THE CANCER LETTER

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PIEDMONT, MID-ATLANTIC ORGANIZATIONS WIN COMPETITION FOR NCI SUPPORT OF NEW REGIONAL COOPERATIVE GROUPS

The Piedmont Oncology Assn., headquartered at Bowman Gray Oncology Research Center, and the Mid-Atlantic Oncology Program, headquartered at Georgetown Univ.-Vincent Lombardi Cancer Research Center, will be the two new regional cooperative groups funded by NCI.

The Piedmont and Mid-Atlantic groups won out in competition with

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In Brief

ONS, ASCO, AACR MEETINGS OPEN IN ST. LOUIS NEXT WEEK; BRISTOL-MYERS ADDS FARBER, McARDLE GRANTS

ST. LOUIS MEETINGS: Oncology Nursing Society 7th Annual Congress opens the 10-day long schedule April 22. Judith Johnson will deliver the Mara Mogensen Flaherty Memorial Lecture April 25. The 18th annual meeting of the American Society of Clinical Oncology, April 25-27, will include the David A. Karnofsky Memorial Lecture by James Holland, "Breaking the Cure Barrier," on April 26. John Ultmann's presidential address will be followed by a special presentation by J. Richard Crout, former director of FDA's Bureau of Drugs, who will talk on "The Development of New Cancer Drugs: A Joint Venture in Public Policy by NCI and FDA." The 73rd meeting of the American Assn. for Cancer Research, April 28-May 1, will mark the 75th anniversary of the organization. James Miller will note the occasion with an address on "Historical Aspects of the Development of Cancer Research in the United States." The Richard and Hinda Rosenthal Foundation Award Lecture will be given by Gianni Bonadonna on "Chemotherapeutic Strategies to Improve the Control of Hodgkin's Disease." Sidney Weinhouse's presidential address is entitled, "Prometheus and Pandora—Cancer Research on Our Diamond Anniversary." The G.H.A. Clowes Memorial Lecture, by George Weber, will be on "Biochemical Programs of Cancer Cells and the Design of Chemotherapy". . . .CLINICAL RESEARCH Committee of the Assn. of Community Cancer Centers will meet in St. Louis during the ASCO meeting, on Sunday, April 25, 7-9 p.m., in the Auguste Chouteau room of the Sheraton Hotel. Any ACCC member may attend. . . . BRISTOL-MYERS has added two more cancer centers—Sidney Farber Cancer Institute and McArdle Laboratory for Cancer Research—to the nine which have been receiving grants from the company. The new grants total $1 million, bringing the company's annual support of unrestricted cancer research to $5.34 million. Emil Frei, who will administer the Farber grant, said it would be used in part to support young people doing studies in molecular biology relevant to developmental therapeutics. Henry Pitot, who will administer the McArdle grant, said it would help young scientists engaged in studies to bridge the fields of chemical and viral carcinogenesis.

REGIONAL GROUPS HEADED BY SPURR, SCHEIN IN LEAD FOR NCI SUPPORT

(Continued from page 1)

15 other regional groups. They will join two other regional groups, the North Central Cancer Treatment Group and the Northern California Oncology Program, and the national groups as NCI supported cooperative groups.

POA is headed by Charles Spurr, director of the Oncology Research Center at Bowman Gray School of Medicine in Winston-Salem, N.C. Chairman of the MAOP is Philip Schein, chief of the Div. of Medical Oncology at the Lombardi Center and assistant director for clinical research, in Washington D.C.

NCI's Div. of Cancer Treatment has set aside $1.5 million to fund new regional groups and had hoped that that amount would support at least three. The POA and MAOP budgets are in the range of $500,000 each, leaving enough money for a third group. However, none of the others scored well enough in the review to be considered.

The reviewers, an ad hoc committee sometimes called "CCIRC B," rated POA's application the best and clearly in a fundable range. MAOP's was next, on the border of what is expected to be the payline but close enough for funding. Although NCI has not made a decision yet on funding MAOP, it does not seem likely that the group would be left unfunded considering the Institute's determination to encourage regional groups.

The Mid-Atlantic Oncology Program includes 11 medical centers and 25 major private practice groups in Delaware, Central Pennsylvania, Maryland, D.C. and Virginia.

The 11 medical centers are Lombardi, George Washington Univ., Howard Univ., Univ. of Maryland Cancer Center (formerly the Baltimore Cancer Research Program component of NCI), Geisinger Clinic, Wilmington Oncology Program, Univ. of Virginia (Charlottesville), Medical College of Virginia (Richmond), Eastern Virginia Medical Center (Norfolk), Washington D.C. Veterans Administration Hospital, and Malcolm Grow Hospital at Andrews Air Force Base.

Jack Maier, who heads radiation oncology at Fairfax Hospital in Virginia, is cochairman of MAOP. Schein said that the group's board of directors includes "strong representation" of surgeons and radiation oncologists and that each disease oriented committee has two cochairmen of different disciplines "to assure that this group will not be dominated by medical oncologists."

The Mid-Atlantic Society of Radiation Oncologists will participate in the group's activities. Statistical support will be provided by EMMES Corp., which provides that service for other cooperative groups.

The Piedmont Oncology Assn. includes 34 institutions in five states among its membership. They are:

North Carolina—Mission Memorial Hospital, Asheville; Stanly Memorial Hospital, Albemarle; Alamance County Hospital, Burlington; Charlotte Memorial Hospital, Charlotte; Gaston Memorial Hospital, Gastonia; Moses H. Cone Memorial Hospital, Greensboro; Catawba Memorial Hospital, Hickory; Moore Memorial Hospital, Pinehurst; Rex Hospital, Raleigh; Nash General Hospital, Rocky Mount; Rutherford County Hospital, Rutherfordton; Rowan Memorial Hospital, Salisbury; Spruce Pine Community Hospital, Spruce Pine; Iredell Memorial Hospital, Statesville; Valdese General Hospital, Valdese; Wilson Memorial Hospital, Wilson; Forsyth Memorial Hospital and North Carolina Baptist Hospital (affiliated with Wake Forest Univ.-Bowman Gray), Winston-Salem.

South Carolina—Aiken Community Hospital, Aiken; Roper Hospital and St. Francis Xavier Hospital, Charleston-Mt. Pleasant; Baptist Medical Center, Richland Memorial Hospital, and Univ. of South Carolina-Veterans Administration Hospital, Columbia; McLeod Regional Medical Center, Florence; Greenville; Self Memorial Hospital, Greenwood; Spartanburg General Hospital, Spartanburg.

Tennessee—Bristol Memorial Hospital, Bristol; Johnson City Medical Center and East Tennessee State Univ.-Mountain Home Veterans Administration Hospital, Johnson City-Mountain Home; Holston Valley Community Hospital, Kingsport; and Johnson County Memorial Hospital, Mountain City.

Virginia—Lewis Gale Hospital, Salem.

Georgia—Memorial Medical Center, Savannah.

Current membership in POA is 82, and the group has 19 active protocols. Douglas White of Bowman Gray is the executive officer and Bradley Wells, also of Bowman Gray, is statistician. The group's executive committee includes two thirds of its membership from the other institutions and is well represented with radiation oncologists, surgeons and pathologists, in addition to medical oncologists. Spurr is a medical oncologist.

Spurr organized the group "when we started seeing many trained clinical investigators going into practice and realized they were competent to go into clinical trials," he said. "They are willing to work if there is a system to help them with the data collection."

In addition to its own protocols, POA cooperates with Cancer & Leukemia Group B and the Gynecologic Oncology Group.

The POA and MAOP grants will go to the National Cancer Advisory Board for approval at its May meeting.

Several of the new regional groups which will not be funded (some of them were approved by CCIRC B but with scores well out of the funding range) may apply for one of the upcoming Community Clinical Oncology awards.

HOPKINS CHALLENGES LITTON BIONETICS FOR RESEARCH CONTRACT AT FREDERICK

Johns Hopkins Univ. has mounted a serious challenge to Litton Bionetics Inc. for the research portion of the Frederick Cancer Research Facility contract, perhapse the most serious since Litton won the contract when it was first competed 10 years ago, ***The Cancer Letter*** has learned.

If Hopkins gets the contract, the university will form a nonprofit corporation to handle it. Personnel working under the contract would be employees of the corporation.

Significantly, most of the scientists at FCRF, who are now employees of Litton, have agreed to switch to Hopkins if the university wins the award. There may be one or two notable exceptions, but the research team would remain intact. The scientists would not necessarily be on the Hopkins faculty, but would be employees of the corporation.

Litton is facing tough competition for all three of the contracts for which it was eligible, including the research. The others are for operations and technical support, as one contract, and animal production as the other. Two other contracts, for computer services and library services, were limited to small businesses, and they also drew spirited competition.

Splitting up the job of operating the facility for NCI into five contracts thus had its intended effect, to provide some competition for Litton. When the contract was recompeted as one job five years ago, Litton had no opposition. There was intense competition when the contract was first awarded in 1972.

Litton has made an all out effort to keep the research, support and animal operations intact and can argue that splitting them up among two or three different organizations inevitably results in duplication, overlap and possibly other inefficiencies.

Hopkins has bid only on the research contract. ***The Cancer Letter*** was unable to learn if any organization other than Litton submitted proposals for more than one of the three major contracts.

The possibility exists that three different organizations will be performing the three major operations at FCRF during the next five years. The operations and support contract was designed to assume much of the overhead from the other contracts. "There are certain overhead costs that will be repeated," one observer said. "You can't have the same personnel office for two or three or five companies, for instance. It's just got to be more expensive to split this up."

On the other hand, splitting it up apparently was the only way that competition could be assured, and NCI is betting that competition will hold costs down.

The RFP did include the requirement for proposers to spell out how interactions with other contractors will be carried out.

The proposals were reviewed by an ad hoc committee established by NCI's Div. of Extramural Activities. Elizabeth Miller, renowned for carcinogenesis studies with her husband James Miller at McArdle Laboratory, was chairman of the committee.

NCI Research Contracts Branch staff was due this week to begin reviewing minutes of the committee's meetings. The staff will then determine competitive ranges for the five contract areas, then initiate oral discussions with those organizations at the top. Those discussions could take up to a month, followed by further responses from the proposers and subsequent NCI evaluations.

The Litton contract expires at the end of September and NCI hopes to announce the awards sometime during the summer.

STUDY SECTION MEMBERS SEEK RETURN TO "NORMALIZATION," SLIDING SCALE

The NCI and NIH budget crunch which has brought about funding of grants at ever lower priority score "paylines" is leading to practices which may compromise the study section process while at the same time placing more significance on those scores than they deserve, members of one study section have pointed out.

Members of the NIH Chemical Pathology Study Section, in a letter they sent as individuals and not representatives of the study section, to Henry Pitot, chairman of the National Cancer Advisory Board, noted that the present situation was allowed to develop when NIH abandoned the "normalization" of priority scores.

Normalization was the process in which "raw" scores assigned to grant applications by each study section were adjusted through a formula to achieve comparability among all of them. That practice was abandoned about two years ago when NIH decreed that henceforth only raw priority scores would be recognized.

The growing pressure on the budget has forced NCI and other institutes to establish paylines to ensure that when significant numbers of approved grants had to go unfunded, only those judged by study sections as of the highest quality would be paid.

The problem with establishing a mandatory payline is that it sets up an "all or nothing" number, paying fully one grant that may be only one point better than another which gets no money at all.

"We're funding grants at their full recommended budgets with a 180 score, while not giving anything to a grant that comes in at 181," one study section member told ***The Cancer Letter.*** "There really isn't that much difference between the two, and in fact the guy at 181 may have put in a proposal that another study section would have scored at 170."

NCI staff members have said they feel that a difference of up to 20 points in priority scores frequently is no difference at all in quality of science.

The letter to Pitot proposed a remedy: funding grants on a sliding scale, along with a return to use of normalized scores.

"We, a group of investigators involved both in the review and receipt of NIH research grants are becoming concerned with the increasing difficulties in translating our judgments on the scientific merit of NIH grant applications into useful guidelines for selecting those grants to be funded," the letter said. "At least two problems have been discussed by us at some length: (a) the delineation of a mandatory cut off priority and (b) the increasing competition among study sections and the impact this is having upon the selection of approved applications for funding.

"The removal of normalization and setting of mandatory cut off priorities has begun a process of competition between study sections. If these trends are allowed to go unchecked, study sections will tend to give all those proposals they judge to be worthy of funding, scores approaching 100 with the consequence that the NIH staff will then be forced to choose from among many "near 100" proposals those to be funded. This could weaken the utility of the study sections and certainly might compromise participation in this process or confidence in it.

"The second problem posed by a mandatory cut off is that it places a significance and precision on the priority score that it does not have. Priority scores have a certain percentage or number of points that represent their imprecision. At times when a small proportion of approved grants is being funded, some mechanisms should be instituted to compensate for this imprecision. We suggest that some mechanism be developed to relieve this problem, for example, the 'sliding scale' as proposed by Mandel, et al., in *Science*.

"The sliding scale could be applied so that, e.g., the top one third of applications could be funded on a scale from 50 to 100 percent of requested funds. This should be done without a reduction in the number of new grants. Such a sliding scale coupled with normalization seems important to us if we are to continue to encourage talented young scientists as well as established workers to make important contributions to cancer research, toxicology, and other important areas of human health."

The letter was signed by George Bowden, Colin Campbell, Nancy Colburn, Emmanuel Farber, John Fraser, Ann Ganesan, Stephen Hecht, Colin Jefcoate, David Kaufman, Ann Kennedy, Charles King, Michael Lieberman, Justin McCormick, Carl Peraino, John Scribner, Hishashi Shinozuka, and Thomas Slaga.

Pitot agreed that their suggestions were reasonable. His response:

"The problems that you have pointed out are of utmost importance to us all and the solutions that you suggested are certainly realistic.

"As you know the cut off priority is not an absolute. The NCAB voted to allow the division directors and the director of NCI to make reasonable exceptions to the cut off priority and pay some grants beyond the priority if specific reasons such as program relevance, importance to the National Cancer Program, etc., could be justified. The Board also explicity requested that any such exceptions should be made known to the Board at the meeting immediately following the funding of the grant. In this way some balance, especially with the elimination of normalization, can be maintained. Since the Board is kept appraised of such decisions, any untoward decisions could be flagged for consideration by the Board.

"However, this format does not adequately deal with the point that you raise in the second paragraph. I am not sure that bringing back the use of normalization of priorities would be the answer but many have certainly suggested it. On the other hand the 'sliding scale' concept of funding is certainly a reasonable one. As you know this was applied to the funding of [cancer center] core grants early in this fiscal year. However, because of budgetary constraints, this was not continued into this calendar year. The 'sliding scale' also has problems as you know, such as the requirement for an absolute cut off in order that the scale be established. Thus no solution is free of problems but hopefully one or another minimizes."

Pitot said he would bring the matter to the attention of the NCAB and its Subcommittee on Planning & Budget.

TOBACCO RESEARCH COUNCIL AWARDS 34 NEW GRANTS; 1981 TOTAL, $6 MILLION

Thirty-four new grants covering a variety of research areas related mostly to cancer, cardiovascular disease and chronic pulmonary ailments have been awarded by the Council for Tobacco Research.

The new projects, together with renewals of continuing studies, came to $6 million and thereby increased the Council's research funding to more than $69 million since 1954.

Among the projects, which were approved in 1981, are studies on interferon, the effects of aging and lipids on the immune system, nicotine and neuronal development, and smoking, detection bias and primary lung cancer.

Grant recipients alone are responsible for disclosing their findings in professional journals or at meetings of their peers. As of the end of 1981, they had published 2,025 scientific reports and articles acknowleding Council support.

Recipients of new grants, their institutions and the titles of their projects:

John Albers, Univ. of Washington School of Medicine, High density lipoportein quantitation.

Thomas Aune, Jewish Hospital of St. Louis, Interferon–activation of suppressor T cell pathways.

Ira Black, Cornell Univ. Medical College, Nicotine and neuronal development.

Vincenzo Buonassisi, Univ. of California (San Diego), Heparan sulfate proteoglycans and blood homeostatic mechanisms.

Edward Bresnick, Univ. of Vermont College of Medicine, Expression of cytochrome P450c.

Jan Chlebowski, Medical College of Virginia, Calorimetric investigation of proteinase–alpha-2 macroglobulin interaction.

Curt Civin, Johns Hopkins Oncology Center, Biochemistry and function of human granulopoietic antigens.

Robert Colman, Temple Univ. School of Medicine, Initiation of plasma coagulation and kinin forming systems in man.

Gidon Czapski, Hebrew Univ., Jerusalem, On the toxicity of oxygen and superoxide ion: Is superoxide toxic?

Alvan Feinstein, Yale Univ. School of Medicine, Smoking, detection bias and primary lung cancer.

Joseph Feldman, Scripps Clinic & Research Foundation, Effects of aging and lipids on the immune system.

Thomas Finlay, New York Univ. Medical Center, Structure, properties and regulation of mouse plasma protease inhibitors.

Birgitta Floderus-Myrrhed, Karolinska Institute, Stockholm, Epidemiologic research on the Swedish twin registries.

Gabriel Godman, Columbia Univ. College of Physicians & Surgeons, Cytoskeletal organization of the endothelial cell in regulation of shape, contractility and surface movement.

Maurice Green, St. Louis Univ. Medical Center, Amplification of human adenovirus transformation proteins in prokaryotic and eukaryotic cells.

Nobuyushi Hagino, Univ. of Texas Health Science Center, Nicotinic receptors of LHRH axon terminals in the median eminence.

Ingegerd Keith, Univ. of Wisconsin School of Veterinary Medicine, Part I: Lung neuroendocrine cell innervation; Part II: Transplacental effect of smoking on lung neuroendocrine cells in the neonate.

Robert Kreilick, Univ. of Rochester, Investigations of the interaction of nicotine with membranes.

Lawrence Kupper, Univ. of North Carolina School of Public Health, Verification of a statistical age-period-cohort analysis of lung cancer.

Gesina Longenecker, Univ. of South Alabama College of Medicine, Studies of platelet and endothelial prostanoid production as possible cardiovascular risk indicators in smokers.

Ronald Luftig, Univ. of South Carolina School of Medicine, Interactions between RNA tumor viruses and chemical carcinogens.

Harold Newball, Johns Hopkins Univ. School of Medicine, The role of proteases and antiproteases in pulmonary emphysema.

Bendicht Pauli, Rush Presbyterian-St. Luke's Medical Center, Local regulation of tumor invasion by host-derived proetinase inhibitors.

Julia Polak, Hammersmith Hospital, London, Investigation of the role of regulatory peptides in human lung disease.

William Pryor, Louisiana State Univ., Free radical chemistry of cigarette smoke.

Ishaiahu Schechter, Tel Aviv Univ., Effect of thiols and disulfides on cholesterol metabolism.

Benjamin Schwartz, Washington Univ. School of Medicine, Comparative molecular studies on HLA antigens.

Robert Sklarew, New York Univ. Research Service, Cytokinetics of heteroploid subpopulations by imaging.

Daniel Steinberg, Univ. of California (San Diego), Arterial degradation of low density lipoproteins in vivo.

D. Lansing Taylor, Harvard Univ., Chemotaxis of macrophages.

Peter Walsh, Temple Univ. School of Medicine, Interaction of platelets with coagulation factors IX and X.

Sigmund Weitzman, Massachusetts General Hospital, Studies of phagocyte-induced mutation.

John Wilson, The isolation and expression of human alpha-1-antitrypsin gene sequences through molecular cloning.

Stanley Yachnin, Univ. of Chicago Medical Center, Models for the pathogenesis of atheroschlerosis: A) biological effects of oxygenated sterol compounds; B) mevalonic acid and cholesterol biosynthesis and the biosynthesis and the regulation of cell growth.

NCI CONTRACT AWARDS

Title: Provision of hematopoietic cell cultures, growth factors, and type-C virus proteins as related to human leukemia
Contractor: Litton Bionetics Inc., $2,897,535.

Title: Intralesional immunotherapy prior to surgery in the treatment of canine breast carcinoma, continuation
Contractor: Univ. of Texas Health Science Center, San Antonio, $78,243.

Title: Adoptive cellular immunotherapy of murine tumors, continuation
Contractor: Univ. of Washington, $198,535.

Title: Cancer Communications Network (CCN)
Contractor: Penrose Hospital, Colorado Springs, $479,913.

PROGRAM ANNOUNCEMENT COMPLETES NCI SWITCH TO CANCER CONTROL RESEARCH

The second part of NCI's effort to replace the existing cancer control core grants, which have supported outreach activities at 23 centers, with support for cancer control research has been initiated with the program announcement for the Cancer Control Science Program (see below).

The first part of that effort, the RFA for Cancer Control Research Units, was published in February. CCRUs will be limited to research with defined populations; CCSPs will be permitted to undertake essentially the same activities but use of a defined population will be optional.

NCI's Div. of Resources, Centers & Community Activities has budgeted $7.5 million for the two programs. In discussions with the DRCCA Board of Scientific Counselors, Carlos Caban, program director for both CCRU and CCSP, had indicated NCI hoped to fund five CCRUs at up to $1 million each.

Lester Breslow, member of the DRCCA Board, had asked that NCI allocate equal amounts for CCRU, CCSP and the Community Clinical Oncology Program. NCI Director Vincent DeVita has said that CCOP would be funded up to $10 million.

It was not in the cards for CCRU and CCSP to get $10 million each, however. The NCI Executive Committee established the total figure at $7.5 million. If it develops that CCRUs are funded at $5 million, that will leave $2.5 million for CCSP.

The latter is a more open ended program than CCRU. Applications will be accepted in each funding cycle, while CCRU applications will be taken only for this first round. CCRU renewals will be considered when the three to five year grant periods expire.

The change in direction of cancer control as supported by NCI is significant and will have considerable impact on the 23 centers which have been getting that support. Those activities involve for the most part public and professional education. The switch to cancer control research, with emphasis on epidemiology, will require staff members with different expertise. And unless alternative support can be found, those outreach activities will go unfunded when the present grants expire.

PROGRAM ANNOUNCEMENT

Cancer Control Science Program, NCI

The Div. of Resources, Centers & Community Activities, NCI, invites grant applications from interested investigators for the support of Cancer Control Science Programs. These programs will provide a scientific focus within which investigators can conduct a variety of cancer control research studies.

This Cancer Control Science Program, together with the Cancer Control Research Units for Defined Population Studies program, replace the outreach program previously supported by NCI through grants to cancer centers. The availability of a Request for Applications for a single competition for Cancer Control Research Units for Defined Population Studies was announced in ***The Cancer Letter*** Feb. 26.

Cancer control research includes both prevention (primary and secondary) and management (diagnosis, pretreatment evaluation, treatment, rehabilitation, and continuing care). It builds on the research and knowledge bases of epidemiological, biomedical, clinical, behavioral and other sciences. It requires carefully designed investigations, often including both study and control goups and/or defined denominator populations.

The national cancer effort includes both research into and application of control methods. These are complementary and not antagonistic activities and are part of an ordered sequence, as indicated in the following statement adapted by the DRCCA Board of Scientific Counselors from the report of the President's Biomedical Research Panel:

The continuum from the discovery of new knowledge and the relating of new knowledge to the application of such knowledge in health care includes a number of steps:

1. Discovery, through research, of new knowledge and the relating of new knowledge to the existing base.
2. Translation of new knowledge, through applied research, into new technology and strategy for movement of discovery into health care.
3. Validation of new technology through clinical trials in defined populations, and in other ways.
4. Determination of the safety and efficacy of new technology for widespread dissemination through demonstration projects.
5. Education of the professional community in proper use of the new technology and of the lay community on the nature of the developments.
6. Skillful and balanced application of the new developments to the populations.

Cancer control includes 2 through 5, although different relative emphasis may be placed on each of those points depending on the specific cancer and whether prevention or treatment efforts are involved.

Control and research must be mutually reinforcing and only the coordinated planning and implementation of research and control strategies will assure maximum yield from the dollars invested, maximum quality for the activities supported, and maximum probability that the research effort will continue to provide advance suitable for future application in the control of cancer.

Cancer control should support three types of activities in defined populations:

1. Research to determine how, whether and to what extent actions proposed for a particular cancer

are effective.

2. Research to determine the optimal strategies for promoting actions proved efficacious for particular cancers.

3. Selective implementation of those promotional strategies proven efficacious for particular cancers.

Cancer control efforts should give highest priority to cancers meeting more than one of the following criteria:

1. Cancers causing the greatest mortality/morbidity in the United States.

2. Cancers for which substantial risk of cancer has been associated with common exposures.

3. Cancers for which apparently effective actions are available.

The development of an effective national program for cancer control requires qualified personnel, particularly with training and experience in the disciplines of epidemiology, biostatistics, and disease control administration, and the placement of these individuals in responsible positions.

DRCCA is testing the idea of categorizing cancer control research studies into phases. Applicants are asked to classify each research project as phase I, II, III, IV, or V, and also as prevention (primary and secondary) or management (diagnosis, pretreatment evaluation, treatment, rehabilition and continuing care). If a study does not fit this classification, the reasons it does not fit should be described.

Phase I—Hypothesis Development—Development of cancer control hypotheses of which control measures, approaches, or interventions should be tested to determine whether they can reduce cancer incidence, morbidity and/or mortality. These hypotheses often will come from basic laboratory, clinical, or epidemiological research which provides evidence for etiological associations or clinical advances for a specific cancer; the basic research itself will not be considered part of cancer control research.

Phase II—Research on Study Components or Methods Needed to Test the Hypothesis—Methodological research is included here, such as development and testing of questionnaires, studies of compliance, development and testing of screening procedures, pilot tests of the control measures identified in the hypotheses, or testing of methods from other diseases or disciplines on cancer problems.

Phase III—Case Control Studies and Other Controlled Studies Which Are Not Defined Population Studies—These are research efforts aimed at testing a hypothesis. While the populations may not necessarily be representative of any larger population, the cancer control idea should receive a careful scientific assessment. Certain cohort or cross sectional studies might be considered here (though technically not case control), if they do not meet the criteria for a defined population study. Controlled studies of cancer control measures or interventions, which test the efficacy of the measure, would be appropriate here. Phase III studies should incorporate the results of Phase II studies in their design.

Phase IV—Defined Population Studies—The primary aim of these studies is to allow estimates of the potential impact of the control measures if more broadly applied to a major segment, or the entire population, of the United States. Therefore, in these studies, the denominator as well as the munerator populations must be identified. Thought should be given to how well the defined population represents the larger population to which results may later be generalized. These studies may avoid the selection biases in some case control studies. Phase III studies generally precede Phase IV studies, and should justify undertaking the Phase IV study.

Phase V—Demonstration and Implementation Studies—This phase follows careful research in each of the preceeding phases and must be justified on the basis of these earlier studies. It includes research and evaluation efforts related to the demonstration and implementation studies.

As new studies are planned, the background or rationale for each study should identify research results from earlier studies that justify the phase of the proposed study. For example, if a Phase III study is proposed, what research has been done of the Phase I or Phase II types; if a Phase V study is proposed, what research has been done of Phase I-IV types? Note that Phase IV defined population studies precede Phase V demonstration and implementation projects.

(Comments and suggestions about how this classification system may be improved are welcome, including suggestions for modifying or expanding the definitions of the various phases in order to cover the total scope of cancer control research.)

Cancer Control Science Program: Scope and Content

Purpose of this program announcement is to encourage the development of Cancer Control Science Programs (CCSP). Grants under this announcement will support a number of CCSPs throughout the United States which together with the Cancer Control Research Units, will be designed to plan and implement cancer control research studies and to serve as a resource for the cancer control research program of the National Cancer Program.

The CCSP is designed to provide support for: a core group of researchers who will perform cancer control research studies; a minimum of three cancer control research projects which can successfully undergo review for scientific merit; developmental funds for pilot projects which are of high scientific merit and have future promise of becoming supported as individual peer reviewed research projects; and other resources, such as data support, which can be justified as necessary to achieve the goals of the CCSP.

DRCCA intends to support these CCSPs as grants for project periods of up to five years. New competing applications will undergo review for scientific merit by an NCI review group and subsequent review by the National Cancer Advisory Board. Renewal of the initial award beyond five years will be contingent upon satisfactory review of a competing renewal application. A maximum of $7.5 million will be available for the combination of the Cancer Control Science Program and the Cancer Control Research Units for the first year of support (FY 1983).

Detailed Cancer Control Science Program: Guidelines are available which describe further the scope of cancer control research, the eligibility for application, the letter of intent procedure, and the review procedures and criteria. A letter of intent should be submitted and discussions with program staff held before a grant application can be submitted. An institution wishing to participate in this effort must submit an application in accordance with the guidelines specified in the CCSP Guidelines.

Application deadlines for the first cycle start with the letter of intent, due May 15. The application receipt date is Aug. 15, with review from September to April, 1983, NCAB review in May 1983, and award July 1, 1983. Subsequent cycles start with letter of intent due dates of Sept. 15, Jan. 15, 1983, and May 15, 1983.

Direct inquiries and correspondence to: Carlos E. Caban, PhD, Program Director, NCI-DRCCA, Blair Bldg. Rm. 716B, 8300 Colesville Rd., Silver Spring, Md. 20910; phone 301-427-8663.

The deadline for letters of intent for responses to the RFA for Cancer Control Research Units in Defined Populations has been changed from March 31 to April 30, and from July 15 to Aug. 15 for submission of applications. Copies of that RFA are still available from Caban.

CANCELLATION NOTICE

The Program Announcement Experimental Research Related to Mammographic Screening for Human Breast Cancer, published in 1980, has been canceled. The Breast Cancer Program of NCI no longer considers it necessary to provide special encouragement for grant applications for animal and tissue culture studies that will provide new and relevant information on problems related to mammographic screening for human breast cancer. Cancelation of this program announcement does not prevent an investigator from submitting a grant related to this topic through the regular DRG mechanism.

ELIGIBILITY OF PROFIT MAKING ORGANIZATIONS FOR GRANTS AND COOPERATIVE AGREEMENTS

Effective Jan. 4, 1982, for-profit organizations became eligible to apply for assistance awards (research grants and cooperative agreements) under most sections of the Public Health Service Act. The application, scientific merit review, and award processes are the same as those applicable to nonprofit organizations.

All information contained in applications will be kept confidential and will be made available only to NIH staff and to the reviewers who provide an evaluation of the proposed project. Applications for research projects are to be submitted on application form PHS-398 which may be obtained from the office listed below.

Annual application receipt dates are on or before: July 1, Nov. 1, and March 1. Research scientists from for-profit organizations are encouraged to request a copy of NIH Extramural Programs, a compendium of the scientific programs of the NIH's Bureaus, Institutes, and Divisions.

Office of Grants Inquiries
Div. of Research Grants, NIH
Westwood Bldg Rm 449
Bethesda, Md. 20205

RFP NIEHS-82-50002

Title: *Mouse lymphoma assay*
Deadline: *May 28*

The National Toxicology Program is interested in receiving proposals designed to generally follow the procedure of Clive and Spector (Mutation Research 31, 17-29 (1975) to determine the mutagenicity of coded compounds in the L5178Y mouse lymphoma forward mutation TK+/− TK−/−bioassay. Each contractor will assay up to 50 chemicals per year. The NTP estimates that this project will be for a four year period.

Contract Specialist: Lynn Greenfield
RCB, Blair Bldg. Rm. 2A01
301-427-8764

NCI CONTRACT AWARDS

Title: Alteration/renovation/maintenance/upgrading projects at Frederick Cancer Research Facility, modification
Contractor: Litton Bionetics Inc., $160,000.

The Cancer Letter _Editor Jerry D. Boyd
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