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P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

Four More Cooperative Groups Disapproved As NCI To Consider New Directions In Clinical Trials

Four more cooperative groups were disapproved by the Cancer Clinical Investigation Review Committee this month, bringing to seven those earmarked for oblivion by the CCIRC of the last eight reviewed. Only the Pediatric Oncology

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In Brief

St. Jude To Stay In Memphis; Katterhagens Move To Illinois; ACCC, Nixon In DC Next Week

ST. JUDE Children's Research Hospital's Board of Governors has decided the institution will remain in Memphis. The board last year announced it was considering a move to St. Louis where St. Jude would be affiliated with Washington Univ. School of Medicine. Key factor in the decision was the concern of many board members over the prospect that by becoming part of a top notch medical center, St. Jude's identity and autonomy might eventually be diminished. . . . **GALE KATTERHAGEN**, director of oncology at Multicare Medical Center in Tacoma and a member of the National Cancer Advisory Board, will become director of the Comprehensive Cancer System at Memorial Medical Center in Springfield, IL April 1. The 650 bed teaching hospital is affiliated with Southern Illinois Univ., and Katterhagen will also hold an appointment there. Katterhagen will supervise further development of the cancer system, including applying for a Community Clinical Oncology Program award in the CCOP recompetition this year. . . . **ANNE KATTERHAGEN** will join her husband May 1 as vice president of Memorial Medical Center for alternative care, which includes home care, high tech home care, and hospice development. She is executive director of the Hospice of Tacoma and president of the Hospice Assn. of America . . . . **12TH NATIONAL** meeting of the Assn. of Community Cancer Centers opens April 2 with the organization's annual blitz of Capitol Hill, when members buttonhole senators, congressmen and their staffs on the cancer research budget and related issues. The five day meeting includes the annual session April 3 with the Assn. of American Cancer Institutes on advances in cancer control; other sessions on managing AIDS patients, CCOPs and free-standing cancer centers; and presentation of the ACCC award to former President Richard Nixon at the April 5 luncheon.

Regional Group Concept Hit; Meeting Scheduled To Plan New Directions

(Continued from page 1)
Group survived those cycles. The last four disapproved were the Southeastern Cancer Study Group (SEG), Northern California Oncology Group, Piedmont Oncology Assn., and the Mid-Atlantic Oncology Program.

The other three previously disapproved, or effectively put out of business by receiving unfundable priority scores, were the bladder and prostate cancer groups which had been transferred from the Organ Site Program, and the Gastrointestinal Tumor Study Group.

SEG, the oldest and more established of the four newest casualties, was considered a national group despite its name. The other three are regional groups, and their demise leaves only one such group still afloat--the North Central Cancer Treatment Group. The concept of regional groups was pushed hard by then Div. of Cancer Treatment Director Vincent DeVita, in the late 1970s. He saw it as a way to make clinical trials available in areas remote from major centers and to reach the increasing number of patients being treated in community hospitals.

The subsequent advent of the Community Clinical Oncology Program has diminished the need for regional cooperative groups, in the eyes of some NCI executives. In fact, "it will be an unusual regional group that can cut the mustard from here on," one staff member told **The Cancer Letter** (NCI and other NIH staff are forbidden from discussing grant disapprovals, for the record, before they have been presented to the National Cancer Advisory Board or other NIH councils). The opinion at NCI now is that regional groups are not able to develop the "critical mass" of patients and clinical and scientific expertise needed to promptly and effectively carry out clinical trials.

The new "slaughter" (as one NCI staff member called it) of cooperative groups leaves several CCOPs without their research bases. SEG was the only research base for the very productive Augusta, GA CCOP. Geisinger Clinic and New England Deaconess, both CCOPs, were two of the most productive members of MAOP. Participants in the Fresno, CA CCOP reportedly were "stunned" by the action against NCOG, their research base.

NCI executives contend that the surviving national groups will fill the gaps by extending their activities into the Eastern, Southeastern and Northern California areas left without cooperative group coverage.

Chairmen of the four groups were reluctant to discuss the situation without the pink sheets detailing deficiencies perceived by CCIRC. POA Chairman Robert Capizzi said he thought the action reflected "a shift in priorities at NCI." He said he thought his group had been "highly successful" in establishing clinical trials within the North and South Carolina, southern Virginia and northern Georgia communities it served. Disapproval "came as a blow." He insisted POA "is not going to disband." The group operated several years without NCI funding.

SEG Chairman George Omura said an appeal of the decision "is a possibility. . . We have been very productive over the last grant period, at least as much as other groups. We don't regard ourselves as regional but we are involved in most of the cooperative clinical reserch in this part of the country."

DCT's Cancer Therapy Evaluation Program has scheduled a meeting April 1-2 with outside advisors, group representatives and others to discuss new directions in clinical research. The meeting will start at 10 a.m., in NIH Bldg 1, Wilson Hall.

Burton's Clinic Reopens; Insurers Reported Reimbursing In Some Cases

Lawrence Burton's controversial Immunology Researching Center has reopened in the Bahamas, reportedly on the condition that the clinic will screen blood products produced at the facility for hepatitis B and HTLV-3.

The clinic was closed by the Bahamian government last July following reports that serum produced there for treating cancer patients was contaminated with HTLV-3, the virus associated with acquired immune deficiency syndrome.

Further fanning the controversy are efforts by Burton and his patients to pressure insurance carriers to reimburse for the unproven treatment, efforts which reportedly have met with some success.

The reversal of the government's decision follows vigorous efforts of Burton supporters to reopen the clinic. The protests apparently caught the eye of at least one member of Congress--Rep. Guy Molinari. The New York Republican became involved in the issue following complaints about the closure of the clinic from constituents who had undergone treatment at the facility.

Molinari held a hearing featuring Burton and supporters of the clinic in New York last month. Staff members of the Congressman pointed out that representatives from NCI, the Centers for Disease Control and the Food & Drug Administration declined to attend. At least one of those agencies, NCI, did not attend on advice of its legal counsel because of a lawsuit pending against the institute by the Immunoaugmentative Therapy (IAT) Patients Assn., an organization of cancer patients treated by Burton.

Noting that it lacks the necessary scientific expertise to evaluate whether Burton's treatment is efficacious, Molinari's office is calling for an evaluation of the therapy. Although no federal agency or private organization has been identified as being the best one to carry out responsibility for such an investigation, the Congressional Office of Technology Assessment has been named as a possible evaluator, Ed Burke, Molinari's press secretary, told **The Cancer Letter.**

NCI Div. of Cancer Treatment Deputy Director Gregory Curt told **The Cancer Letter** that he supports the initiation of an investigation into the treatment. Curt estimates that Burton has treated about 3,000 patients since opening the clinic in 1978, a sufficient number to enable an analysis of the therapy.

Aside from the issue of contamination of the serum products, the major controversy surrounding the clinic is the efficacy of the therapy. Critics point out that it has not been formally evaluated nor have any clinical results been published in a peer reviewed journal.

Third party reimbursement has surfaced as another controversy surrounding Burton's operation. His charge for one cycle of treatment at the outpatient clinic is approximately $10,000.

Although many health insurance policies specifically exclude reimbursement for experimental therapies, several major insurers are reported to have reimbursed patients who have undergone treatment at the facility, including Aetna and Blue Cross-Blue Shield. An Aetna spokesman vigorously denied his company had done so, however, although acknowledging that some reimbursement to Burton patients might have slipped through by mistake. In fact, the company is being sued by one or more of Burton's patients over the issue.

Blue Cross-Blue Shield had not responded to phone calls from **The Cancer Letter** by press time.

There are reports that some insurers have paid claims from Burton patients to avoid lawsuits. A handbook for patients at the clinic outlines steps for preparing insurance claims and what to do if a claim is rejected. It states that "more and more insurance companies are readily accepting IAT claims for full or partial reimbursement," but advises that " the success of any claim will depend upon the quality of its presentation." It notes that the center's insurance administrator "can provide patients with specific information related to the claims experience with almost all of the major U.S. insurance carriers."

It recommends that patients submit a personal letter from the center's staff physician, attesting to the fact that the patient is under treatment; a printed statement from the center that describes IAT and summarizes the attending medical staff's credentials; and "(optional) If your doctor back home will write a brief letter stating the facts of your progress, this could be helpful." The patient's doctor "does not have to comment on IAT, [but] simply state the 'before' and 'after' results of your X-rays, scans, whatever."

If a patient's claim is rejected, the brochure recommends that patients "understand the grounds on which you were rejected" and "insist on a statement in writing." It also advises patients to contact the IAT Information Center or the clinic for information on making an appeal.

The reopening of the clinic continues to concern Curt, who specifically questions whether the Bahamian Ministry of Health has adequately addressed the question of contamination of blood products from the clinic.

Repeated efforts by **The Cancer Letter** to obtain details from the Bahamian Ministry of Health of the conditions surrounding the reopening of the clinic were unsuccessful. A spokesman for Molinari's office, however, said the clinic will screen its products for contamination with HTLV-3 and hepatitis B, and that HTLV-3 testing equipment had already arrived on the Grand Bahama island at the time of the clinic's closure in July.

In addition to HTLV-3 contamination of products from the facility, NCI examination of the treatment materials in the past has revealed contamination with hepatitis B

surface antigen or anticore antibody or both, as well as several species of bacteria.

An analysis of the products conducted by NCI in 1984 found that materials submitted by the family of a deceased IAT patient were dilute blood proteins, the major component of which was albumin. None of the materials were electrophoretically pure, and all fractions were devoid of the four compounds described by Burton as being essential to activity, according to an article published by Curt, National Cancer Advisory Board member and Tacoma oncologist Gale Katterhagen, and Francis Mahaney of NCI's Office of Cancer Communications in the "Journal of the American Medical Assn."

The article describes analysis of materials obtained from an additional five patients that "were uniformly contaminated with bacteria (pseudomonas, corynebacterium, staphylococcus, bacillus, proprionibacterium, and achromobacter species)." Of materials screened from four patients for hepatitis B, all disclosed surface antigen or anticore antibody or both.

CDC has also reported 16 cases of abscess formation at injection sites in patients receiving IAT. Nocardia asteroides was Burton cultured from four patients, one developed nocardial pneumonia and in two patients, the abscesses were refractory to medical and surgical treatment. According to the article, a review of IRC's records suggested an attack rate for abscesses at injection sites of 4.5 cases per 100 patients.

The closure of the clinic last year was based in large part on the finding of HTLV-3 antibodies in eight of 18 products from the clinic tested in Washington state. All 18 were positive for hepatitis as well. CDC was able to isolate the HTLV-3 virus from one of the samples and issued a warning to IAT patients that they "may be at risk of acquiring HTLV-3 LAV and HBV infections" in its Aug. 9 issue of "Morbidity and Mortality Weekly Reports." The agency recommended that "patients who have received such therapy should consult their physicians."

Despite the well publicized problems with consistent hepatitis contamination of the serum and the recent contamination with HTLV-3, supporters of the clinic have not been dissuaded. Curt notes in his article that "although there are, to our knowledge, no clinical or preclinical data in scientific, peer-reviewed journals to support the contention that IAT is in any way effective in the treatment of any disease, there have been, nonetheless, efforts to legalize its use." A law passed in Florida by an override of the governor's veto allowed certain patients to obtain IAT, but was repealed in 1984. A similar law passed in Oklahoma in 1981 requires patients to sign an informed consent document that states the efficacy of the treatment is unproved. Curt notes that in both cases, "the use of an unproved therapy was legalized with neither characterization of the treatment itself nor confirmation of its efficacy."

The report from the Pan American Health Organization's site visit to the clinic in July has not been made public by the Bahamian government. However, the 1978 PAHO site visit report found that "the material being used to treat the patients is...a totally unknown quantity. Although the various fractions are referred to by Dr. Burton as 'antibody fractions' and 'complement fractions,' there is in fact no evidence that any of these fractions do contain antibody of any relevance to the tumor involved or that in fact there are any active or even inactive complement components."

The 1978 PAHO report found that "it was difficult to pin down the nature of the followup procedures that have been or will be applied to patients who remain under treatment but who leave the Bahamas. There were comments indicating that physician cooperation among physicians in the United States was so poor that it was very difficult to obtain desirable followup information. This means that the only potential for accurate followup is when (or if) the patient returns to the clinic. The poor quality of medical evaluation at the clinic makes realization of even this limited potential unlikely."

Although NCI officials remain concerned that previous problems with contamination of the serum could persist and that patients with cancers treatable by conventional therapy are spending large sums of money on an unproved treatment, they are eager to see an investigation of the treatment's clinical results. Apparently, Burton's supporters believe so strongly in the treatment that they may be willing to go along with it as well.

If the data sought by PAHO over the past several years is made available by the clinic, the estimated 3,000 cases treated should provide an ample data base for an

effort at evaluation.

Jurisdictional aspects of the treatment have been a problem for U.S. officials concerned about the clinic's treatment of American citizens, since Burton moved his operations to the Bahamas to avoid what he considers unnecessary restraints by federal agencies such as the Food & Drug Administration. The patient brochure states that Burton "moved to Freeport so that he could continue his research unhindered and also provide therapy for many patients who chose his method of cancer control."

In fact, following the closure of the Freeport clinic in the summer, Burton announced plans to open another clinic in Cuernavaca, Mexico. The status of that facility remains uncertain in light of the reopening of the clinic in the Bahamas.

The 1978 site visit by PAHO found that "it was impossible to achieve any evaluation of the clinical results obtained in this program. No tabular information was presented giving the number of patients who had been considered for admission to the program, the number accepted, the number with any particular tissue diagnosis, the numbers of patients living or dead, or survival."

NCI Advisory Group, Other Cancer Meetings For April, May, Future

The War on Cancer: 15 Years of Progress--April 2-6, Hyatt Regency on Capitol Hill, Washington D.C. 12th national meeting of the Assn. of Community Cancer Centers. Contact ACCC, 12th National Meeting, 11600 Nebel St. Suite 201, Rockville, MD 20852, phone 301-984-9496.

National Council on Radioprotection & Measurements--April 2-3, Washington. 22nd annual meeting. Contact NCRP,7910 Woodmont Ave., Suite 1016, Bethesda, MD 20814, phone 301-657-2652.

Diagnosis & Treatment of Neoplastic Disorders--April 3-4, Johns Hopkins Medical Institutions, Baltimore. Contact Diane Heydinger, Program Coordinator, Office of Continuing Education, Johns Hopkins, Turner 22, 720 Rutland Ave., Baltimore 21205, phone 301-955-6046.

Head & Neck Cancer: Strategies for Cure--April 3-4, Westin Hotel, Detroit. Contact Div. of Continuing Medical Education, Wayne State Univ. School of Medicine, 4201 St. Antoine, 4-H, Detroit 48201, phone 313-577-1180.

Gastrointestinal Oncology 1986--April 3-4, New York. Contact CME Conference Planning Office, C-180, Memorial Sloan-Kettering Cancer Center,1275 York Ave., New York 10021, phone 212-794-6754.

Topics In Bone Marrow Transplantation: 1986--April 4-5. Brent House Hotel, New Orleans. Contact Susan Kindrachuk, CME Coordinator, Alton Ochsner Medical Foundation, 1516 Jefferson Highway, New Orleans 70121, phone 504-838-3702.

American Radium Society--April 6-10, San Francisco. 68th annual meeting. Contact Suzanne Bohn, ARS, 925 Chestnut St., Philadelphia 19107, phone 215-574-3179.

Interferons as Cell Growth Inhibitors and Antitumor Factors--April 6-12, Steamboat Springs, CO. Contact UCLA Symposia, Molelcular Biology Institute, Los Angeles 90024, phone 213-206-6292.

National Conference on Urologic Cancer--April 9-11, Adams Mark Hotel, Philadelphia. Contact American Cancer Society, 90 Park Ave., New York 10016.

Status Report on Mutagens in the Diet--April 9, Sheraton Inner Harbor Hotel, Baltimore, 8 p.m. Public symposium as part of the annual meeting of the Environmental Mutagen Society. Contact John Heddle (York Univ., Toronto), 416-667-3053.

Central Cancer Registry Operation--April 10-12, Chicago. First national conference. Contact Cancer Dept., American College of Surgeons, 55 E. Erie St., Chicago 60611, phone 312-664-4050.

President's Cancer Panel--April 11, St. Jude Children's Research Hospital, Memphis, 9 a.m., open.

New Concepts in Breast Cancer Management--April 12, Cleveland. Contact Barbara Guy, Lowman 211, University Hospitals of Cleveland, 2074 Abington Rd., Cleveland 44106, phone 216-844-7856.

Recent Advances in Bone Marrow Transplantation--April 13-18, Keystone, CO. Contact UCLA Symposia, Molelcular Biology Institute, Los Angeles 90024, phone 213-206-6292.

American Roentgen Ray Society--April 13-18, Sheraton Washington Hotel, Washington DC. 86th annual meeting. Contact ARRS, 1891 Preston White Dr., Reston, VA 22091, phone 703-648-8900.

In Vitro Toxicology: Approaches to Validation--April 14-15, Baltimore. Johns Hopkins Center for Alternatives to Animal Testing. Contact Program Coordinator, Office of Continuing Education, Johns Hopkins School of Hygiene & Public Health, 720 Rutland Ave., Baltimore 21205, phone 301-955-6046.

Biological and Therapeutic Aspects of Cancer Metastasis--April 14-17, Vitoria, Spain. International conference sponsored by the Univ. of the Basque Country. Contact Secretariat, Apartado 1299, 48080 Bilbao, Spain.

Concepts in Chemotherapy and Recent Developments in Cancer Treatment--April 17, Roswell Park continuing education in oncology. Contact Gayle Bersani, Cordinator for Continuing Education, RPMI, 666 Elm St., Buffalo, NY 14263, phone 716-845-2339.

Flexible Sigmoidoscopy Workshop--April 19, Roswell Park continuing education in oncology. Contact above).

Food Antioxidants: International Perspectives--April 21-23, Loew L'Enfant Plaza Hotel, Washington DC. Contact Elain Auld, International Life Sciences Institute--Nutrition Foundation, 1126 16th St. NW, Washington 20036, phone 202-659-0074.

Cancer Therapeutics Program Project Review Committee--April 21-22, NIH Bldg 31 Rm 6, open April 21 8:30-9 a.m.

Biometry & Epidemiology Contract Review Committee--April 24-25, NIH Bldg 31 Rm 7, open April 24 8:30-9 a.m.

Oncology Nursing Center Stage--April 30-May 3, Los Angeles. 11th annual congress of the Oncology Nursing Society. Contact Nancy Berkowitz, ONS, 3111 Banksville Rd., Suite 200, Pittsburgh, PA 15216, phone 412-344-3899.

American Society of Clinical Oncology--May 4-6, Los Angeles Convention Center. 22nd annual meeting.

American Assn. for Cancer Research--May 7-10, Los Angeles Convention Center. 77th annual meeting.

Current Concepts in Breast Cancer--May 7, New York. Contact Beverly Baptiste, Medical Education, Beth Israel Medical Center, First Ave. at 16th St., New York 10003, phone 212-429-2000.

Div. of Cancer Prevention & Control Board of Scientific Counselors--May 8-9, NIH Bldg 1 Wilson Hall, 8:30 a.m. both days.

Society of Surgical Oncology--May 11-14, J.W. Marriott Hotel, Washington DC. 39th annual Cancer Symposium.

Society for Clinical Trials--May 11-14, Montreal. 7th annual meeting. Contact Genell Knatterud, 600 Wyndhurst Ave., Baltimore, 21210, phone 301-435-4200.

21st Congress of the International Society of Hematology and 19th Congress of the International Society of Blood Transfusion--May 11-16, Sydney, Australia. Contact Congress Secretariat, Box 2609, GPO Sydney, New South Wales, Australia 2001.

Freestanding Cancer Center Development--May 13-14, Fox Chase Cancer Center, Philadelphia. First national conference. Contact Ron Gilden, CDP Group, 5901 Peachtree Dunwoody Rd. NE, Suite C-100, Atlanata, GA 30328, phone 404-391-9872.

Intraoperative Radiation Therapy--May 15-16, Dana Center for Continuing Education, Toledo. International symposium. Contact CME Office, Medical College of Ohio, C.S. 10008, Toledo, OH 43699.

National Cancer Advisory Board--May 19-21, NIH Bldg 31 Rm 6, 9 a.m. Closed May 20 for grant review. Committee meeting schedules to be announced later.

Integrated Approach to the Management of Pain--May 19-21, NIH Clinical Center. NIH consensus development conference. Contact Peter Murphy, Prospect Associates, 2115 E. Jefferson St., Suite 401, Rockville, MD 20852, phone 301-468-6555.

Hormonal Therapy of Prostatic Diseases--May 21-24, Milan. Basic and clinical aspects. Contact M. Motta/M. Serio, Dept. of Endocrinology, Univ. of Milan, 21, Via Andrea del Sarto, 20129 Milan, Italy.

11th Annual Mental Health Conference--May 22-23, Medical Center Holiday Inn, Houston. M.D. Anderson Dept. of Pediatrics. Contact Office of Conference Services, Box 131, M.D.Anderson Hospital & Tumor Institute, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

American Industrial Health Council Washington Conference--May 22, Hyatt Regency Capitol Hill, Washington DC.

American Assn. for the Advancement of Science--May 25-30, Philadelphia. 152nd national meeting. Contact AAAS, 1333 H St. NW, Washington DC 20005.

GI Tract Cancer: Update on Combined Modality Therapy--May 29-30, Heidelberg, West Germany. EORTC symposium. Contact Dr. P. Schlag, Chirurgische Klinik, Universitat Heidelberg, Im Neuenheimer Feld 110, 6900 Heidelberg, West Germany.

Advances in Cancer Pain Control--May 30-31, Bunts Auditorium, Cleveland Clinic. Contact Center for CME, Cleveland Clinic Educational Foundation, 9500 Euclid Ave., Rm TT3-301, Cleveland 44106, phone (local) 444-5696; (Ohio) 800-762-8172; (elsewhere) 800-762-8173.

FUTURE MEETINGS

Toxicology Update '86--June 9-11, Turner Bldg, Johns Hopkins Medical Institutions. Contact Program Coordinator, Office of Continuing Education, 720 Rutland Ave., Turner 22, Baltimore 21205.

Supportive Care of the Cancer Patient--June 20-21, Holiday Inn, Pensacola. Physicians seminar. Contact Dolly Partridge, Director of Education, Baptist Hospital, PO Box 17500, Pensacola, FL 32522, phone 904-434-4819.

Critical Molecular Determinants in Carcinogenesis--Sept. 16-19, Stouffer's Hotel, Houston. Contact Office of Conference Services, UT M.D. Anderson Hospital, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

Oncology Nursing in an Evolving Society--Sept. 23-26, Westin Galleria Hotel, Houston. Contact Conference Services, UTMDA, Box 131, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

Interaction of Radiation Therapy and Chemotherapy--Sept. 28-Oct. 1, Williamsburg, VA. Contact Suzanne Bohn, American College of Radiology, 925 Chestnut St., Philadelphia 19107, phone 215-574-3181.

Mechanisms of Drug Resistance in Neoplastic Cells--Oct. 15-16, Washington DC. 9th annual Bristol-Myers Symposium on Cancer Research. Contact Lillian Kamal, Administrator, Lombardi Cancer Research Center, Georgetown Univ., 3800 Reservoir Rd. NW, Washington DC 20007.

10th Scripps Cancer Symposium and 6th Scripps Cancer Symposium for Nurses--Oct. 27-29, Sheraton Harbor Island Hotel East, San Diego. Contact Nomi Feldman, Conference Coordinator, 3770 Tansy, San Diego 92121, phone 619-453-6222.

RFAs AVAILABLE

RFA 86-CA-06
TITLE: Cooperative human tissue network
Application receipt date: July 15

The Diagnosis Program of the Div. of Cancer Biology & Diagnosis invites applications for cooperative agreements from institutions capable of and interested in participating in a cooperative network of human cancer tissue laboratories located in or near major centers of biomedical research in the U.S.

The purpose of this network is to stimulate cooperative efforts to collect and distribute human tumor tissues and thereby to stimulate research utilizing those tissues. These activities are expected to encourage basic and developmental studies in many

areas of cancer research, including molecular biology, immunology and genetics. Numerous investigators have indicated that a major obstacle to cancer related research is the lack of access to cancer tissue and related control tissue from the same patient. The major benefit from the development of a human cancer tissue network will be improved access to human tumor tissue and improved techniques for its collection and distribution.

All applications received in response to this request will be reviewed by the same NCI review group. Applicants, if funded under this RFA, will be supported through cooperative agreement awards.

Investigators in the cooperative tissue network will be responsible for planning and directing the program with the assistance of NCI program staff. NCI will assist in setting priorities and in annually evaluating progress, and will approve operating policies prior to implementation. An applicant institution may apply for a period of support of up to three years under this RFA. A maximum of three awards will be made.

Support mechanism for this program will be the NIH cooperative agreement. This mechanism is used when the NCI, with concurrence of a board of scientific counselors, wishes to stimulate investigator interest and proposes to advise in planning in an important and opportune area of research support. In the initial year, $1,036,000 has been set aside in support of this program.

Principal investigator of a human tissue laboratory should be an experienced pathologist and have demonstrated research experience in an area related to cancer. The PI should also be actively involved in the operation of a pathology laboratory with demonstrated access to a wide range of human cancer tissues. The general duties and responsibilities of the PI should be clearly delineated in the application. The applicant should also clearly describe the relationships among major collaborators and tissue sources.

Potential applicants are strongly encouraged to consult with NCI staff and to obtain a copy of the complete RFA before submitting an application in response to this announcement. Requests for the full RFA as well as requests for further information and other inquiries concerning development of the application should be directed to Roger Aamodt, PhD, Program Director for Pathology/Cytology, Diagnosis Program, DCBD, Westwood Bldg Rm 10A15, Bethesda, MD 20892, phone 301-496-7147.

The concept from which this RFA was derived was approved by the DCBD Board of Scientific Counselors last spring and reported in The Cancer Letter June 7, 1985, page 6.

RFA 86-CA-11
TITLE: Increasing the use of mammography and breast palpation for early detection of breast cancer

Application receipt date: July 14

The Div. of Cancer Prevention & Control invites applications for community intervention studies aimed at increasing and sustaining the use of state of science mammography and breast palpation for the early detection of breast cancer in women 50 years of age and older. These studies are limited to applicants from within the U.S. The intent is to fund up to three awards for four years each.

Until more is known about the possibility of primary prevention of breast cancer, early detection is the key to cancer control at this site. There is general agreement that mammography and physical examination benefit women 50 years of age and older. For younger women, the benefit/risk ratio is still the subject of scientific discussion. Recent studies support the thesis that mammography combined with breast palpation or mammography alone can substantially reduce mortality from breast cancer.

Based on scientific evaluation, NCI and the American Cancer Society recommend the routine use of state of science mammography and breast palpation for women 50 years of age and older. However, national data indicate that this position has not been accepted or adopted by the medical profession and its clientele. Studies report that only 4 to 15 percent of women over the age of 50 are receiving mammography annually. Breast palpation by a health professional is a much more popular procedure. However, little is known about the quality of these examinations, and an inverse relationship exists between age and the frequency of breast palpation.

The interventions that will be developed, implemented and evaluated in this research are expected to address and remedy the barriers to routine and competent use of state of science mammography and breast palpation among women 50 years of age and older. Unless exceptions can be justified, the research should focus on geographically defined population areas. No community should have fewer than 10,000 women 50 and over. It is anticipated that separate but complementary interventions will be designed for the women and their health care providers. If subgroups of women do not have established sources of care, special attention should be given to expediting their access to mammography and breast palpation within the existing health care system or through creative outreach programs. No funds in the grant are to be used to offset the cost of screening procedures, screening equipment, or stationary or mobile facilities; but the funds can be used to stimulate plans and consortiums for lowering cost.

Applicants should address the issue of quality assurance measures for mammography and breast palpation by health professionals. The intention of NCI is to improve and sustain the quality of mammography and breast palpation over time. Therefore, NCI is encouraging applicants to select quality assurance approaches that will be acceptable to the target community during the years of the study and in the future.

An evaluation of the effectiveness of the health promotion activity must be undertaken by the applicant per se or by one or more subcontractors. It can be assumed that NCI funds for the intervention activity will expire in three years. However, the evaluation effort should be budgeted for an additional year--four years altogether. The applicant should address the measurement of process variables that link the interventions to behavioral change or nonchange among specific groups of women and their health care providers. To control for behavioral change that occurs independent of the intervention strategies, applicants should address the issue of control communities or subcommunities as well as baseline assessments.

A copy of the complete RFA, review procedures and criteria, the method of applying and an extensive bibliography may be obtained by contacting Dr. Jan Howard, Health Promotions Branch, DCPC, NCI, Blair Bldg Rm 415, Bethesda, MD 20892, phone 301-427-8656.

RFPs Available

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise

noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda, MD 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, MD, but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CP-61013-56

Title: Support services for epidemiologic studies

Deadline: Approximately April 15

The Environmental Epidemiology Branch of the Epidemiology & Biostatistics Program of the Div. of Cancer Etiology is seeking a contractor to provide support for epidemiologic research by the conduct of multiple epidemiologic studies, and the maintenance, acquisition and use of epidemiologic data bases. This contractor must also be capable of providing support for specimen collection and laboratory assays and be able to provide rapid turnaround to requests from the NCI project officer relating to these studies. Activities involved in the performance of these studies include but are not limited to:

1. Initiation of communication and liaison with parties whose cooperation or approval is required for the conduct of the individual studies; 2. development of appropriate study materials, data collection forms, procedural manuals, coding schemes, and training programs; 3. identifying and tracing study subjects; 4. data preparation and processing which includes the design and small scale computer systems to store and maintain the data; 5. interviewing study subjects and abstracting medical and other records; 6. performing physical examinations and phlebotomies on study subjects.

The contractor shall be required to provide documentation of steps followed in the conduct of each study to assure adequate monitoring and quality control of work performed. The contractor shall obtain biologic specimens from study subjects, arrange for specimen storage and/or standard laboratory tests or assays, and perform other support activities as requested by the NCI project officer in completion of these studies.

The concept from which this RFP was derived was approved by the DCE Board of Scientific Counselors last spring and reported in The Cancer Letter May 24, 1985, page 7.

This is a recompetition of two current contracts, one with Westat Inc. and the other with Research Triangle Institute. It is anticipated that an incrementally funded, cost reimbursement, level of effort contract will be awarded for a three year period.

Contract Specialist: Donna Winters
RCB Blair Bldg Rm 114
301-427-8888

RFP NCI-CP-61002-56

Title: Tracing individuals for environmental epidemiologic studies on cancer

Deadline: Approximately April 15

NCI intends to recompete its master agreements (MAs) for tracing subjects of epidemiologic studies of cancer who are moderately to very difficult to find. Their vital status must be ascertained. If deceased, the exact date and town or city and state where death occurred must be provided. A pool of contractors is to be assembled which are very experienced in using the resources needed for tracing through credit bureaus, motor vehicle bureaus, publicly available directories and/or all other resources and sources.

An offeror may be certified in any or all of these four methods of tracing. MA holders may respond to multiple master agreement orders (MAOs) RFPs. The MAO award will be made to a MA holder based on the award criteria set forth in the individual MAO/RFP. Each offeror must name a tracing manager to be responsible for all the tracing tasks and must demonstrate the capability and experience of supporting personnel. Weekly and other specific reports must be sent to NCI with tracing results. Contractors must report all new information and findings to NCI on special log forms.

Eligible organizations are those which are engaged in tracing individuals, utilizing any of the four defined methods. Contractors must have kept detailed records of past tracing projects so as to be able to describe their tracing success rates utilizing any of these four specific tracing methods.

Multiple MAO/RFPs will be issued each year. A MA holder is free to respond or not respond to any particular RFP without having any effect on its MA. MAs may be issued for a period of five years.

Contract Specialist: Donna Winters
RCB Blair Bldg Rm 114
301-427-8888

RFP NCI-7883-26

Title: Clinical quality control headquarters for heavy particle radiotherapy trials

Deadline: June 2

NCI requires a clinical quality control headquarters to coordinate the scientific activities of group members and committees in heavy particle (neutrons, protons, heavy ions) clinical trials.

The requirements of the proposed contract are the (a) managment of the heavy particle clinical quality control program (radiotherapy quality control); (b) administrative support for group functions; (c) providing of data management review; (d) establishment of the data base required by the statistical unit; (e) providing of administrative support for heavy particle committees; (f) providing financial support for foreign members to participate in studies; (g) collaboration with clinical investigators on the statistical and scientific aspects of planning new studies; (h) devising of data collection forms; (i) verification and summarization of all study data and (j) developing and maintaining of the necessary computer softwear to perform statistical analyses.

A four year period of performance is projected for this project, beginning approximately January 1987.

Contract Specialist: Carolyn Swift
RCB Blair Bldg Rm 228
301-427-8737

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