THE CANCER LETTER

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CCOP RFA ISSUED: 'CHOP-LIKE' ELEMENTS PERMITTED BUT NOT REQUIRED; NO 'CAP'; CONSORTIA ALLOWED

The long awaited, hotly debated request for applications for the Community Clinical Oncology Program, which includes details on requirements which must be met to compete for the awards that will support clinical research in community hospitals, has been completed. Its provisions probably will not completely satisfy all of the various groups

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In Brief

BRISTOL HAS CHANGE OF HEART, AGREES TO SUPPLY NCI WITH VP-16 FREE FOR GROUP C DISTRIBUTION

BRISTOL-MYERS has switched directions and agreed to supply NCI free of charge the investigational drug VP-16 for distribution through the Div. of Cancer Treatment's Group C mechanism. The DCT Board of Scientific Counselors had advised against continuing free distribution of the drug to physicians, which had been costing a half million dollars a year, unless Bristol could be persuaded to provide it at no cost. Bristol balked (***The Cancer Letter,*** June 25), but in negotiations conducted by DCT Deputy Director Saul Schepartz, the company agreed to provide free quantities of the drug equal to any purchased by NCI for use in clinical trials, presently costing about $500,000 a year. Bristol executive Max Gordon said the major obstacle had been the issue of liability, which was removed when NCI agreed to continue distributing the drug through Group C until it is approved for marketing by FDA. . . .**NCI RETIREMENTS: Margaret Edwards,** long time head of clinical education programs, credited with developing some of NCI's most successful efforts in professional education. The Assn. of American Cancer Institutes approved a resolution commending her for the outstanding contributions she has made. **Clyde Dawe,** chief of the Comparative Oncology Section in the Laboratory of Pathology. His major interests have been polyoma virus studies and tumors in cold blooded vertebrates. **Walter Hardy,** biologist in the Radiobiology Laboratory, who worked in the lab's long term mouse lung toxicity and radiation effects studies. . . . **NIH APPOINTMENTS: Richard Crout,** who left the Food & Drug Administration after 10 years as director of the Bureau of Drugs, named associate director for medical applications of research and head of the Office of Medical Applications of Research. He replaces Charles Lowe, who will remain as Crout's special assistant. Lowe had been acting director since the departure of Seymour Perry to head the National Center for Health Care Technology, which subsequently was abolished by Congress. Perry has since been with the Assn. of American Medical Colleges as director of the Div. of Biomedical Research. **Claude Lenfant,** director of the Fogarty International Center at NIH, named director of the National Heart, Lung & Blood Institute.

CCOP RFA SETS AUG. 23 FOR LETTERS OF INTENT, NOV. 9 FOR APPLICATIONS

(Continued from page 1)

which contributed to its development, but NCI executives feel it is a workable compromise which they hope will form the basis for one of the most ambitious and visible programs the Institute has ever undertaken.

The most controversial aspect of the program was whether it would provide for support of cancer control activities, other than clinical research. Proponents argued that at least the RFA should require CCOPs to include "CHOP-like" elements—features of the Community Hospital Oncology Program such as patient management guidelines, professional and patient-family education efforts, and other programs aimed at involving primary care physicians.

The RFA does not include that requirement, but it does permit those activities. Robert Frelick, program director for CCOP in NCI's Div. of Resources, Centers & Community Activities, acknowledged the view by some "that CHOP-type guidelines may alert physicians to the potential a research protocol may have for patients and thus help recruit patients for CCOP research protocols. Although they are not required as part of CCOP, they may be used if justified in the proposal."

NCI executives feel that much of the controvery arising in development of the RFA was caused by a misunderstanding of the nature of the funding mechanism, which will be cooperative agreements. That mechanism is very much like an NIH grant, in that a considerable degree of flexibility is permitted. Specific details such as are usually reuqired by the contract mechanism are avoided, thus allowing participating institutions substantial latitude in designing the type of programs they wish to undertake.

Frelick stressed that while cancer control elements are not required by the RFA, they will be considered in the review and will count in the evaluation of proposals.

Other controversial provisions in the RFA include:

• The "tithe." The requirement that a minimum of 50 patients a year will be entered on study protocols, and at least 10 percent of eligible patients "in suitable disease categories" available for study to participating physicians be included, remains in the RFA. NCI insists that this is a flexible requirement in that CCOPs and their research bases may negotiate that number in advance, with CCOPs permitted to determine then the mix of patients they will be committed to supply. Patients referred to centers, as opposed to those treated in the communities, each will count as 1.25 toward the 50 minimum and tithe.

• There is no "cap" on the number of patients which CCOPs may enter on research protocols, nor is there a limit on the number of institutions that may participate in a single CCOP.

• When community hospitals now participating in the Cooperative Group Outreach Program successfully compete for a CCOP award, their funding from the cooperative groups will be terminated *and that money will revert to NCI's Cancer Control Program.* This inevitably will shrink the size of the cooperative group program, but NCI executives say that this will be more than made up through affiliations of the groups, as research bases, with CCOPs. Cooperative group leaders are skeptical.

• Cooperative groups also have been worried over the prospect that CCOP-research base agreements will result in some groups securing patients at the expense of others. The RFA requires that patient allocation be agreeable to all research bases affiliated with a CCOP.

Delays in issuing the RFA have put the program at the limit in deadlines if funding is to start during the 1983 fiscal year. The first deadline is Aug. 23, when letters of intent are due. That does not allow applicants much time to pull together the elements they will need just for the letter (see section on letters of intent in the RFA). Deadline for complete applications is Nov. 9.

The RFA includes names, addresses and phone numbers of various individuals and offices at NCI to contact for more information and assistance.

The complete RFA follows, with some editing to eliminate background material.

RFA No. 10-NIH-NCI-DRCCA
COMMUNITY CLINICAL ONCOLOGY PROGRAM

The director of NCI is interested in establishing a large scale cancer control effort which involves practicing community oncologists in the NCI clinical trials programs. The purpose of the program is to utilize as a resource the increasing number of highly trained oncologic specialists who have entered community practice in recent years. Combining the expertise of community physicians with ongoing clinical research projects will result in a dynamic development and exchange of the newest clinical treatment research findings at the community level. The Community Clinical Oncology Program (CCOP) should: (1) provide adequate support for expanding the clinical research effort in the community setting; (2) involve primary care physicians early in the course of clinical treatment research to provide the benefits of clinical investigation to communities; (3) establish a base for an extension of other cancer control efforts in the areas of prevention, early detection, rehabilitation, and supportive care; and (4) examine selected issues in CCOP performance (e.g., patient accrual and evaluability) and the diffusion of innovative information.

The CCOP initiative is intended to meet the needs of cancer patients by utilizing the trained specialists now practicing in community hospitals and clinics and establish a system of community clinical oncology programs which will participate in clinical research trials. Over 80 percent of patients with cancer are treated in the community with only a small number entering clinical trials.

Experience within several cooperative groups has indicated that physicians caring for cancer patients in the community can maintain high quality clinical research activities similar to that of the academic centers. Evidence exists that new technology can be transferred effectively by having community

physicians participate in clinical research activities.

CCOP will be developed and supported by DRCCA. Participating community programs will be required to enter or refer into NCI-approved clinical trials, designated as high priority by a research base with which the CCOP is affiliated. These research bases may be national or regional multidisease cooperative groups, specialized cooperative groups or cancer centers currently participating in NCI approved clinical research protocols. Participants are encouraged to enter patients with early stage disease with common cancers and to enter or refer, if appropriate, patients with uncommon cancers.

Patient entry onto clinical trials will be done through collaboration with a maximum of (1) two primary multidisease research bases (with two, only one may be a cooperative group) having a spectrum of clinical trial protocols available and (2) a maximum of three specialty research bases. Participation with specialty or multidisease research bases will be considered equal and a CCOP may choose only one of either or a maximum of five when combined affiliations occur. Eligible patients in a single disease category should be allocated to one protocol in the case where multiple affiliations have resulted in overlapping protocols.

The diffusion hypothesis will be tested during the course of the program. A separate CCOP evaluation is planned to test this hypothesis. According to this hypothesis, it is anticipated that participation of some patients in research will beneficially influence those patients not participating in research protocols. Information diffusion in future cancer control programs of the NCI will similarly be tested.

The CCOP initiative is designed:

A. To bring the advantages of clinical research to cancer patients in their own communities, by having practicing doctors and their patients participate in clinical treatment research protocols, and thus foster an exchange between clinical research and cancer control.

B. To reduce national mortality by speeding the transfer of newly developed cancer treatment technology to widespread community application.

C. To provide a basis for involving a wider segment of the community in cancer control activities and investigate the diffusion of cancer therapy advances in community medical practices. The diffusion hypothesis presumes that introduction of quality controlled clinical research trials in the community will also benefit those patients not treated as part of this protocol.

D. To develop programs to serve as part of a broadly based nationwide resource for quality controlled distribution of increasing numbers of experimental anticancer agents.

E. To facilitate wider community participation in future cancer control and prevention research activities planned by NCI.

CRITICAL ELEMENTS FOR A CCOP

A. The CCOP may be a single clinic, a group of practicing physicians, a single hospital, or a consortium of physicians and/or clinics and/or hospitals.

NCI recognized comprehensive and clinical cancer centers (holding core grants) are not eligible. A university hospital which is the major teaching institution for that university will not be eligible. University hospitals and Veterans Administration hospitals may participate as a nondominant member of a consortium led by a community institution. University hospitals participating as Div. of Cancer Treatment funded cooperative group members will not be eligible. Unfunded, non-university group members will be eligible. Those institutions that currently participate as part of the DRCCA funded Cooperative Group Outreach Program or Cancer Centers Outreach Program will be eligible. Cooperative Group Outreach Program support will be terminated for successful CCOP applicants. This funding will revert to the NCI Cancer Control Program.

B. Each CCOP must have a demonstrated potential and stated commitment to contribute a minimum of 50 evaluable patients per year to approved clinical research protocols active in the center or group with which the community center is affiliated. Although the CCOP is most appropriate for adult patients, for pediatric CCOPs, the 50 patient minimal requirement will be reduced for those applicants able to place a majority of their eligible patients on protocol. The written affiliation agreements between the CCOP and its research bases will specify the priority protocols which can meet this obligation. As one measure of performance, it is expected that 10 percent or more of eligible patients in suitable disease categories available for study to physicians listed as participating in a CCOP application will be placed on protocols. The mix of cancer patients to meet the reporting requirement will be negotiated in advance with the research base. Patients transferred from the community to any NCI supported clinical research program in order to receive protocol treatment, will be credited to the CCOP. Referrals to centers for NCI supported protocol treatment will result in a credit to the referring CCOP of 1.25 per patient toward the minimum patient requirement.

C. Each CCOP is expected to have a committed multidisciplinary professional team appropriate for their expected protocol participation. This may include surgeons, radiation oncologists, medical oncologists, pathologists, oncology nurses, and psychiatrists. Administrative and data management personnel will be necessary. Other appropriate disciplines may be added (e.g. gynecologic oncologists, pediatric oncologists). One of this group will serve as principal investigator. An associate investigator should be named to assure continuity in the event of departure of the principal investigator.

D. Each CCOP must delineate its patient referral area. Consideration will be given to demographic and geographic distribution of CCOPs in the final selection process. Multiple CCOPs competing for the same patient population will be considered but may not be awarded unless warranted by the population density. Individual institutions or consortia may apply but a single administrative focus should be designated.

E. Each CCOP must provide evidence that an affiliation has been established with a nationally recognized clinical cancer research base (e.g. clinical or comprehensive cancer center, national or regional cooperative group). A list of research base options is available upon request. Multiple affiliations are permitted provided they are not conflicting. These affiliations must exist in the form of a written agreement between the CCOP applicant and corresponding research base(s) at the time of application submission. This agreement must specifically state how the problem of competing protocols is to be resolved. Initial affiliations must be maintained during the first three year funding cycle. Unusual circumstances may require changes in research base affiliations, subject to NCI staff approval. CCOP affiliations with centers and regional cooperative groups must be geographically appropriate. A CCOP applicant may not bypass regional research base programs to establish ties with distant centers unless there is clear justification and NCI staff approval.

F. The conditions of affiliation with a maximum of two multidisease research bases (with two, only one may be a cooperative group) and three special category research bases must be provided in the CCOP Resea ch Base Affiliation Agreement(s).

G. Quality controlled clinical research data is a performance requirement. Assurance of quality is the joint responsibility of the CCOP and its research base affiliate(s). Quality control procedures, operational in the center or group, will be applied to the CCOPs and must be specified in the CCOP-

Research Base Affiliation Agreement.

H. Each CCOP must have a defined space for administrative activities and administrative personnel which will serve as a focus for data management, quality control, and communication.

I. Allocation of CCOP funds to support community and research base costs for receipt, handling, and analysis of patient data should be specified in the written agreement between the CCOP applicant and its research base. Allowable items in the budget would be for administrative personnel, data handlers, and study assistants, supplies and services directly related to study activities (e.g. processing and sending material for pathology review, processing and sending port films for radiation therapy quality control) and limited travel to meetings directly related to study activities. Physician compensation would be allowable only for time spent on the project other than clinical care. Total funding as well as allowable physician compensation may be increased proportionately for participating in future NCI initiated cancer control activities. Initial funding is to be for three years.

J. The following administrative requirements prior to award will apply to all CCOP programs.

1. Management of federal funds–This ability includes the following basic requirements: A formal organization structure capable of managing the project and safeguarding the disposition of federal funds; adequate cost accounting and bookkeeping procedures including the capacity to separately monitor federal funds; time and effort policies to account for personnel costs; and accountability for all equipment, supplies and other necessary project expenditures.

2. Mandated assurances–These may be found in the Grant Application Form 398 (Rev. 5/80): Civil rights, handicapped individuals, sex discrimination, and protection of human subjects.

3. Cost Sharing–The appropriation act for HHS requires that grantee institutions share in the cost of activities supported by research grants. Some direct or indirect contribution should be made to the project.

4. Indirect costs–Unless directed otherwise, successful applicants who have not negotiated an indirect cost rate must do so. The negotiation of the indirect cost rate may begin just prior to, or immediately following, notification of grant award. Guidance on this requirement will be made available by the NCI upon approval of the application.

5. Payment procedures–Payments for grants awarded by NIH are made through the departmental federal assistance financing system. Guidance for payment will be made by NCI to successful applicants at the time of award. Under no circumstances will pre-award costs, (i.e., expenses incurred prior to actual funding) be allowed.

K. The following operational prerequisites are expected.

1. A list of protocols which will be used by the CCOP to meet patient accrual requirements must be stated in the initial application. Protocols initiated after the initial award must be filed with DRCCA staff. Protocol review and approval procedures for the CCOP will be consistent with that of the research base.

2. Each CCOP agrees to maintain a new patient log or minimal registry to include age, sex, primary site of cancer, stage of disease, and treatment disposition for the potential eligible patient pool.

3. Radiotherapy equipment must have its calibration verified by the Radiological Physics Center (RPC) or one of the regional Centers for Radiological Physics (CRP) in order for institutions to participate in this program. Information is available upon request. Prior to award, a letter of compliance will be provided.

4. Each CCOP agrees to accept periodic on site monitoring by representatives of its research base(s) or NCI or an NCI designee. The purpose of such on site monitoring may include monitoring of use of investigational drugs, accuracy of data recording, completeness of reporting adverse drug reactions, protocol accrual and quality control analysis, fiscal and administrative review.

5. Each CCOP agrees to an annual review of its progress by the executive committee of its research base(s) and DRCCA staff. This review will include, but not be limited to, overall case accrual, accrual to high priority protocols, patient eligibility, patient evaluability, and timeliness and quality of data reporting. This annual review may be the basis for probationary status or adjustment in funding.

CCOP AND RESEARCH BASES–COOPERATIVE ACTIVITIES

In preparation for submission of the application, negotiations between the CCOP and the research base should result in agreement about protocol participation, method of support for the research base (for data management) and the expected cost to the research base as a result of case accrual. Cooperation is anticipated in:

A. Planning for program development and training of support personnel (e.g. data managers, study assistants, oncology nurses, etc.).

B. Developing and/or making available appropriate clinical research protocols.

C. Establishing standards for surgery and pathology reporting procedures of the research base, community members and affiliates.

D. Holding regular meetings of the research base, community members and affiliates for review of ongoing research activities, planning of future activities, and related professional education.

E. Instituting quality control procedures for data recording, protocol compliance, and reporting of adverse reactions.

F. Instituting control procedures for treatment planning such as standardization of radiation equipment, doses and fields.

G. Establishing an organizational mechanism for the relationship between the CCOP and research base(s) and the reimbursement of research base costs. Circumstances may vary from CCOP to CCOP.

RESEARCH BASE PARTICIPATION

The general function of a research base is to collaborate to a degree appropriate to the applicant CCOP, providing protocol access, assistance in data quality control and feedback information on clinical trials performance. The CCOP-research base agreement should define mechanisms for community participants to have input as active research base members.

Each research base will need to develop a plan to support additional administrative and data management functions and to provide annual reports on protocol accrual and quality control analysis for review by DRCCA staff.

Three options for research support are available. The research base(s particpating with approved CCOPs may receive appropriate support through a supplement to their existing primary grant which will be subject to the appropriate review and approval process. Costs will be based on anticipated protocol participation and data management expectations, negotiated by NCI staff after appropriate review.

An alternative method of fiscal support for the research bases may come directly through a single CCOP, or through a lead CCOP which distributes funds to its research bases and to affiliated CCOPs in the consortium.

RESEARCH BASE OPTIONS

A. A multidisease research base–(may choose one or two)

1. NCI-funded comprehensive and clinical cancer centers

(list available on request).

2. Cooperative Groups (contact NCI for addresses and phone numbers). These are Cancer & Leukemia Group B, Eastern Cooperative Oncology Group, North Central Cancer Treatment Group, Northern California Oncology Group, Southeastern Cancer Study Group, Southwest Oncology Group, Mid-Atlantic Oncology Group, and Piedmont Oncology Group.

B. Special category research bases (maximum three)

1. Pediatric oncology research base (may choose one)—Childrens Cancer Study Group, Pediatric Oncology Group.

2. Other research bases (may choose more than one)—Gynecologic Oncology Group, Radiation Therapy Oncology Group (must clarify patient allocation if protocols overlap with category A choices), National Surgical Adjuvant Breast & Bowel Project (participation in the adjuvant protocols of this group may be a potential conflict with the protocols of a category A research base and allocation of patients must be clarified and both NSABP and the category A research base must concur in this allocation plan), Gastro-Intestinal Tumor Study Group (participation in the protocols of this group may conflict with protocols of a category A research base and allocation of patients must be clarified and both GITSG and the category A research base must concur in this allocation plan), and Lung Cancer Study Group (participation in the protocols of this group may conflict with protocols of a category A research base and allocation of patients must be clarified and both LCSG and the category A research base must concur in this allocation plan).

MECHANISM OF SUPPORT

The CCOP awards will be made as cooperative agreements. These are assistance relationships supporting projects that require substantial collaboration and involvement with NCI staff. Depending on individual CCOP costs, up to 200 awards with a total not to exceed $10 million per year, will be allocated for this program. Awards will be for periods of three years to establish the initial capabilities of the participants. Repetitive RFAs are planned. Renewal of grants after three years will be contingent upon satisfactory review of a competing application by a scientific peer review committee and the National Cancer Advisory Board.

LETTER OF INTENT

Letters of intent should precede the submission of the grant application and are due Aug. 23, 1982. These are to be detailed documents suitable for review for responsiveness to this RFA. Those judged to be nonresponsive will be returned with an explanation and the applicants will be encouraged to respond to future issuances of the RFA.

The letter of intent should address the following issues succinctly (about one page per topic):

A. A description of the CCOP organization (including catchment area and patient availability).

B. Existing cancer control activities in the area of the CCOP.

C. Names and type of practice (e.g., medical oncology, internal medicine) of participants.

D. Research affiliations, planned protocol participation and estimated patient accrual per protocol.

The total pages for the letter should not exceed 15. Applicants whose letter of intent is responsive will be notified and asked to submit full applications.

Complete applications are due on or before close of business Nov. 9, 1982. Applications must address all requirements as presented in this RFA. Applications for CCOPs and research bases should be submitted on Form PHS-398 (revised 5/80), the application form for the traditional research project grant, which is available in the business or grants and contracts office at most academic institutions and research institutions, or from the Div. of Research Grants, NIH, Bethesda, Md. 20205. This CCOP application request has no page limitation; however, applications should be as concise as possible. The words "Community Clinical Oncology Program" should be typed in bold letters on line number 2 of the face page of the application and also on the outside of the mailing package.

Additionally, a brief covering letter should accompany the application indicating that it is being submitted in response to this request. The original and six copies of the application should be submitted to the Div. of Research Grants, NIH, as directed in the grant application instructions. Two additional copies should be sent to: Referral Officer, Grants Review Branch, Div. of Extramural Affairs, NCI, Room 826, Westwood Bldg., Bethesda, Md. 20205.

REVIEW PROCEDURES AND CRITERIA

Applications responsive to this RFA will be reviewed by an appropriate peer review panel of NIH. Final review is provided by the National Cancer Advisory Board.

Reviewers will assess the ability of the CCOP to meet the requirement for entering a minimum of 50 evaluable patients per year on clinical trials. Evaluable patients are those eligible individuals who have had the appropriate diagnostic workup, treatment, and followup to complete the study as outlined in the protocol. Available patients are those seen by CCOP physicians who may be considered eligible for study. Only the patients available to the CCOP applicants will be counted toward the denominator constituting the 10 percent minimum requirement. The population referral area should be specified. Information (tumor registry and/or clinic visit data) should be provided which demonstrates the number of cases (by disease category) seen per year by the participating physicians and/or institutions during 1980 and 1981. An explanation of how the numbers were derived should be provided. Special attention should be given to those disease categories for which the CCOP has agreed to enter patients on protocol.

Reviewers will consider the availability, training, experience and commitment of participating physicians as appropriate for the treatment of patients on the protocols in which the CCOP has agreed to participate (e.g., if protocols require radiotherapy, the availability and qualifications of radiation therapists will be considered, etc.). The work experience of participant oncologists gained from residency, fellowship, or post training inthe entry and treatment of cancer patients on research trials should be described. A curriculum vitae (not to exceed two pages each) and a signed statement of commitment to enter patients on selected protocols chosen by the CCOP from each participating physician should be provided.

Reviewers will appraise the availability of treatment facilities, both inpatient and outpatient; these should be described in the application. If the CCOP plans to enter patients on studies involving radiation therapy, available equipment should be described. A statement of commitment from each participating institution should be provided.

Reviewers will consider the quality and effectiveness of existing cancer control efforts. These include educational programs, tumor board conferences, patient management guideline development, formal supportive care efforts, and participation in formal cancer control network, outreach and research programs. Such activities will be regarded as a positive feature in an application and an indication of the institutional commitment to quality cancer care. No one activity will be considered a requirement.

Reviewers will appraise the affiliation agreements with research bases provided in the application. The appropriateness of the affiliation and of the protocols chosen, the adequacy of quality assurance mechanisms for both treatment and data, and the adequacy of investigational drug monitoring procedures and data management procedures will be considered.

Reviewers will consider the qualifications and experience of the principal investigator related to his/her ability to organize and manage a community oncology program.

The qualifications and experience of all proposed nonphysician personnel will be assessed by the reviewers. A clear description of the proposed duties for each named and to be named position should be provided.

SOURCES OF FURTHER INFORMATION

Inquiries related to the identification of eligible research base options and general information on CCOPs should be directed to: Office of Cancer Communications, Public Inquiries Section, Bldg. 31 Room 10A18, 9000 Rockville Pike, Bethesda, Md. 20205.

Residents of all states but Maryland may call the toll free number: 800-638-6694, or 800-638-6070 in Alaska and Hawaii. Maryland residents may call: 800-492-6600.

Correspondence related directly to application development and letters of intent should be directed to: Robert W. Frelick, M.D., Program Director, NCI-DRCCA, Blair Bldg. Room 7A01, 8300 Colesville Rd., Silver Spring, Md. 20910, 301-427-8708.

Questions pertaining to business matters should be directed to: John G. Dell, Grants Management Specialist, Grants Administration Branch, OD, NCI, Room 854, Westwood Bldg., 5333 Westbard Ave., Bethesda, Md. 20205, 301-496-7444.

SEVENTEEN OF 23 CHOPs APPROVED FOR IMPLEMENTATION CONTRACTS

Seventeen hospitals have been awarded implementation contracts in the Community Hospital Oncology Program, having successfully completed the 18 month planning phase of the program. Six of the 23 hospitals with planning contracts from NCI's Div. of Resources, Centers & Community Activities fell by the wayside.

The 17, with the amount of the award for the two year contracts, are:

Borgess Medical Center, Kalamazoo, $292,893; The Christ Hospital, Cincinnati, $374,789; Deaconess Hospital, Evansville, Ind., $376,438; Hackensack Medical Center, N.J., $297,666; Memorial Medical Center, Savannah, $322,457; Mercy Hospital, Scranton, Pa., $322,115; Methodist Hospital, Brooklyn, $475,156; Our Lady of Lourdes Hospital, Binghamton, N.Y., $382,104; Penrose Hospital, Colorado Springs, Colo., $302,262; St. Louis Park Medical Center Research Foundation, St. Louis Park, Minn., $378,305; St. Vincent Medical Center, Los Angeles, $355,828; The Toledo Hospital, Toledo, Ohio, $315,992; California Hospital Medical Center, Los Angeles, $378,825; Marshfield Medical Foundation, Marshfield, Wisc., $388,796; Roanoke Hospital Association, Roanoke, Va., $362,306; St. Francis Regional Medical Center, Wichita, $394,678; and Southwest Washington Hospital, Vancouver, $390,848.

The six which were not approved for implementation were Georgia Baptist Medical Center, Atlanta; Riverside Methodist Hospital, Columbus, Ohio; St. Peter's Hospital, Albany, N.Y.; St. Paul Hospital, Dallas; South Fulton Hospital, Atlanta; and St. Luke's Hospital, Bethlehem, Pa.

CHOP is a forerunner of the upcoming Community Clinical Oncology Program. Unlike CCOP, CHOP does not have the requirement for clinical research but instead emphasizes development of other aspects of hospital oncology programs. Also, CCOP has been envisioned as a program with long term commitment of NCI support. CHOP is a demonstration program, with the understanding that the individual programs will be continued with local support when NCI funding ceases.

NEW MISSOURI CENTER RECRUITING DIRECTOR, WILL AFFILIATE WITH UNIV.

The Missouri State Cancer Center, newly created by act of the legislature, is in the process of recruiting a permanent director and that process should be completed by the end of September, according to Ned Rodes, who is serving as acting director.

The act creating the center was approved unanimously by both houses of the legislature and signed into law by Gov. Christopher Bond last April. Rodes, who is administrative director of the Cancer Research Center at Columbia, Mo. (which is one of the member institutions of the new center), was detailed to serve as acting director of the new center in its early organizational stage. He will return to the Research Center when the permanent director is hired.

The Ellis Fischel State Cancer Hospital is another member institution of the new center. The act permits the center to enter into affiliations with other institutions, and negotiations are under way with the Univ. of Missouri Health Sciences Center. The university will participate as a full member, with access to shared resources and research facilities and in the matter of staff appointments.

Rodes said the new center eventually would compete for an NCI cancer center core grant. Seventy percent of the research center's budget now comes from NCI R01 and program project grants.

The center will be governed by a cancer commission of seven members appointed by the governor. The center director will be appointed by and be responsible to the commission.

THE FY 1984 BYPASS BUDGET: HOW NCI WOULD SPEND $1.074 BILLION

Publication of the narrative describing how NCI would spend the $1.074 billion requested in the FY 1984 bypass budget is completed below, starting with the estimate for rehabilitation research, which completes the research budget description, and following with resource development and cancer control.

J. Rehabilitation Research—Decrease of $724,000 below the 1983 estimate of $1,562,000.

—Studies to improve physical restoration, prosthetic fabrication, bone and joint transplantation and reconstructive surgery will be emphasized.

—Micro-surgical techniques in reconstructive

surgery will be clinically evaluated.

—Research on bone and joint transplantation following cancer surgery will be continued.

II. Resource Development

A. Cancer Centers Support—Increase of $6,976,000 over the 1983 estimate of $76,924,000.

Support for those elements of a cancer center required for planning, development, evaluation, and administration activities to maintain an active and unified center will continue. Cancer centers include laboratory and clinical research. This funding mechanism contributes to the stability of the center by providing support for staff, special facilities and services, alterations and renovations, and developmental research activities. Based on the experience of the past five years, the total number of centers will not change significantly.

B. Research Manpower Development

1. Clinical Cancer Education Grants—Increase of $1,000,000 over the 1983 estimate of $6,000,000.

Innovative curricula in medical and dental schools, teaching hospitals and schools of public health will be encouraged in order to improve the acquisition of knowledge and skills most essential to cancer prevention, early diagnosis and optimal management of cancer patients.

Medical and dental students will continue to be taught the elements of cancer research methodology as a part of their clinical training.

Continuing cancer education courses for practicing physicians and dentists will be increased.

2. National Research Service Awards—Increase of $6,435,000 over the 1983 estimate of $22,065,000.

The increase will provide 55 new individual fellowships and 20 new institutional awards.

Cancer Research training grants, fellowships and awards will continue in the basic and applied sciences.

Research training in cancer epidemiology and biostatistics will continue to be given a top priority.

Special emphasis will be given to recruiting physicians requiring long term research training in preparation for research careers.

More cancer nutrition research training will be supported.

Research training in the cancer control sciences will be emphasized.

3. Research Career Program—Increase of $527,000 over the 1983 estimate of $4,973,000.

The increase will permit funding for nine additional Research Career Development Awards. These awards provide support for young scientists who have demonstrated a high potential for developing into outstanding independent researchers in the cancer-related sciences.

A new program for supporting the research career development of clinical researchers will be implemented. This program will provide support for promising new investigators on the basis of recent performance and accomplishment.

C. Construction—Increase of $18,000,000 over the 1983 estimate of $2,000,000.

The NCI Construction Program will continue to support a broad base of cancer research activities. Program areas and initiatives that will be supported include the following:

—Renovations for biohazard containment laboratories.

—Renovations of existing laboratories for molecular biology, chemoprevention and chemical carcinogenesis research activities.

—Renovations for upgrading of research animal facilities.

—Renovations of on-campus facilities, including those at the Frederick Cancer Research Facility.

III. Cancer Control

A. Prevention—Increase of $4,722,000 over the 1983 estimate of $18,005,000.

A major research effort initiated in FY 1983 will be continued and expanded in the areas of chemoprevention and nutrition. The following studies will be included:

Chemoprevention:

—A program of quality assurance and analytical methods development to increase the accuracy and precision of vitamin and trace element determination for chemopreventive agents of interest will be initiated.

—Retrospective epidemiological investigations employing stored sera specimens to investigate the role of chemopreventive agents of interest will be conducted.

—Studies will be supported to investigate biological indicators such as serum markers, enzyme levels, etc., for examining the impact of selected chemopreventive agents.

—Cohort studies will be conducted in populations consuming varying levels of the chemopreventive agents to determine the relative risk for the development of cancer.

—Clinical trials of chemopreventive agents in neoplasia free populations to determine effects of the substances in reducing cancer incidence will be developed and initiated.

—Studies will be supported to examine the long-term consequence of chronic intake of various compounds to monitor for possible adverse health effects.

—Data systems to assess the consumption of vitamins and other chemopreventive agents will be developed.

—National data sources will be utilized as the National Health and Nutrition Examination Survey to examine the role of chemopreventive agents and diet.

—Epidemiological studies will be designed and initiated to test in human populations hypotheses generated in animal or other epidemiological studies.

—Studies will be initiated to ascertain what length of exposure to chemopreventive agents is required for effective reduction in cancer incidence.

—Research on identifying dose limits of chemopreventive agents which may effectively reduce cancer incidence without toxic side effects will be conducted for those agents indicating a protective influence.

Diet and Nutrition:

—Epidemiological and clinical investigations will be initiated to examine the relationship of dietary fat intake and cancer incidence.

—Studies will be initiated to investigate whether particular foods are protective against intestinal cancer.

—The potential interactions between diet and other cancer risk factors such as smoking, high risk occupation, familial cancer history, alcohol consumption, etc., will be examined to see if dietary alterations affect the influence of these other cancer risk factors.

—Various approaches to accurately quantify and measure dietary intake will be assessed and developed.

—Data bases for monitoring food consumption patterns in the general population will be developed.

Smoking and Health:

—Studies will be initiated which are concerned with reducing smoking in populations at high risk, as well as reducing tobacco use in adolescent populations.

—Studies will be conducted with the aim of isolating factors associated with successful smoking cessation.

—Knowledge gained from experimental and survey studies related to successful smoking cessation will be translated into public health initiatives (e.g., via the effective use of mass media) in order to prevent tobacco related cancers in the population at large.

Behavioral research to reduce worker exposure to environmental carcinogens will continue.

Activities aimed at improving image quality and reducing radiation dose in the diagnosis and treatment of cancer are in progress. Research support to ensure safety and quality control in medical x-ray equipment is being emphasized. The six Centers for Radiological Physics will continue to provide radiological quality assurance in 251 cancer treatment facilities located throughout the country.

The assessment of detection and screening technologies in asymptomatic individuals and the identification of risk factors in high risk groups will continue.

A new program, Cancer Control Research Units (CCRU), for defined populations will be initiated in order to investigate research questions on control studies in prevention, management, or both. This research will involve multidisciplinary participation and will require access to defined populations so that measurement of the impact of cancer control activities can be made.

Cervical cancer studies to characterize the natural history of disease will be conducted utilizing the data base from pervious cervical cancer screening efforts.

Cancer control research studies are being encouraged by the Cancer Control Science Program (CCSP) which are intended to stumulate new research in all aspects of cancer control, and provide additional scientific foundations for the process of technology transfer.

B. Centers and Community Oncology—Decrease of $1,053,000 below the 1983 estimate of $30,444,000.

The Community Clinical Oncology Program will be operational. This is a major cancer control program designed to bring resources of the community hospitals and clinics and national clinical cancer research programs together to conduct research at the community level. This program meets the needs of cancer patients in the community, utilizes the specialist practicing in community hospitals, and facilitates clinical research and cancer control research goals.

Studies of continuing care designed to improve the functional quality of life for the cancer patient and family will be supported. Also, the control of pain emphasizing comparative studies will continue to be encouraged.

Studies of rehabilitation methods for improving the functional quality of life for the cancer patient and family will be supported.

C. Education—Increase of $987,000 over the 1983 estimate of $5,060,000.

Cancer Communications Network (CCN) will continue to support the dissemination of the latest cancer research findings to health professionals as well as conduct education research studies for specific populations at risk.

The effectiveness of education at the worksite in reducing carcinogenic exposures or risk will be estimated.

Evaluation of graduate level curricul in oncology for nurses will continue.

An in house career development program providing training and on the job experience in cancer prevention and control projects is to be developed and implemented.

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