school. Organized by a team of senior scientists, the program would seek an equal number of recently graduated PhDs and MDs with two years house-staff experience with an interest in research on whole human beings. The participants would "teach each other by working together as partners on research themes" under the supervision of their advisors.

"'Graduation' would occur on completion of research programs deemed by the integrative and reductionist organizers to signify the development of independent researchers who are now qualified to seek and win R01" funds. Tuition would be free and stipends would be compatible with salaries of third-year medical residents. PhDs would not become MDs and MDs would not become PhDs.

The outcome of the program, which could last for up to five years, "would be independent integrative scientists who have learned the enormous benefits of cooperation with a complementary breed of graduate student, and who thereafter would seek and find partners in research, working in tandem and continuing to learn from each other."

▶ **Support** for patient-oriented research needs to be strengthened in U.S. medical schools. "The only solutions that I can see for the future health of medical education are to separate as much as possible the teaching-research function from the service function in U.S. academic health centers and to reduce the number of MDs graduated each year," Ahrens writes. "Then, in schools scaled down in size and streamlined in costs, we must seek a better balance between teaching and research in which each professional group is rewarded fully and appropriately for its special skills.

"However it is attained, collegiality among medical school faculties must be re-established for the sake of students, faculties, and patients. The purposes: protected time for more inspired teaching and cultivation of a spirit of inquiry, distinct from rote learning; protected time for a smaller number of more highly qualified researchers working in all phases of clinical research; and the opportunity for faculties to re-assess their values in regard to reward systems and the reduction of barriers between MDs and PhDs."

▶ **New strategies** at NIH: "NIH is no longer setting the pace in clinical research nationally, or in POR [patient-oriented research] in particular, even though it controls the major share of financial support for those activities. It can reassert this leadership if it gives serious consideration to righting the imbalances that have come to exist in the backing of non-clinical and clinical research extramurally and intramurally.

"To the NIH Director, attention is called to the urgent need for more effective extramural evaluations of all intramural activities, and especially of the bedside research at the Clinical Center; to the eminent desirability of concentrating more on the development of scientific talent and less on protocol-driven research; and to the need to enunciate the understanding of the NIH that the current imbalances between reductionist and integrative research disciplines will be reduced.

"To the directors of the various NIH Institutes and of the Clinical Center, attention is called to the immediate need to set aside funds for training and grants in Basic POR; to the essentiality of committing their bedside research facilities to experimental studies in human subjects that cannot be done elsewhere in the United States; to the eminent wisdom of creating extramural panels to review the quality of the bedside research of each Institute in the Clinical Center; to the advantages of furnishing all Clinical Center resources free of charge to each of the Institutes by pressing Congress for a separate budget line item in support of the Center; and to the wisdom of creating a single agency in charge of [patient-oriented research] at the Clinical Center and all General Clinical Research Centers [GCRCs]...

"To the [Div. of Research Grants], attention is called to the need for a number of re-structurings in its present study sections: more MD members with personal experience in POR and fewer who are out-and-out reductionists, and a stronger focus on innovative research and less on strictly protocolized projects. Above all, attention is called to the essentiality of establishing one or more new study sections for review of POR applications by experts with personal experience in POR."

NCI Advisory Group, Other Cancer Meetings For August, September

Autografting for Chronic Myeloid Leukemia–Aug. 20, Portofino, Italy. Contact Dr. Ann Murphy, AlphaMed Press, 4100 South Kettering Blvd., Dayton, OH 45439.

American Cancer Society National Conference on Breast Cancer–Aug. 26-28, Boston, MA. Contact Andy Cannon, ACS, phone 404/329-7604, fax 404/636-5567.

Oncology Certified Nurse Exam Review–Aug. 27, Dallas, TX. Contact Deb Flanders, program coordinator, Baylor Univ. Medical Center, phone 214/820-2317.

Concurrent Modalities of Cancer Treatment–Sept. 9-11, Dearborn, MI. Contact Dr. Donald Bronn, Michigan Institute for Radiation Oncology, phone 313/338-0300.

Living Fully With Cancer–Sept. 10-11, Houston, TX. Contact Jeff Rasco, MD Anderson Cancer Center, phone 713/792-2222.

Xenogenization of the Cancer Cell: From Basics to the Clinic–Sept. 13-14, Frederick, MD. Contact Margaret Fanning, NCI-Frederick Cancer Research & Development Center, phone 301/846-1089, fax 301/846-5866.

Molecular Mechanisms of Radiation and Chemical Carcinogen-Induced Cell Transformation–Sept. 19-24, Mackinac Island, MI. Contact Dr. J. Justin McCormick, Michigan State Univ., phone 517/353-7785, fax 517/353-9004.

Oncogenes Research and Applications–Sept. 20-22, San Francisco, CA. Contact Cambridge Healthtech Institute, phone 617/487-7989.

Multidrug Resistance and Cancer–Sept. 22-24, San Francisco, CA. Contact Cambridge Healthtech Institute, phone 617/487-7989.

Future Meetings

Toward 2000 IX–Oct. 1-2, Philadelphia, PA. Contact Kathy Smith, Fox Chase Cancer Center, phone 215/728-5358.

Advances in Cancer-Related Anemia–Oct. 28, Philadelphia, PA. Contact Kathy Smith, Fox Chase Cancer Center, phone 215/728-5358.

American Cancer Society National Conference on Clinical Trials–Nov. 3-5, Atlanta, GA. Contact Andy Cannon, ACS, 1599 Clifton Rd NE, Atlanta, GA 30329-4251, phone 404/329-7604.

Pittsburgh Cancer Conference: Breast Cancer Into the 21st Century–Nov. 4-5, Pittsburgh, PA. Contact Univ. of Pittsburgh, Diane Applegate, phone 412/647-8263.

American Geriatrics Society/American Federation for Aging Research Annual Meeting–Nov. 15-19, New Orleans, LA. Contact AGS, phone 212/308-1414.

Pediatric Hematology/Oncology Care–Nov. 18-20, Orlando, FL. Contact Nancy Cowen Pollock, Seminar Coordinator, Florida Assn. of Pediatric Tumor Programs, PO Box 13372, Gainesville, FL 32604-1372, phone 904/375-6848.

NCI-EORTC Symposium on New Drugs in Cancer Therapy--March 15-18, 1994, Amsterdam, The Netherlands. Contact Technical Resources Inc., 800/883-6338.

American Radium Society Annual Meeting–April 22-26, Bermuda. Contact Office of the Secretariat, phone 215/574-3179.

RFAs Available

RFA CA-93-034

Title: **Developmental research in Native Pacific populations**
Letter of Intent Receipt Date: Aug. 18
Application Receipt Date: Oct. 20

The Special Populations Studies Branch of NCI's Div. of Cancer Prevention and Control invites applications for developmental studies that: 1) assess cancer control need, 2) determine barriers to cancer control, and/or 3) validate intervention methods and assessment instruments in native Pacific populations; i.e., American Samoans, Guamanians (Chamorros), Palauians, and Northern Marianians. This initiative will define the cancer prevention and control needs of native Pacific populations and those of similar ancestry located in the Pacific as well as the U.S. mainland.

Applications may be submitted by domestic (including U.S. Territorial possessions) public and private, for-profit and non-profit organizations serving native Pacific populations. Teams of applicants are encouraged. Support will be through the NIH research project grant (R01). Four awards will be made at approximately $300,000 total costs per year. Approximately $1.2 million in total costs per year for three years will be set-aside to fund applications.

Studies conducted under this RFA will seek to define cancer prevention and control needs/services of the native Pacific population segments (Phase I). Studies to test ways in which existing intervention methods can be used or adapted for the target populations (Phase II); or studies of new methods designed to be sensitive to the needs of the target populations (Phase II); or methodologic research on validation of assessment instruments in target populations (Phase II) are eligible for consideration under the RFA. This "developmental cancer control research" (Phase I and Phase II) is absolutely essential to future development of cancer prevention and control research for native Pacific populations.

The following definitions apply for this RFA:

Cancer Control--the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results.

Phases of Cancer Control--Cancer control research studies are classified in the five phases that represent the orderly progression noted in the above definition: (I) Hypothesis development; (II) Intervention methods development and testing; (III) Controlled intervention trials to establish cause and effect relationships; (IV) Research in defined human populations; and (V) Demonstration and implementation studies.

The research of interest in this RFA falls into either Phase I or Phase II studies. Hypothesis development (Phase I) studies should focus on the assessment of cancer prevention and control needs in communities or organizations within native Pacific populations or studies that identify barriers to cancer prevention and control within these indigenous populations. Methods development and testing studies, Phase II, should focus on: 1) validating the use of existing intervention methods (e.g., dietary modification, health services, tobacco cessation) applied in the target populations described above; 2) developing and pilot testing unique methods that are sensitive to the needs of the target populations described above; or 3) developing and validating assessment instruments to measure the cancer control related needs of the target populations or for use in evaluating the effectiveness of intervention methods in the target populations.

Inquiries: George A. Alexander, M.D., Div. of Cancer Prevention and Control, NCI, Executive Plaza North Rm 240, 6130 Executive Blvd., Bethesda, MD 20892-4200, Tel. 301/496-8589, Fax. 301/496-8675.

RFA HS-94-002

Title: **Medical treatment effectiveness research--PORT-IIs**
Letter of Intent Receipt Date: Oct. 1
Application Receipt Date: Nov. 16

This announcement solicits applications to conduct innovative and timely research that will provide convincing evidence for or against the effectiveness and cost

effectiveness of alternative clinical interventions for the prevention, diagnosis, treatment, and management of common clinical conditions. The Agency for Health Care Policy and Research (AHCPR) developed this solicitation as part of the Medical Treatment Effectiveness Program (MEDTEP). These awards will constitute a new generation of MEDTEP research and an extension of work carried out by AHCPR's Patient Outcomes Research Teams (PORTs).

Applications may be submitted by domestic and foreign non-profit organizations, public and private.

This RFA will use the research project grant (R01) mechanism. Total project period may not exceed five years. While grants under this solicitation may vary in cost, most individual projects are expected to request less than $1 million total direct costs per year. Earliest award date will be July 1, 1994. The AHCPR expects to award up to $7 million in FY 1994 to support the first year of 5 to 10 studies.

PORT-IIs will focus on the establishment of direct linkages between practice and outcomes and on research methods that facilitate direct comparisons of alternative clinical strategies. They should start with carefully formulated research questions and employ research strategies tailored to the selected condition and the population at risk in order to ascertain convincingly and efficiently which clinical strategies lead to the desired outcomes.

AHCPR's Medical Treatment Effectiveness Program is concerned with enhancing the effectiveness, cost effectiveness, and appropriateness of health care. "Effectiveness," as distinct from "efficacy," refers to the outcomes experienced by or observed in patients in routine clinical practice.

Typical "efficacy" studies, because their results have limited generalizability, are not responsive to this RFA. The RFA does, however, include clinical trials that are designed to answer effectiveness questions, i.e., questions about outcomes in persons who are representative of those with the condition that is being studied.

In assessing effectiveness, cost effectiveness, and appropriateness, investigators are encouraged to measure outcomes that emphasize the patient's perspective and to consider how patient preferences influence evaluations of the outcomes.

This RFA accommodates an extremely wide range of clinical subjects. Greater importance will be placed on questions with significant potential to improve outcomes and/or decrease costs. The formulation of the problem should reflect understanding of the issues regarding clinical decisionmaking and the translation of findings into clinical practice. The important questions about outcomes should be answerable within the proposed grant period.

Most PORT-II studies will focus on a particular condition or technology. This includes conditions and technologies that are significant in the Medicare population, adults under age 65, children, or adolescents. It includes well-defined diseases as well as symptoms and conditions (e.g., headache, fatigue, obesity). While acute or chronic conditions may be selected, the AHCPR is especially interested in studies of chronic problems and those treated in ambulatory settings. The selected condition must have all of the following characteristics: high incidence or prevalence in the general population or in major population subgroups; controversy or open questions over the effectiveness and relative effectiveness of available clinical strategies; and high costs.

PORT-IIs are expected to compare two or more distinctly different clinical approaches to the prevention, diagnosis, treatment, management, or rehabilitation of common clinical conditions, e.g., comparisons of medical vs. surgical treatment, psychotherapy vs. pharmacotherapy; and care prescribed or provided by different kinds of health care professionals.

Methods. Investigators are encouraged to design new research strategies, to use new combinations of methods, or to tailor existing methods to their research question(s) so that convincing evidence will be obtained for, or against, the effectiveness of alternative clinical interventions. Research methods that can be employed include, but are not limited to, quasi-experimental designs, case-control studies, cohort studies, effectiveness trials, meta-analyses, cost-effectiveness analyses, decision modeling, and combinations of these. Sources of data can include: new, established, or adapted surveys of patients and providers; clinical registries; and clinical records from practice-based networks, health maintenance organizations, and other health care providers.

Project Organization. To adequately address the clinical and non-clinical dimensions of effectiveness questions, most studies will require multidisciplinary research teams. It is expected that the team include at least one individual who is actively involved in the type(s) of patient care central to the study and who contributes understanding of how and why clinical decisions are made in routine clinical practice.

Inquiries: Richard Greene, MD, PhD, Director, Center for Medical Effectiveness Research, Agency for Health Care Policy and Research, 2101 East Jefferson St., Rockville, MD 20852, Tel. 301/594-1485.

RFA CA/HD-93-033

Title: **Rehabilitation and psychosocial research in younger women with breast cancer**

Letter of Intent Receipt Date: Aug. 31

Application Receipt Date: Nov. 9

NCI's Div. of Cancer Prevention & Control and the National Center for Medical Rehabilitation Research, National Institute of Child Health & Human Development invite investigator initiated grant applications for research directed at decreasing the medical and psychological morbidity and disability associated with breast cancer diagnosis and treatment in younger women. Applications must develop and test interventions that address health issues, psychosocial problems, and potential disability faced by women diagnosed with breast cancer during early adult life.

Domestic and foreign organizations are eligible to apply. Applications from minority individuals and women are encouraged. NIH R01 grant will be used. Award date is July 1, 1994. Size of award may vary. Direct costs per award will vary from $100,000 to $400,000. Total costs of $2.4 million per year for four years will be committed to fund applications. Four to seven awards will be made.

Objectives are to 1) identify and describe the medical, psychosocial, and disability-related sequelae of breast cancer diagnosis and treatment in younger women and 2) develop and test interventions directed at the specific problems associated with breast cancer diagnosis and treatment in this age group. Projects will develop, implement, and evaluate interventions directed at problems including 1) medical sequelae of therapy, 2) body image, sexuality, and

reproductive issues, 3) interpersonal and family relationships, 4) concrete needs, 5) education, career development/advancement, employment and insurance, 6) living with medical uncertainty, 7) special needs of younger patients during periods of progressive disease and/or terminal care, or 8) the impact of ethnic and cultural factors on issues listed above. Younger women are defined by chronologic age (<50 years) or by menopausal status (pre- and/or peri-menopausal) at diagnosis and study entry, depending on the study intervention. Formal evaluation of efficacy is require, with outcome variables of health related quality of life, domains reflecting medical and psychological morbidity, and relevant aspects of disability, such as personal productivity and community participation. A multidisciplinary research approach is recommended.

Inquiries: Dr. Susan Nayfield, NCI Div. of Cancer Prevention & Control, Executive Plaza North Rm 300-F, Bethesda, MD 20892, Tel. 301/496-8541; or Dr. Louis Quatrano, National Center for Medical Rehabilitation Research, NICHD, 6100 Executive Blvd., Rm 2A-0, Tel. 301/402-2242.

RFA CA-93-035
Title: **Cancer pain management in the outpatient setting**
Letter of Intent Receipt Date: Aug. 12
Application Receipt Date: Nov. 16

NCI invites investigator initiated grant applications for research directed at developing and testing interventions to improve the management of cancer pain outside of the acute care or hospice settings, thereby improving the quality of life of persons with cancer living at home or being managed on an outpatient basis.

Domestic and foreign organizations are eligible to apply. Applications from minority individuals and women are encouraged. NIH R01 grant will be used. Award date is July 1994. total costs of $1.5 million per year for four years will be committed to fund applications. Five awards will be made.

Objectives are to 1) test interventions to promote the ransfer of technology in a variety of health care delivery systems to improve knowledge about pain management for cancer patients living at home, 2) evaluate interventions to address patient and health care provider factors that are barriers to effective transfer and use of state of the art cancer pain management techniques, and 3) improve the acceptability and use of pain control strategies through improved management of the side effects of analgesics and/or modifications of attitudes towards the use of narcotics for pain management.

Research applications should address issues in at least one of the following areas: effect of patient concerns, choices, decision making strategies, and care giver values on effective pain management; impact of systematic use of clinical practice guidelines and documentation of the effect of the intervention on patient care outcomes; overcoming barriers to application of state of the art knowledge about cancer pain management; interface of ethical and legal codes; and the effect of adherence to each on the quality of pain management.

The application should define the study population, identify the problem, describe the intervention, and outline the evaluation plan. The design must include a testable intervention and a systematic plan of evaluation of the intervention using qualitative and quantitative methods.

Inquiries: Claudette Varricchio, NCI, Executive Plaza North Suite 300, Bethesda, MD 20892, Tel. 301/496-8541.

NCI Contract Awards

Title: SBIR--Prototype for pen-based hand-held wireless PC access to PDQ & Cancerlit databases
Contractors: Hilton Systems Inc., Jackson, MS; $49,937. Lexical Technology Inc., Alameda, CA; $49,998.

Letter to the Editor

St. Petersburg Cancer Center Needs Cancer Drugs, Seeks Help

Dear Colleague and Friend:

I appeal to you with a deep hope for the possibility of rendering humanitarian aid to the oldest and one of the greatest oncological centers in Russia, the N.N. Petrov Research Institute of Oncology in St. Petersburg.

Because of the economic situation, the Institute of Oncology is unable to provide its patients with the needed anticancer drugs and equipment. The Institute of Oncology, as other hospitals in St. Petersburg, suffers from the absence of anticancer drugs, including vincristine (Oncovin), dactinomycin (Cosmegen), tamoxifen (Nolvadex), aminoglutethimide (Cytadren), farlutal (5-FU) and megestrol (Megace).

In addition, we have a severe shortage of plastic systems for blood and solutions transfusions. Portable pumps for permanent infusion of solutions are absolutely absent. We also need aerosol inhalators.

Not only adult cancer patients, but also children who are treated at the Institute of Oncology suffer from these shortages of drugs and equipment.

It is understandable that cancer patients connect their hopes for recovery with the Department of Chemotherapy. Therefore, it is up to me, head of that department, to appeal to you for help.

To our regret, we have not been receiving U.S. drugs and equipment through humanitarian aid programs. We will be very grateful to you if you could find a way to respond to our appeal. I understand that anticancer drugs are very expensive and it causes great difficulty to provide our Institute with them.

To my mind, the solution is to send us the drugs which are nearing the end of their shelf life and which may be hardly used in hospitals in the U.S. We can use them very quickly.

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