THE CANCER LETTER

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Controversy Raging On Whether To Release Data On 5-FU/Levamisole, Stop Untreated Control Arm

The possibility that three year results of an intergroup colon cancer adjuvant therapy clinical trial are showing substantial benefits for patients who received 5-fluorouracil and levamisole compared to untreated controls has resulted in sharp divisions among NCI staff members and among clinical

(Continued to page 2)

In Brief

NIH Alumni Assn. Formed; Henney Named Kans. Vice Chancelor; Bloomfield To Move To RPMI

NIH ALUMNI Assn. has been established for the 50,000 persons who have worked at NIH. **Abner Notkins** is chairman of the organizing committee. A board of directors has been formed, and **Harriet Greenwald** has been appointed executive director. An NIHAA office is operational, located at the Foundation for Advanced Education in the Sciences Social & Academic Center, 9101 Old Georgetown Rd., Bethesda, MD 20814, phone 301/530-0567. Annual dues are $25; current NIH employees may join as associate members, also for $25. Life membership is $250. . . . **JANE HENNEY**, former NCI deputy director, has been named vice chancelor for health programs and policy at the Univ. of Kansas Medical Center. She has been associate vice chancelor and, for several months last year, was acting dean of the medical school. **Martin Pernoll**, chairman of obstetrics and gynecology at Tulane, was appointed dean in January. . . . **CLARA BLOOMFIELD**, professor of medicine at the Univ. of Minnesota, will become chief of medicine at Roswell Park Memorial Institute. She accepted the offer from Roswell Park after determining in her opinion that she had no chance to succeed **B.J. Kennedy** as director of medical oncology. Kennedy had planned to retire this year, and Bloomfield was his choice to replace him. Bloomfield said the search committee named to recommend Kennedy's successor "was stacked against me" and refused to apply for the job. After the controversy became public, the search committee was disbanded and a new one named. Kennedy has agreed to stay on for another year. After he retires as director of medical oncology, he plans to continue to see patients and conduct research. . . . **AUDREY MARS**, long time activist with the American Cancer Society, died of ovarian cancer last week at her apartment in Washington DC. She also had worked with the UICC and had established the Mars Fellowship program for cancer scientists.

NCCTG Update Supports Positive Finding; DCT Revises Consent Form

(Continued from page 1)
investigators over disclosure of that information and the continued use of observation only arms in colon cancer.

If the intergroup study does turn out positive, it would confirm an earlier trial conducted by the North Central Cancer Treatment Group and reported at the American Society of Clinical Oncology meeting about three years ago. Following surgery, patients were randomized to 5-FU and levamisole or to no further treatment. The results reported at ASCO were that there was significant delay in recurrence among patients with Dukes B_2 and C cancer who received chemotherapy, as well as a more modest improvement in survival.

More recent followup has solidified those results and further established a survival benefit, at least for Dukes C patients. But NCI executives and NCCTG Chairman Charles Moertel disagree over the significance of those results.

Div. of Cancer Treatment Director Bruce Chabner, in his report to the division's Board of Scientific Counselors at its meeting this week, said that "the North Central study, which was reviewed at our board meeting two years ago, has demonstrated a significant reduction in recurrence rate for patients with Dukes B_2 and C colon cancer, and a significant improvement in survival for Dukes C patients treated with levamisole and 5-fluorouracil."

Moertel told **The Cancer Letter** this week that the NCCTG study is now showing "a modest improvement" in survival over that reported previously, but insisted it is not enough to warrant any change of directions in ongoing trials. His report on the NCCTG trial update has been accepted by the "Journal of Clinical Oncology" and will be published within three months, Moertel said.

To confirm the NCCTG findings, Moertel organized and headed up the large intergroup trial, again testing the two drugs against an untreated control arm. Median followup now is three years.

In the meantime, leucovorin has emerged as a potent enhancer of 5-FU activity, with a number of small trials leading to another large intergroup adjuvant study. This one compares 5-FU plus leucovorin against an untreated control arm. That study began only recently and is still accruing patients, with a goal of enrolling 1,300. Half of them will be randomized to no treatment after surgery, and that is one facet of the controversy.

Another is the report, leaked from a closed meeting of the National Cancer Advisory Board and possibly other sources, that the intergroup 5-FU/levamisole trial is showing a major difference in recurrence. Some NCI staff members have argued that the improvement is good enough to warrant disclosure, one way or another.

Moertel refused to confirm that report. "It would be grossly premature" to make public any interim information, he told **The Cancer Letter**. "These things wax and wane." He added that representatives of each of the cooperative groups participating in the study had recently agreed unanimously "there is nothing about the study at this time to justify the conclusion that it is a positive study."

Those who have argued for disclosure now of the updated NCCTG and intergroup results contend that failure to do so deprives Dukes C colon cancer patients of therapy which could improve their chances of survival. "That would be most of those patients," one cancer center director said. "Of course, those of us who know about that study would have access to that treatment, if we or a member of our families needed it."

That was the issue NCI Director Samuel Broder was referring to, although perhaps not to that specific trial, when he said at last month's ASCO meeting:

"When you don't publish a clinical trial, you are setting up a disequilibrium of knowledge. In addition, you are setting up an oligarchy . . . of doctors who are aware of the trial and know the information, and you are setting up another system in which people do not have access to the information and therefore cannot protect themselves."

Of the estimated 160,000 new cases of

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colon cancer that will be diagnosed in the U.S. this year, about half will present with Dukes C disease. Five year survival among Dukes C patients is about 40 percent. An effective adjuvant treatment could have a major impact on America's second leading cancer killer (behind lung cancer).

An academic community oncologist told **The Cancer Letter** he agreed with those who feel it is "outrageous" for the new intergroup 5-FU/leucovorin study to continue a no treatment arm. The NCCTG study provided enough basis to use 5-FU and levamisole as the control in subsequent studies, especially if it is being confirmed in the intergroup trial, he said.

Chabner and Cancer Therapy Evaluation Program Director Michael Friedman attempted to address that issue this week at the DCT board meeting when they presented a revised informed consent form they had drafted for use in colon cancer trials.

"Because of the positive nature of (the NCCTG) trial, we have asked participating groups to revise the informed consent forms on all ongoing trials in colon cancer to reflect the positive data in the levamisole trial," Chabner said. "As a matter of policy, we will ask that in the future, all NCI sponsored trials should contain informed consents that fully reveal the results of other trials, published or unpublished, that have a direct bearing on the patient's decision.

Information Withheld

"It is lamentable that too often investigators have assumed that their patients will be confused by data, and have withheld information about relevant positive studies. A particularly striking example is the decision of certain Boston physicians not to offer adjuvant chemotherapy to node negative breast cancer patients, except in the context of a clinical trial. You can be sure that the same physicians discuss the pros and cons of adjuvant chemotherapy with their own family members when a relative is found to have breast cancer or colon cancer.

"We feel that all patients have the right to have access to potentially beneficial therapies, and will press for updating of informed consents, the early placement of potentially helpful drugs in group C, and the early release of results of clinical trials."

Two DCT Board members objected to the idea of providing patients information on the intergroup trial.

Board member Lawrence Einhorn asked whether the new informed consent would be mandated or suggested.

"It's a suggestion," Chabner said. "But if a protocol comes in with a consent form that doesn't mention a trial which has been completed and resulted in group C status for the drug, then it would be deficient."

Chabner said that a "sticking point" between NCI and the investigators is that, "if you inform, you may disrupt accrual to an ongoing trial. We feel that when you put an article into publication, you are obligated to inform the patient."

Board member James Cox objected. "This would limit the ability to do a confirmatory trial," he said. "There is conflicting information, but you are not going to require that the conflicting information be presented."

"We're not saying that you are only obligated to mention only one positive result," Chabner said. "We're asking that a statement that some trials using adjuvant chemotherapy has led to an improvement in response."

Simpler Approach

Friedman said that new wording for the informed consent forms was first proposed that went into great detail on the trials, but they were too confusing.

"We took a different approach, saying that some trials demonstrate a relapse free survival, and that if a patient wants more information, to discuss it with the physician. Anyone reading it would see there are conflicting results."

Einhorn said the action "seems to be self serving statement for chemotherapists, and that's not NCI's role."

"It is our role to review informed consent," Friedman responded.

"You can pick and choose the science to which you want to call attention," Cox countered. "That's what bothers me."

"I think NCI is doing the right thing on the side of patient advocacy," said Board member William Hryniuk. He said that he recently treated the president of a medical society who had colon cancer and "went through all of this (with the patient) in a detailed discussion on the medical and ethical responsibilities."

"I feel very strongly about this," Chabner said. "Someone said to me recently that you can't explain these results to blue collar workers. I resent that. I know that if someone in my family had colon cancer, I would discuss this with them."

"You have totally missed the point," Cox

said. "The science to which you want to call attention is a confusing body of knowledge."

Board Chairman John Niederhuber quieted the discussion. "All of us in clinical research feel strongly about informed consent in general. I think no one on the board is arguing against having informed consent."

"I understand there's disagreement over what constitutes a positive result," Chabner said. "We will err on the side of the conservative. But where the facts are clear, we have to be sure patients are aware of them."

Later in the meeting, Friedman read a proposed addition to the informed consent form which has been agreed to by the principal investigators in the intergroup trial. The paragraph is inserted under a section on alternatives to participation in the trial:

"Alternatives for treatment that could be considered include no further therapy, or several types of chemotherapy. The investigator who answers questions about this study will be able to discuss the benefits and side effects of the various treatments available. Some clinical trials have suggested that tumor recurrence may be delayed in patients who receive additional therapy after surgery, compared to those treated with surgery alone. It has not been established, however, that survival or cure rate has been improved. The advantages and disadvantages of additional treatment should be discussed with the investigator when considering participation in this proposed clinical trial."

Friedman concluded, "I'd like to challenge you to tell me what's unacceptable about that. It seems a very fair, balanced, even handed statement."

No board member offered a comment on the issue.

Moertel strongly defends continued use of untreated controls in the new study. "It would be quite irresponsible to abandon a very important study in progress on the basis of those limited results."

Why couldn't 5-FU and levamisole be substituted for the untreated control arm on the study? Moertel's answer: If there is a little advantage for the levamisole combination, the design of the trial may not be adequate to demonstrate a small advantage for the leucovorin combination. The only way to use the levamisole combination as a control would be to junk the present trial and start over.

Actually, an adjuvant colon cancer trial without untreated controls using all of those combinations is getting under way. The National Surgical Adjuvant Breast & Bowel Project has received approval of a protocol to assess the efficacy of 5-FU and leucovorin, 5-FU and levamisole, and 5-FU with both leucovorin and levamisole. This study will include both Dukes B and C colon cancer.

Moertel has no argument with using 5-FU and levamisole in clinical trials, "but I would not encourage anyone to use it on a routine basis."

The combination most likely is headed for wider use, whether or not that could be considered routine. NCI has obtained FDA approval for placing levamisole on the "Group C" list, which means NCI will provide it an no charge to qualified physicians for use in private practice. Patients do not have to be enrolled in clinical trials to get Group C drugs, but physicians are asked for reports on their use.

Group C status for levamisole was made on the basis of the NCCTG data and not on the unsubstantiated reports from the intergroup study of a major difference in recurrence rates. But Moertel insists that the NCCTG data are not sufficient to warrant general acceptance of the regimen. He did, however, support NCI's request for Group C designation.

How do you square those two positions?

Group C approval now means the agent will be on hand and available in case new data turn up supporting a positive result, Moertel said.

Clinical Alert?

Chabner told the DCT board that an interim analysis has been scheduled for later this year.

Moertel discussed the studies with the National Cancer Advisory Board at a closed meeting earlier this year. Broder and Chabner reportedly argued strongly for disclosure of the interim data, but Moertel would not budge.

Some NCI staff members have urged Broder to consider sending out a "clinical alert." He has resisted that so far, and told **The Cancer Letter** that he would prefer instead for the results to be published expeditiously in a peer reviewed journal.

NCI sent a clinical alert--a letter widely distributed to physicians and the media--last year on the results of node negative breast cancer trials. The institute was strongly criticized by many for bypassing peer review, but the action did make known those results nearly a full year before they were finally published in the "New England Journal."

It has now been at least four months since "insiders"--Moertel and his colleagues, NCI staff members, NCAB members, and probably others--have been aware of the updated information from the NCCTG trial. It will be at least three more months before it is published. If the intergroup study is confirming those findings, how many more months will elapse before that is made public is anyone's guess.

The 60,000 Americans destined for diagnosis with Dukes C colon cancer this year averages to about 165 a day. Sixty percent of them will die of that disease unless they receive effective treatment after surgery.

"Those are the people we ought to be thinking about. They are the ones who are paying the price for continuing untreated arms in those studies," a former NCI staff member said between sessions of last month's ASCO meeting. "That is the only reason the information on levamisole has not been widely disseminated--to protect accrual to that study."

Not all ASCO members agreed with the suggestion that extraordinary means should be employed to notify physicians and the public about the potential of 5-FU and levamisole. Nor do all NCI staff members feel any action should be undertaken.

"Those data belong to the investigators," an NCI branch chief told **The Cancer Letter**, expressing concerns heard in discussions with others inside and outside of the institute. "It should go through the peer review process. If we start bypassing peer review, you don't know how much junk will get out in the name of science."

On the other hand, "How in hell can we expect physicians to know enough about levamisole's apparent effectiveness to request it from Group C unless we tell them about it, with the supporting information?" another staff member said. "Here we have the ridiculous situation in which we have a treatment available that might have more impact than anything else we have done. We have the drugs, one free from Group C, the other on the market. The regimens are in PDQ. But all this will just sit there while we wait on peer review and publication."

The FDA Oncologic Drugs Advisory Committee was scheduled to consider today (June 9) the NDA for leucovorin in combination with 5-FU for treatment of metastatic colon cancer.

Claude Pepper, Who Helped Establish NCI In 1937, Dead From Cancer At 88

The eulogies for Claude Pepper which have filled pages of the Congressional Record and the country's newspapers since his death last week have dwelled on his record as a champion of the elderly. His reputation in that regard is deserved, because of his support for Social Security, Medicare, Older Americans Act, and other measures benefitting the aged.

Overlooked by most was Pepper's contribution, first as a U.S. senator and later as a congressman, to cancer research and all biomedical research.

Pepper was elected to the Senate from Florida in 1936. When he attended a dinner two years ago sponsored by the Coalition for Cancer Research on NCI's 50th anniversary, Pepper said that one of the bills he was most proud of in all his years in Congress was that which created the National Cancer Institute in 1937. It was one of the first he cosponsored and voted for; the measure creating Social Security that year was another.

Pepper was instrumental in establishing other institutes at NIH, and personally took command of legislation creating the National Institute on Aging and National Institute of Arthritis & Musculoskeletal & Skin Diseases. His last major legislative battle came last year when he successfully pushed through the measure setting up an institute on deafness.

Pepper gained national attention in the 1930s and 40s as a rare liberal from the deep South, primarily because of his support for civil rights. That reputation cost him reelection in the McCarthy era frenzy of 1950, when George Smathers defeated him in the Democratic primary.

Pepper went into private law practice for 12 years, becoming wealthy in the process. He returned to Congress in 1962 as a representative from Miami. In 1971, he had the opportunity to vote for the National Cancer Act, supported each of its renewals, and could always be counted on to vote for budget increases for NCI and NIH. He helped push through legislation requiring Medicare reimbursement for mammography screening, and he was instrumental in the effort establishing a catastrophic health insurance program.

Congress passed a bill earlier this year naming Building 31 on the NIH campus the Claude Denson Pepper Building.

Cancer claimed Pepper's wife, Mildred, in 1979, and took him, at age 88.

ASCO Survey Leads To New Plans Including A Permanent DC Office

Growing concerns about funding of cancer research, reimbursement, and other economic and political issues have led to a decision by the American Society of Clinical Oncology to consider establishing an office in Washington DC.

Those concerns were expressed in a survey of ASCO members initiated last year by President Charles Coltman, who reported the results and recommendations of a Strategic Planning Committee to the membership at the society's 25th annual meeting in San Francisco last month. The recommendations were ratified by the membership at the business meeting.

The Washington office should be staffed with one to three professionals and secretarial support, the committee recommended. This would be in addition to support provided by the Bostrom Corp. out of ASCO's Chicago headquarters. It would also be in addition to the Washington representation services provided John Gruppenhoff.

The Strategic Planning Committee was chaired by Sydney Salmon, director of the Arizona Cancer Center. Other members were Karen Antman, Denman Hammond, Samuel Hellman, Cary Presant, Stephen Schimpf, and Robert Young.

The questionnaire was developed by CDP Inc. as a consultant to ASCO, and the survey was carried out by that firm. The questionnaire was mailed to 7,394 members throughout the world and 3,054 responded.

The committee, ASCO board members and key committee chairmen Vincent Cagianno, Irvin Fleming, Sharon Murphy and Rodger Wynn met in a two day retreat to consider survey responses and develop recommendations based on them.

Among the issues which turned up in the survey were those involving dominance of the society by medical oncologists in the face of growing membership of radiation, surgical, gynecologic, pediatric and other oncologists; and what had been perceived as a split between academic and practicing or community oncologists.

Also, "there are senior clinical investigators among us who remember the ASCO of old, and who abhor today's trade show mentality with huge exhibits and huge crowds and who long for the good old days of scientific and intellectual discussions with an audience of small size, in which nary a strange face was to be seen," Coltman said.

Those concerns were considered in the actions which were adopted or affirmed by the ASCO board and presented by Coltman:

"The first emphasizes that ASCO must remain a scientific and educational society without peer or compromise." To that end, the board will explore establishing an annual national meeting with educational emphasis, "geographically and seasonal opposite" to the regular annual meeting.

"ASCO reaffirms the multidisciplinary nature of the society and will do so by requiring committees to remain multidisciplinary and the nominating committee to propose both multidisciplinary as well as nonacademic names for office.

"A large majority of ASCO members are medical oncologists and it is the principal organization representing medical oncology and will effectively do so. . . In policy decisions and public statements, ASCO will always speak on behalf of all disciplines. In rare instances of unresolvable conflict between medical oncology and other disciplines, ASCO will speak on behalf of medical oncology after informing all organizations representing other disciplines.

"ASCO must now and in the future respond to the array of government regulations, reimbursements and other legislative issues to adequately represent all segments of our society. ASCO must strengthen its political and economic activities through the Public Issues and Clinical Practice Committees.

"The Public Issues Committee will focus on funding of basic research, research funding for NCI, reauthorization of the National Cancer Act, interaction with other organizations on political and economic issues and as a spokesman for ASCO to Congress.

"The Clinical Practice Committee will deal with practice problems, problems in reimbursement including technology transfer, clinical investigation in private practice, and will function as a clearing house for regional reimbursement and other regional issues.

"In order for ASCO to respond to these new initiatives that have been adopted by the board, additional technical and analytical support, in addition to that currently provided by the Bostrom Corp., will be required. This will involve additional staff support and should take the form of a Washington based office staffed with one to three professionals and secretarial support to provide continuous assistance to the Public Issues and Clinical

Practice Committees." No timetable was set for carrying out this recommendation.

Coltman added that "it should come as no surprise that some revenue enhancement will be required to meet the future needs of our society. The board is currently defining the mechanism and quantity of these issues."

Survey respondents expressed strong support for a dues increase: 47 percent approved a $25 increase, and 25 percent a $50 increase. Only 21 percent opposed any increase.

Coltman closed by noting that the survey asked members which other societies or associations they would like to hold their meetings with. "Medical oncologists chose AACR, radiation oncologists chose ASTRO, and 91.6 percent of surgical oncologists said they wanted to meet with the Oncology Nursing Society."

Incoming ASCO President Robert Young emphasized in a discussion with **The Cancer Letter** a few other recommendations which he is eager to implement: establishing a Patient Advocacy Committee and a permanent Committee on Cancer Control and Prevention; publishing an ASCO newsletter "so members can get information on a timely basis. ASCO is so large, with so many activities, there's a lot going on members don't know about.

"We reaffirmed our desire to remain a scientific society and an important educational society. At the same time, we want a bigger voice in national and governmental issues. That is a new direction. The survey clearly indicates the members feel the society needs a major voice in Washington."

Young said his tenure as president "will be a year of implementation, of expansion, participation, information dissemination. The society is healthy and willing to accept an increase in dues if needed."

"Last year, there was concern by some that ASCO was fragmenting, and possibly might split up. The survey showed those are not strongly held views. The survey was a successful and calming endeavor."

Young said he expected ASCO to grow during the next year at about the same rate, when membership increased from just over 7,300 to more than 8,000. Two thousand of the 4,600 who attended the San Francisco meeting were not ASCO members. One of his concerns is that only 8 percent of members serve on committees or as officers. "That's high for societies, but we're not satisfied with it."

NCI Adds $700,000 To CCOP Budget, Makes Four New Awards To Total 56

NCI has pumped an additional $700,000 into the Community Oncology Program, permitting the funding of four more CCOPs this year and the addition of $300,000 to budgets of existing CCOPs for patient accrual increases.

That makes the total CCOP budget for FY 1989 $12.2 million, and increases the number of CCOPs to 56.

The new awards were effective June 1. They are three year awards, which means they (a) will not have to participate in the recompetition coming up this year of all other CCOPs; and (b) will be the first to recompete under the "institutionalization" of the program, which spreads out the competition and review. Henceforth, CCOP awards will be made every year, with those getting the best scores receiving five year awards, next best four years and the rest three years.

The new CCOPs are:

<> Bay Area Tumor Institute Community Clinical Oncology Program, Oakland, CA. Michael Cassidy is the principal investigator.

<> Milwaukee Community Oncology Program. Ronald Hart is the PI.

<> San Diego/Kaiser Permanente Community Clinical Oncology Program. Scott Browning is the PI.

<> Rapid City Community Clinical Oncology Program, Rapid City, SD. Larry Ebbert is the PI.

The new CCOP RFA went out last month, and NCI expects a record number of applicants. The institute would like to support as many as 80 CCOPs, in addition to the eight it hopes to award as Minority Based CCOPs (see RFA announcement below). However, there is only $12 million in the President's FY 1990 budget for CCOPs, the amount supporting the current 56. To make 80 awards, the budget would have to be in the neighborhood of $18 million, which Congress could make possible in the impending mark up of appropriations bills.

RFAs Available

RFA 89-CA-96
Title: Minority based Community Clinical Oncology Program
Letter of intent receipt date: July 14
Application receipt date: Oct. 13

The Div. of Cancer Prevention & Control is interested in establishing a cancer control effort which is designed to link physicians involved in the care of minority cancer patients to the NCI clinical trials program, and to provide minority cancer patients/subjects with state of the art treatment and cancer control research opportunities.

DCPC invites applications from domestic institutions with greater than 50 percent of new cancer patients from minority

populations for cooperative agreements in response to this Minority Based Community Clinical Oncology Program (Minority Based CCOP) request for applications.

Overall, survival rates from cancer in minority populations are less than in whites. For example, data from the SEER Program show that the five year relative survival rate (1975-84) for all cancer sites in blacks is 39.6 percent compared to 51.3 percent for whites. Site specific survival rates of black patients with breast, rectal, corpus uteri, and bladder cancers are lower than those for whites by 12, 12, 30, and 22 percents, respectively. In addition to poorer survival outcomes, cancer incidence and mortality rates for selected cancer sites in minority populations are higher compared to whites.

One way to develop and implement effective treatment and cancer control strategies in minority populations, and thereby reduce disparities in cancer incidence, morbidity, and survival rates between whites and minority populations, is to provide broader access to clinical research and greater involvement of minority populations in the clinical trials process. In general, there is limited participation in clinical trials research by black, Hispanic, Asian American, Native American, and other minority cancer patients. A major factor influencing participation in clinical research by minority patients is access to the clinical trials process.

The Community Clinical Oncology Program, which was initiated in 1983, has proven to be a successful model for bringing the benefits of clinical research to cancer patients in their communities by providing support for community physicians to enter patients on treatment and cancer control research protocols. During the first phase of CCOP, a patient log record keeping system on all new cancer patients seen by a participating physician, and for whom protocols were available, showed that 7 percent of CCOP patients were minorities. This compares to 13 percent minority representation in SEER and 20 percent in the general U.S. population. A similar ethnic profile of minority patient participation in clinical trials is seen during the second phase of CCOP. Through the Minority Based CCOP, DCPC aims to meet a need of minority cancer patients and individuals at risk for cancer by establishing a system of oncology programs for participation in clinical research trials through the NCI network.

The Minority Based CCOP initiative is designed to:

* Bring the advantages of state of the art treatment and cancer control research to minority individuals in their own communities by having practicing physicians and their patients/subjects participate in clinical treatment and cancer control research protocols.

* Provide a basis for involving a wider segment of the community in clinical research by increasing the involvement of primary health care providers and other specialists in treatment and cancer control research.

* Provide an operational base for extending cancer control, and reducing cancer incidence, morbidity, and mortality in minority populations by accelerating the transfer of newly developed cancer prevention, detection, treatment, and continuing care technology to widespread community application.

* Facilitate wider community participation in future treatment and cancer control research approved by NCI.

* Examine selected issues in Minority Based CCOP performance and evaluate its impact in the community.

Awards will be made as cooperative agreements. Depending on individual costs and available funds, NCI anticipates making up to eight awards under this RFA with total funding not expected to exceed $1.2 million per year. Awards will be for three years.

Additional information and copies of the RFA may be obtained from Carrie Hunter M.D., Program Director, CCOP, CORB, DCPC, NCI, Executive Plaza North Rm 300-G, Bethesda, MD 20892, phone 301/496-8541.

RFPs Available

Requests for proposals 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 Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-07313-72

Title: Operational systems development in support of the Developmental Therapeutics Program

Deadline: July 30

The Developmental Therapeutics Program of NCI's Div. of Cancer Treatment, Information Technology Branch, is seeking an organization to provide systems design and development services, and equipment monitoring. These services will be used under a task order managed, level of effort contract. Under such a contract, as a specific need arises, the work to be accomplished will be determined by a task order.

At this time, specific details cannot be provided for the tasks. In general, computer programs will be required for maintenance support, operations support, or development support. Objectives may include such items as the conversion of a file from one graphic format to another, the interfacing of a software package or new equipment with an existing system, or the resolution of specific operating problems. There will be a specific requirement for a task to plan all of the other task orders.

In addition, a task will be maintained to provide a full time attendant to tend two large laser printers and a microVAX located in the Executive Plaza North Building in North Bethesda.

Experience is required in the following areas: planning and designing scientific information systems; implementing large and complex data bases; various computer systems, such as the IBM 370 model 3090, the VAX 8800 series, the Hewlett-Packard 3000; various computer languages, including FORTRAN, C, SAS, SQL, and assemblers; the programming of text and graphics applications using specialized terminals, work stations, personal computers, as well as laser printers; data communication, multipoint networks, data concentrators, various types of multiplexers, etc; laboratory automation, and the use of robots and their controllers. Personnel proposed should include programmers, a chemist/biologist, and a statistician/mathematician.

This is recompetition of a contract currently performed by ORI Inc. It is anticipated that a single award will be for a five year period of performance with incremental funding each year, requiring approximately 50,000 direct labor hours over the entire period of the contract.

Contracting Officer: Jacqueline Ballard
RCB Executive Plaza South Rm 603C
301/496-8620

RFP NCI-CP-05618-32

Title: Biomedical computing, design and implementation

Deadline: Approximately Aug. 15

The Environmental Epidemiology Branch of NCI's Div. of Cancer Etiology seeks computer related support for its biostatisticians, epidemiologists, and others within the branch in the form of data management and analysis of large sets of biomedical data. This computer related support falls into three main categories:

1. Data management activities, consisting of keying, formatting, and editing data collected from field studies.

2. Systems design and development, consisting of defining technical specification requirements and developing the program language code required to implement automated solutions.

3. Statistical analysis and modeling, consisting of using standard software packages and specialized software to carry out analyses under the general guidance of the Environmental Epidemiology Branch personnel.

This is a recompetition of a contract currently providing computer related services for approximately 40 studies per month. This is a 100 percent small business set aside.

Contract Specialist: Richard Hartmann
RCB Executive Plaza South Rm 620
301/496-8611