THE CANCER LETTER
RESEARCH
EDUCATION
CONTROL

Vol. 4 No. 44
Nov. 3, 1978

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Subscription $100 per year

BCDDP FOLLOWUP TO COST $1.6 MILLION ANNUALLY FOR FIVE YEARS OKAYED; LIMITED TO 59,000 WOMEN

The Cancer Control & Rehabilitation Advisory Committee last week approved a plan to follow 59,000 participants in the Breast Cancer Detection Demonstration Program for at least five years. The study will cost $1.6 million a year.

Followup of screenees in the controversial program was recommended both by the Consensus Panel, which examined the variety of issues in-

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In Brief

NCAB TO HEAR REPORT ON TREATMENT PROGRAMS, DISCUSS HOGNESS PLAN FOR NEW TYPE OF REVIEW

NATIONAL CANCER Advisory Board's November meeting has been cut back to one day, Nov. 20. The Board's November meetings are limited to program review, and this time it will hear reports on Div. of Cancer Treatment programs. The Board also will discuss the suggestion by former member David Hogness to establish a new review mechanism to analyze research on fundamental biological processes to speed development of new relevant areas of research (*The Cancer Letter*, July 14). . . . **LEWIS THOMAS**, president of Memorial Sloan-Kettering Cancer Center, and George Hitchings, director of Burroughs Wellcome Co., have been selected for the annual Pap Awards presented by the Papanicolaou Cancer Research Institute. . . . **CANCER RESEARCH** center at Boston Univ. has been named the Hubert H. Humphrey Cancer Research Center. Sidney Cooperband is director of the center, which has a budget of about $4 million a year. . . . **"MANY OF US** went to the Cancer Congress in Buenos Aires with some skepticism that it would be successful," NCI Director Arthur Upton told the President's Cancer Panel. "We were pleasantly surprised. It was well organized. There were many young people among the participants. There was an enormous appreciation by our Latin American colleagues that the Congress was being held in Latin America." . . . **"COUNTER CONGRESS"** held in Paris by scientists who were boycotting the Argentina meeting in protest over human rights violations drew a small turnout of 100-200. U.S. participants included Bruce Chabner, Leonard Hertzenberg, Henry Kaplan, Frank Lilly, Henry Rappaport, and William Terry. . . . **NEW PUBLICATIONS**: "Asbestos: An Information Resource," a 192-page monograph prepared by Stanford Research Institute under contract with NCI. It presents evidence of the carcinogenicity of asbestos, examines possible sources of exposure, describes what can be done to protect workers and the public from effects of exposure. Available free from NCI's Office of Cancer Communications, Bethesda, Md. 20014. Also, a new UICC publication, "Public Education About Cancer: Recent Research and Current Programs." Available for 8 Swiss francs from Managing Editor, UICC, 3 rue du Conseil-General, CH-1205, Geneva, Switzerland.

DECISION DELAYED ON NEW CLINICAL TRIALS TO STUDY MAMMOGRAPHY EFFECTS

(Continued from page 1)

volved in mammography screening, and the Beahrs Working Group, established by NCI to review the BCDDP projects.

A total of 280,000 women are participating in the program, but the followup will be limited to those in which cancer was found (4,500 estimated); those with abnormalities which were found benign by biopsy (17,500); 22,000 normal controls; and 15,000 for whom biopsies were recommended but were not performed.

The followup plan was developed by a committee chaired by Larry Baker and Gerald Metter. Other committee members were Thomas Carlile, George Foradori, Robert Hoover and Becie Jones.

The committee report commented that the followup will "provide the opportunity to test hypotheses in detection, etiology, and natural history of breast disease. Carefully designed epidemiologic followup studies on the risks associated with mammographic or thermographic patterns or pathology subtypes can be carried out. For example, morbidity and mortality endpoints may be used to determine estimates of risk as well as to provide detailed information on the biology or natural history of breast disease for the following groups in a screened population:

"A. Cancers detected by modalities within the screening program.

"B. Cancers in BCDDP participants not detected by the screening program.

"C. A screened population with biopsies recommended but not performed.

"D. A screened population with biopsies performed but not recommended.

"E. Specific pathological subtypes of cancer with emphasis on carcinoma in situ and invasive carcinoma less than one centimeter in diameter.

"F. Pathological subtypes of ductal atypia and other gradations of benign breast disease.

"G. Screenees with benign breast disease documented by mammography or physical examination only.

"H. Screenees without breast disease as documented by mammography and physical examination over a five year period.

"I. Screenees with specific abnormal mammographic patterns.

"J. Screenees with specific abnormal thermographic patterns.

"K. Screenees with specific demographic risk factors."

The committee report said that, despite the lack of a non-screened comparison group and the self selected nature of the screened population, it felt that it has identified a "broad range of important scientific issues which can be investigated in followup of carefully selected subgroups. The BCDDP population of 280,000 women, intensively screened over a five year period, provides a unique base for studying these issues." The committee recommended that:

A. The cohort of all women having undergone a biopsy whether or not recommended (including those with cancer), controls matched to these women, and those women for whom a biopsy was recommended but not performed should be followed.

B. This followup should be performed annually for five years with an evaluation at the end of four years to decide whether to continue for an additional five years.

C. The subcommittee strongly suggested that plans be formulated to implement this program including the development of a protocol and format for data collection prior to pilot testing.

D. In addition to followup records, it is necessary to provide access to and security of screenee charts by physicians and institutions. Provisions should be made at each project to continue records storage and to provide library or record management support. If records cannot be stored or maintained at the project, it was recommended that a local medical institution or college be funded to provide that service, or that another nearby BCDDP project assume that responsibility. This service should be provided for a minimum of five years from the BCDDP termination date. Ultimate disposition of these charts such as to screenee physicians, health care institutions, a central repository, or destruction should be decided on after further study by NCI.

E. Centralized data management and coordination should be established to support the local library activities by providing forms, direct mailing of program wide forms and questionnaires and computer and analytic support and quality control as needed.

F. NCI should conduct basic studies of morbidity and mortality within the defined population with appropriate quality assurance during the followup period.

G. In addition to the basic analyses, the data set, including both existing data and that collected in the followup be made available for scientific inquiry subject, with appropriate quality assurance, to peer review by a committee whose members are familiar with the BCDDP.

Metter told the CCRAC that the annual cost per project would be about $50,000, including about 45% for overhead, or $30 per screenee. The total of $1.6 million a year includes $350,000 for data management and analysis. The breakdown of personnel cost for each project would be:

Project director (5% of his time), $2,500. Coordinator (100%), $14,000. Clerical (25%), $2,500. Fringe benefits, $2,850. Total personnel costs, $21,850.

Other costs include:

Equipment and maintenance, $1,000. Space rental,

$5,000. Supplies, $4,500. Travel, $2,000. Overhead, $15,500. Total for each project, $49,850.

"These figures may not be firm," CCRAC Chairman William Shingleton commented. "We're being asked to approve the concept, not the details or cost breakdown."

CCRAC member Oliver Beahrs said that the recommendations were consistent with those of the Working Group which he chaired. "I could support these, with the caution that there would be an evaluation after four years to determine if it should continue for another five years."

CCRAC member Kenneth Casebeer brought up the question of whether or not all 280,000 screenees should be included in the followup. "Certain promises were made at the start about followup, perhaps not to the level of a contract," he said.

The Beahrs Group had recommended that all 280,000 women not be followed after completion of the five years of screening, except for the well defined subsamples. "The only justification for followup of the entire group would be a determination that the information obtained could answer questions still outstanding regarding the efficacy of screening for breast cancer," the Beahrs Group report said. "Answers to such questions cannot be derived from BCDDP."

The Baker-Metter committee agreed. "The identified lack of a non-screened comparison group and the self selected nature and size of the BCDDP population prohibits an evaluation of the efficacy of screening or the hazards of radiation," the committee report said. Because of the low level of radiation involved, the number of participants would have to be several times 280,000 in order to determine comparative risks, the Beahrs and Baker-Metter groups agreed.

But some CCRAC members and Div. of Cancer Control & Rehabilitation Director Diane Fink were concerned about any legal or moral obligations to include all 280,000 in any followup studies. "I can't tell you what the representations to screenees were," Fink said. "But we have to take into account this issue. What is our moral obligation?"

Baker pointed out that records and the base line mammograms would be retained on all 280,000 and will be available to their physicians, whether or not they participate in the followup.

The motion to approve the followup concept included a provision that DCCR staff determine what the minimal followup should be on participants not included in the recommended study.

Richard Costlow, chief of DCCR's Detection, Diagnosis, & Pretreatment Evaluation Branch, said he was not prepared to discuss another recommendation of the Beahrs Group, that new clinical trials be established to determine the efficacy of mammography screening for women under age 50. "It seems unlikely that clinical trials could be worked out in detail for funding in FY 1979," Costlow said. Also, similar trials are being developed in Europe and Canada, and Costlow suggested delaying until details on those studies are available.

The Beahrs Group recommended that randomized controlled trials be designated to determine, in addition to the benefit of mammography for women 40-49, the magnitude of benefit and net benefit/risk with use of mammography for screening for both the younger and older age groups; and the effect on benefit from screening of increasing the interval between screening, that is mammographies once every two years instead of annually.

A total of 240,000 women in six study and control groups would be required. The study would compare breast self examination vs. mammography plus physical exam, and breast self exam vs. physical exam only in women 40-49; and mammography plus physical exam vs. physical exam only, and mammography plus physical exam annually vs. biennially in women 50-59. If the full study could not be implemented, the Group recommended that the issue of periodicity be dropped, reducing the number of participants to about 130,000.

CCRAC agreed to delaying further consideration of such clinical trials to a future meeting.

TWO YEAR COP EXTENSION APPROVED; EXPANSION OF PROGRAM NOT RESOLVED

One major issue to be resolved soon by the Div. of Cancer Control & Rehabilitation and its Advisory Committee is whether to proceed with expansion of the Clinical Oncology Program, which presently has programs in seven communities with a total budget approaching $1 million ayear.

When DCCR proposed earlier this year that the program be expanded to another 10 or 15 communities, the CCRAC objected primarily because of possible duplication and overlap with other community related programs.

DCCR staff last week presented CCRAC with documents describing the various accomplishments and efforts under way in the seven existing programs. The staff presentation also summarizes each of the activities which CCRAC members felt might be duplicative of the Clinical Oncology Program, compares them with COP, and concludes that little or no duplication exists and that none of them have the same objectives as COP.

Donald Buell, DCCR program director for clinical oncology, did not ask the committee last week for approval of the expanded program, preferring to give members an opportunity to study his presentations. He did ask for permission to extend the existing programs for two years (they were originally awarded three year contracts, and some will expire next year) and to develop methods to evaluate them. The committee approved that request.

G. Bennett Humphrey, director of the Oklahoma Cancer Center at the Univ. of Oklahoma Health Sci-

ences Center, described accomplishments of the Ada-Shawnee group involved in the Clinical Oncology Program.

The program is designed to demonstrate that community hospitals can provide effective multidisciplinary diagnosis, treatment and rehabilitation services to patients in their own communities. Patient management guidelines have been developed for the evaluation and treatment of the most frequently seen tumors. Referral links to major medical institutions and cancer centers and advanced rehabilitation and continuing care methods have been implemented. Cancer educational activities for community practitioners are also being developed.

"This program appears to have the most clearly documentable direct impact upon patient care and a thorough program area evaluation is needed," Buell's report said. "The impact is likely to remain long after DCCR support ends."

Congress provided DCCR with some powerful support for expanding the program.

In extending the National Cancer Act for two years, Congress added language which adds detection, rehabilitation and counseling to Cancer Control Program authority and specified that sucy programs shall include professional information programs and demonstration programs for health professionals in early detection and referral of patients.

Buell included in his report language from the House committee report on the bill extending the Act which explains the Health Subcommittee's intent in the amendment.

The amendment "reflects the committee's recognition of the importance of education and demonstration programs initiated within the local communities and hospitals where most of the cases of cancer are detected and treated," the report said. "In the past the implementation of the Cancer Control programs of the National Cancer Institute has taken place primarily at the national level and through comprehensive cancer centers. The committee, therefore, intends this provision to encourage local initiatives to disseminate the most recent information regarding agents identified as carcinogens and cocarcinogens, new methods of diagnosis of cancer, and the most advanced and effective treatment protocols to oncologists and physicians engaged in routine health care delivery.

"Specifically, this provision calls for the establishment of locally initiated education and demonstration programs, including regional networks of such programs, to transmit research results and to disseminate information on the detection, diagnosis, prevention, and treatment of cancer and for the rehabilitation and counseling of cancer patients to physicians and other health professionals who provide services and care to those who have cancer.

"The committee intends this provision to assist in bringing the latest medical information to physicians who are not affiliated with major medical schoosl, research institutes, or comprehensive cancer centers. Support should be provided by the Cancer Control Program office of the National Cancer Institute for the establishment of information exchange networks between groups of medical practitioners. It is expected that this type of organization would help to identify deficiencies in local diagnostic and treatment capabilities and facilitate the continuing education of physicians. Such networks should, where possible, be allied with the appropriate comprehensive cancer centers in order to extend the effectiveness of the centers' education and demonstration programs, and to establish a more efficient patient referral mechanism. Such a relationship should result in every physician becoming aware of the most advanced preventive, diagnostic, and treatment methods as soon as possible, and in each cancer patient receiving the most effective therapy.

"The committee expects the National Cancer Institute to carry out thorough oversight of this program to insure proper direction and leadership at the local level, and to coordinate the program with the education and demonstration provisions of the national cancer program and the programs originating in the comprehensive cancer centers.

"In order to guarantee that the perspective of physicians primarily engaged in the treatment of individuals who have cancer is representated at the national level, and especially to make sure that the local programs described above are coordinated with the national programs, the committee included a provision which would require that two of the members of the National Cancer Advisory Board be physicians who, as their major activity, treat cancer patients. It was pointed out in the subcommittee's hearings that approximately 80% of those who are treated for cancer are diagnosed and treated at local community hospitals. Thus, these locally initiated programs, to be well integrated with the comprehensive centers and NCI at the level of the National Cancer Advisory Board, should be a great asset to the control programs of NCI.

"The House committee clearly intends that NCI support locally developed programs which in turn will 'be allied with the appropriate comprehensive cancer centers' to their mutual benefit," Buell's report said. "The existing Clinical Oncology Programs in Ada-Shawnee, Allentown, Grand Rapids, Walla Walla, San Antonio, Indianapolis and San Jose as they have evolved, correspond closely to the kind of locally initiated programs recommended in the committee's detailed directive."

CCRAC members still not convinced had better be prepared with some solid arguments when Buell asks for approval of the expanded program, possibly at the committee's meeting Nov. 16-17.

Porgrams CCRAC members felt might overlap with

COP were the comprehensive center community outreach grants; the Community Based Cancer Control Program; the American College of Surgeons Commission on Cancer accreditation programs; and the Cancer Control Program for Clinical Cooperative Groups.

About 700 hospitals have been accredited by the ACOS Commission on Cancer. Buell pointed out that accreditation requirements for a system for quality of care evaluation with documentation are similar to those required of COP participants.

Commenting on the ACOS program, Buell's report said, "Traditionally, the emphasis has been on the tumor registry. Also, approval is for single hospitals, not cooperative programs. If a proposed COP participant has an ACOS approved program, we would have greater confidence that a good standard of cancer care existed in the hospital than at a non-approved hospital.

"Despite requirement for quality of care evaluation, approval under this program has not resulted in the kind of multidisciplinary cancer management guidelines and auditing documents for evaluation that have been developed under the existing COPs. For example, in Grand Rapids, four of the five COP hospitals have ACOS approval, yet the development of the current elegant guidelines and community-wide program came only after COP funding. Of 19 hospitals currently involved in the seven COPs, only 10 have ACOS approval. Several of these have obtained approval since the COP was organized.

"In summary, even ACOS approval of the majority of hospitals in a community does not result in the quality of multidisciplinary care achieved under the COP, particularly in oncology nursing and rehabilitation," the report said.

NCI SUPPORT OF VA LUNG GROUP ENDS, BUT VASAG FUNDING TO BE CONTINUED

The Div. of Cancer Treatment and the division's Board of Scientific Counselors have agreed to end NCI's support of the VA Lung Group, a cooperative group of Veterans Administration hospitals conducting lung cancer treatment studies.

The Board accepted DCT's recommendation to continue support of the VA Surgical Adjuvant Group. The VASAG will receive approximately $800,000 in FY 1979 from NCI; phasing out VALG will reduce NCI's interagency agreement with the VA by $482,000 under the 1978 agreement.

The DCT Board earlier this year had demanded that both VA groups undergo independent review of their programs to qualify for continued NCI support. DCT staff had felt that those groups had not been reviewed as often or as thoroughly as the other cooperative groups. Since the VA groups were supported by the interagency agreements rather than by grants, the regular Cooperative Group study section—the Clinical Cancer Investigation Review Committee—has no jurisdiction over them.

A review body was set up, including four members named by the VA and four by NCI. "There was intensive debate among the reviewers over both groups," Franco Muggia, director of DCT's Cancer Therapy Evaluation Program, told the Board. "We came out feeling that much of the VA Lung Group's work duplicated that of the Cooperative Groups and others, and it was not considered as adequate.

"The VA Surgical Adjuvant Group, on the other hand, was viewed as a unique resource, conducting trials that are not being done elsewhere. The possibilities were to phase out one of the existing groups, reduce both of them, or to achieve a merger. We decided it was necessary to phase out the Lung Group and to continue full support of the Surgical Adjuvant Group."

The Board also agreed to trimming the interagency agreement with Walter Reed Army Medical Center by $17,000 under 1978, holding to to $50,000 for its clinical studies. DCT is encouraging Walter Reed to submit a grant application for participation in the Cancer & Acute Leukemia Group B activities. The National Naval Medical Center agreement was also extended for one year and the center is being encouraged to submit a grant application for participation in Eastern Cooperative Oncology Group studies.

NCI CONTRACT AWARDS

Title: Holding facility to support intramural research on RNA viruses and breeding for detecting of tumor virus information, continuation
Contractor: Flow Laboratories, $46,123.

Title: Support services for the National Non-melanoma Skin Cancer Study
Contractor: Pacific Consultants, Boston, $127,221.

Title: Case control study of carcinoma of endometrium, continuation
Contractor: Boston Univ., $28,863.

Title: Wild mouse studies, continuation
Contractor: Univ. of Southern California, $400,000.

Title: Research in etiology and epidemiology of cancer, continuation
Contractor: Univ. of Southern California, $175,000.

Title: Immunogenetic and virological study of leukemogenesis in the AKR mouse
Contractor: Sloan-Kettering Institute for Cancer Research, $467,870.

Title: Isolation and characterization of type-C RNA viruses and diagnostic testing, continuation
Contractor: Microbiological Associates, $43,100.

Title: Development of ultrasonic endoscopic probes to be inserted through endoscopes for use in cancer diagnosis, continuation
Contractor: SRI International, $576,212.

Title: Determine the feasibility of a state-wide coordinated cancer control activity
Contractor: State of New Jersey, $276,110.

Title: Support of activities of the US National Committee for the International Union Against Cancer (UICC), modification
Contractor: National Academy of Sciences, $24,563.

Title: Diet and cholesterol metabolism in relation to human breast cancer risk
Contractor: Mount Sinai School of Medicine, $635,200.

Title: Followup of fluoroscopically examined tuberculosis patients in relation to incidence of cancer
Contractor: Harvard College School of Public Health, $113,380.

REQUESTS FOR APPLICATIONS

The Div. of Cancer Control & Rehabilitation of NCI will announce this week three new RFAs (request for applications) describing research the division plans to support through investigator initiated grants. The three programs are summarized below.

Applications will be reviewed by the NIH Div. of Research Grants and NCI staff for responsiveness to the announcements. If application is judged unresponsive, the applicant will be given an opportunity to withdraw the application or to submit it for consideration in the traditional grant program of NIH.

Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group and secondly by the National Cancer Advisory Board.

The factors considered in evaluating each application will be:

1. Relevance of the proposal to the scope and objectives provided in the announcements.
2. The technical merit of the proposed approach.
3. Expertise and qualifications of the principal investigator and proposed staff.
4. Sufficient commitment of time by the principal investigator and proposed staff.
5. Evaluation plan and timetable.
6. Relationship of cost proposal to the research endeavor.

Each prospective applicant should submit a letter of intent containing a brief description of the proposed project. Letters of intent are due Dec. 1, 1978; Feb. 1, 1979; or June 1, 1979. Applications are due Jan. 15, 1978; March 1, 1979; or July 1, 1979. Letters of intent should be addressed to Lawrence Burke, Program Director for Rehabilitation, NCI, Room 617, Blair Bldg., Bethesda, Md. 20014.

Applications should be submitted on Form NIH-398. The conventional presentation for grant applications should be utilized. The standard procedures for submitting a grant application to DRG should be followed. A brief covering letter should accompany the application indicating that it is in response to the specific RFA—refer to the appropriate title. The words "Cancer Control" should be typed in block letters in the upper right hand corner of the first page of the application. A copy of the covering letter should be sent to Burke.

Program for Improved Care of Cancer Patients With Terminal Disease

The Div. of Cancer Control & Rehabilitation is inviting grant applications for the purpose of implementing and evaluating innovative projects for the improved care of cancer patients with terminal disease. Such patients require a different clinical approach than the cancer patient under treatment directed toward cure. The terminal cancer patient needs active palliative care, sophisticated medical management of symptoms, and psychological and social support for the patient and family.

Despite marked improvement in the medical management of cancer and increased survival rates, a significant percent of cancer patients will succumb to their disease. Yet, most modern hospitals are acute care/cure-oriented facilities that are neither well equipped nor psychologically well prepared to meet the total needs of the terminal cancer patient.

The emphasis on cure and maintenance of health might not always be compatible with caring and active attention to symptom management when cure is not possible. Cancer affects not only the patient, but the family as well, to a degree that is both economically and sociologically significant. Proposals should address the morbidity to the family as well as to the patient.

Proposals may select a single aspect of terminal care that needs further study or address terminal care more comprehensively. Practical and effective methods for better understanding and ameliorating specific problems common to terminal disease are an objective of this RFA.

Investigators should have access to terminal cancer patients and also have considerable experience and training in oncology and management of terminally ill patients. The terminally ill patient is defined in this RFA as that cancer patient who has received the maximum definitive treatment but has not received a remission or significant eradication of his disease and whose medical doctor indicates that life expectancy is limited to a few months.

Applicants should present a program for implementing and evaluating original methods and techniques for improved care including, but not limited to the following:

1. An entire program will not be funded. A description of the proposed project should include: a.) modes of treatment and care available in the study, b.) implications of the problem in this particular environment, c.) implications of proposed program in terms of how it could alter terminal cancer for

patient and family, and d.) review of research studies directed at identifying better means of managing symptom states, including pain research.

2. Identification of specific problems in terminal illness which warrant new study.

3. Description of proposed study (method). Areas that might be explored: the best location for treatment of terminal patients; relationship of equipment to facilities for optimal care; relationship of facility to type of care, cost of care quality of care; improved means for providing pain relief; role of supporting health care staff in relation to patient and family; the methods and techniques effective for educating and communicating with the patient and family.

4. Outline of the research design, data collection and data analysis and evaluation, including protocols for implementation. This might include the sampling methods for accessing patients into the study, methods of assessing effectiveness of the proposed improved care, and description of comparison and/or control groups to be accessed. Randomized trials for symptom relief will be considered.

5. Establishment of a timetable for carrying out study, data collection, collation and analysis and presentation of findings.

6. Each application must include clear objectives and means to evaluate the stated objectives.

The following will not be considered under the scope of this RFA:

1. Duplication of ongoing hospice demonstration programs which are currently funded under NCI contract. 2. Funding for the provision of service only. 3. Funding for construction and/or renovation. 4. Evaluation of existing projects. 5. Development of a new facility or expansion of an existing terminal care facility.

The Role of Nutrition in the Rehabilitation of Cancer Patients

DCCR is inviting grant applications from investigators for studying the effect of specially designed nutrition programs on the cancer rehabilitation process.

Advances of modern medicine have increased survival time and longevity for an increasing number of cancer patients. Aggressive treatment required to achieve such results frequently causes serious residual physiological and psychological consequences to the patient. Impairment must be early attended to if the patient is to enjoy the optimal benefit from remission or cure. Rehabilitation must employ newer modalities and explore unique approaches if the morbidity so common to cancer is to be reduced. A number of studies have suggested that nutrition, when properly understood and utilized may be just such a modality. The primary objective of this RFA is to encourage nutritional research which will lead to practical and effective methods of improving cancer rehabilitation. Research may address any of the components of nutrition as it relates to:

1. Prevention of impairment secondary to the disease and/or treatment.

2. The earlier restoration of lost physical and psychological capabilities.

3. Regimens for host maintenance during course of treatment.

4. Altering states of disability through nutritional manipulation.

5. Effect of nutrition on the psychological state of the cancer patient.

This list of suggestions is not meant to be either restrictive or exhaustive. Nutrition should not be considered as synonomous with diet. Investigations of dietary practices are not a proper submission for this RFA.

Applicants should address all of the following points:

1. Identification and description of the patient population to be studied. A description should include the sample characteristics of each study group and selection rationale.

2. Control groups are recommended. Diet management programs, hyperalimentation studies must be related to a specific cancer impairment and should investigate specific rehabilitation aspect.

3. Identification of specific impairments specifically resulting from cancer and/or its treatment.

4. Rationale for selecting a particular nutritional program—and how its contribution to the rehabilitation of the patient is to be measured.

5. Description of methodology or plan of study. This statement should include a clear presentation of the problem, study design, method of data collection and data analysis, a timetable (or milestone chart) for accomplishing objectives and discussion of how the findings are to be presented.

Identification and Evaluation of Counseling Techniques for Cancer Patients

DCCR is inviting grant applications from investigators for identifying and evaluating the effectiveness of selected counseling techniques in helping cancer patients cope with the psychological and emotional problems.

Cancer patients frequently experience a wide range of emotional difficulties and symptoms which often have devastating effects on personality, behavior and relationships with others. A significant number of cancer patients have expressed a need for support in coping with their emotional reactions. While there have been a variety of counseling interventions to improve the emotional well being of the cancer patient, little objective evidence exists to document the benefit of any given counseling technique.

It is the intent of this RFA to stimulate research to identify and evaluate the effectiveness of selected counseling techniques for cancer patients with identified specific psychological problems. Greater speci-

ficity must be achieved in the area of cancer patient counseling.

For the purpose of this RFA, counseling techniques can be defined as those methods of therapeutic intervention which seek to aid, guide and support the cancer patient in confronting and coping with the emotional stress encountered as a result of the disease and its treatment. The primary recipient of the counseling in this study should be the patient.

The investigator should select and define specific counseling techniques which allegedly have universal application to psychosocial problems of a cancer patient. Specific technique(s) should be applied to a designated, diagnosed cancer related, emotional problem(s). While the value and benefit of family counseling is well recognized, it is the purpose of this RFA to address more directly the need for patient directed counseling.

Applicants should address the following points, although support is not limited to these subjects:

1. Identification and description of the patient population to be studied. Patients should be subdivided into groups according to such common characteristics as age, stage of disease, organ site. Rationale for sample selection should be explained. Control groups are recommended.

2. Identification of specific emotional and psychological problems that require counseling. Problems selected for study should include those which are commonly associated with a majority of cancer patients.

3. Analysis of relationship of specific emotional and psychological problems to specific counseling techniques. Investigator should clarify the rationale for matching a given counseling technique to a given psychological problem. The theoretical basis for the counseling should be fully articulated.

4. Include methodology for testing and evaluating selected counseling techniques, as well as the method of data collection and data analysis. The investigator should describe the measures for assessing and quantifying the benefit of the identified counseling techniques to the patient or patient group.

5. Establish a timetable for accomplishing objectives and presentation of findings.

RFP ECI-78-135

Title: *Examine the characteristics of cigarette smoking*

Deadline: *Dec. 15*

Characteristics include total lifetime exposure, quantity, inhalation pattern, etc.), and related risk factors (e.g., occupation, alcohol consumption, etc.) associated with the incidence of lung, bladder and pancreatic cancer, and myocardial infarction. The project is to consist of case-control studies in several U.S. cities. It is presently estimated that the period of performance will be three years.

Enviro Control Inc.
One Central Plaza, 11300 Rockville Pike
Rockville, Md. 20852
Attn: G. Hall, Subcontracts Administrator

SUBCONTRACT ANNOUNCEMENT 78-A-2 (296)

Title: *Long term carcinogenesis bioassay testing using mice and rats for the test of a variety of chemicals*

Deadline: *See below*

Administration of the test agents may be dosed-feed, dosed-water, gavage, or skin-painting. A highly qualified veterinary or medical pathologist with experience in laboratory animal rodent pathology, a veterinarian qualified in laboratory animal science, an HT/ASCP registered technician, a chemist, and a toxicologist must be available for the program.

Chemistry, histology, and pathologic diagnosis activities may be a subcontractual arrangement. Facilities for dosing and maintaining animals in a situation that will maintain the integrity of the experiment and will permit safe operations for animals and laboratory personnel are necessary. A basic ordering agreement (BOA) with cost plus fixed fee task orders, is the type of contractual agreement that is contemplated. Indicate in request letter how many chemicals you feel you are qualified to test at a time, i.e., 2, 3, 6, 9, or more; the time frame for handling testing, e.g. 'Cannot handle any tests now, expect to be able to handle three chemicals around Jan 79;' and the route(s) of administration capabilities.

Interested laboratories should request Tracor Jitco's Bidder's Mailing List Application and BOA 78-B-1. Those companies currently on the program will be sent a copy of the BOA package automatically. There is no deadline for submission; laboratories will be analyzed for qualification on a quarterly basis.

Technical proposals received by Nov. 30, 1978 will be acted upon from Dec. 1 through 15; by January 1979, from Feb. 1 through 15, etc. Announcements will appear periodically.

Tracor Jitco Inc.
Attn: Subcontract Administrator
1776 East Jefferson St.
Rockville, Md. 20851.
Telephone 301-881-2305
(Tracor Jitco is the prime contractor for NCI's Carcinogenesis Testing Program.)

The Cancer Letter —*Editor* JERRY D. BOYD

Published fifty times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090.