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AACI COMMITTEE MAKES CASE FOR CLINICAL RESEARCH IN CENTERS; CANCER CONTROL, GROUP FUNDS EYED

Alvin Mauer, cochairman with Steve Carter of the Assn. of American Cancer Institute's Task 10 Committee, opened last week's meeting of the committee at NIH with the statement that "we are here to consider some special problems and attributes of clinical research in cancer centers." During the next day and a half, the committee reached a consensus on what those attributes were, developed recommendations for meeting the problems and suggestions for improving review procedures, heard key NCI staff members disagree sharply among themselves over

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In Brief

INNOVATIVE ANTISMOKING EFFORTS NEEDED, CCRAC TOLD; ILLINOIS TO GO AFTER NEUTRON CONTRACT

"WE HAVE the knowledge to cure or prevent 75% of all cancer," A. Hamblin Letton, former president of the American Cancer Society and member of NCI's Div. of Cancer Control & Rehabilitation Advisory Committee, commented at a recent meeting of the committee. He based the 75% figure on estimates that about 40% of cancer patients now are being cured, and that 35% or more of cancers are related to cigarette smoking. To develop effective education programs against smoking, "we need someone to be innovative," Letton said. . . . **ILLINOIS COMPREHENSIVE** Cancer Center plans to compete for one of the two contracts NCI will award for development of a clinical neutron therapy facility. The center would draw on expertise at the Fermi Clinical Facility, Argonne National Laboratory and the radiobiological programs in the center's participating universities. . . . **LOUIS THOMAS**, chief of NCI's Laboratory of Pathology since 1969, has retired after 33 years of federal service. He headed a task force which published in 1968 the "Manual of Tumor Nomenclature and Coding," participated in a nationwide review of angiosarcoma cases which provided a conclusive link between that cancer and vinyl chloride, and took part in pathology review of mammography which led to modifications in the Breast Cancer Detection Demonstration Program. . . . **"PROGRESS, PERSPECTIVES** in Lung Cancer Treatment" will be the subject of an EORTC symposium May 3-5 in Brussels. . . . **NEW PUBLICATIONS**: "Dysplasia, Very Early Cancer and Cancer of the Cervix," by Caroline Derbyshire and Robert Knapp, published by Sidney Farber Cancer Institute. Free, from the institute Communications Office, 44 Binney St., Boston 02115. "What Black Americans Should Know About Cancer," free from NCI Office of Cancer Communications, Bldg 31 Rm 4B39, Bethesda, Md. 20014. A series of 25 pamphlets on various types of cancer, free from NCI, same address. The pamphlets answer questions often asked by patients and families. Write for order forms and list of the 25.

DEVITA, JOFTES CLASH ON ADEQUACY OF CLINICAL RESEARCH PEER REVIEW

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certain aspects of the problems, and cast covetous glances at funds allocated for cancer control and the Clinical Cooperative Groups.

No one suggested that the meeting was supposed to come up with a defense of single institution clinical research for presentation at the long planned and sometimes feared review of clinical trials next March before the Div. of Cancer Treatment Board of Scientific Counselors. The Cooperative Groups have suspected that the review will turn into a criticism of their program and have mounted a major effort to present their case.

Some DCT Board members have expressed concern that the review would not accord single institution studies the attention they deserve. If last week's Task 10 Committee meeting was not specifically set up to counter the Groups' presentation, it could have that effect.

The committee listened to descriptions of five examples of clinical research in cancer centers:

- Emil Freireich discussed M.D. Anderson's studies of acute myeloblastic leukemia in adults. Patients treated with anthracycline and ara C are achieving complete remission at a rate of 65%. Freireich and his colleagues have observed that there are virtually no recurrences in patients who survive three years. Perhaps most significantly, they have found that the subset of patients who never respond, from one third to one fourth, have certain observable characteristics which permit their identification prior to initiation of therapy, Freireich said.
- Joseph Simone discussed studies at St. Jude in which acute lymphocytic leukemia in children was treated with intensive chemotherapy and CNS irradiation, with five year survival of 60%. The studies demonstrated that CNS leukemia is preventable, that biologic cell features may provide the basis for improved specificity of therapy, and that certain therapy could be reduced without decreasing response, Simone said.
- Saul Rosenberg described Stanford's lymphoma trials in which the cure rate went from 25% in 1962 to 75% now. An extremely important factor in this progress, Rosenberg said, "is that we have to present and defend clinical cancer research" to other elements of the institution, including basic scientists. Mauer noted this was a "continuous healthy critique from the entire environment of the center, not just those working in cancer."
- Michael O'Connell discussed colorectal cancer studies at Mayo in which 36 single agents have been tested, along with various drug combinations, immunotherapy, and CEA as a screening tool (it was not useful for that purpose), O'Connell said. None of the combinations extended survival, he noted.
- Edward Beattie discussed Memorial Sloan-Kettering's studies in treating cancer of the bladder, prostate and testicle. More than 400 patients with bladder cancer treated with three regimens of radiation plus surgery and one with surgery alone had comparable five year survival for those with superficially infiltrating tumor; more than twice the survival rate for each of the three irradiated groups over surgery alone for deeply infiltrating tumor; and zero five year survival in all four groups for those with metastatic tumor. In prostatic cancer, Beattie said that adjuvant radiotherapy to the pelvis for those with positive nodes did not improve survival, so it was abandoned.

Beattie discussed a potential problem that centers may soon be facing as a result of the development of successful new therapies: the changing character of patients. With testicular cancer as an example, Beattie said, "as more physicians are trained, medical oncologists particularly, and as more agents are released for use outside of clinical investigation, we will get more patients who were treatment failures."

That led to a discussion on the impact of cancer treatment in community hospitals on clinical research.

"Everyone says ALL in children is a prominent example of curable cancer," said Edward Henderson, Roswell Park. "People say centers or research institutions are not as necessary, that community hospitals can treat cancer just as good as we can. The fact is those results didn't go from 3% to 50% because of what good physicians did in the communities. These things that wind up at 50% may never get any better . . . Centers may not have access to patients for research."

"In centers, you can put together a multidisciplinary study group for each problem," said R. Lee Clark, Univ. of Texas. "We have 15 study groups. There is continuing evaluation of the state of the art. Money is allocated for adventuresome ideas."

"It would be tragic if all we get out of clinical research is that A is better than B," Freireich said. "Centers have regular interaction with basic scientists at all levels. . . . It would be particularly cruel if a diminishing budget leads to emphasis on straight clinical research without interaction with scientists."

"You can't escape the fact that we're training more people to go out into the communities," said Paul Carbone, Univ. of Wisconsin. "It would be very bad for this group to go on record that research should be done only in centers and that all patients should go to centers.

"We have a unique opportunity in centers," Carbone continued, "with a critical mass of multidisciplinary skills, to cull out some patients. We should maintain communication with the community people, bring them in, work with them, and pretty soon you'll start getting the patients you want. If not, they'll go to NCI on their own, and set up a community clinical cancer council. There are certain key

clinical biological questions that can be answered in community hospitals, and some questions that can be answered only in centers."

O'Connell pointed to the North Central Cancer Treatment Group, a satellite program involving practicing oncologists administered through Mayo, with cooperation of NCI and the Eastern Cooperative Oncology Group. "It keeps referral patterns open and provides an opportunity for phase II and phase III studies in communities."

John Laszlo, Duke Univ., complained about NCI's new distribution plan for experimental drugs. "I feel deprived. There are certain formal ties that are required. If you belong, OK. If not, you're out. I'm displeased with the new system, the way it has worked out. But perhaps we just haven't learned how to use it."

"I'm surprised to hear that comment," said Div. of Cancer Treatment Director Vincent DeVita. "I thought it was going very well." DeVita said NCI had no choice but to adopt the system, under FDA regulations. Group A drugs, those in phase I and early phase II test, are available only to a limited number of investigators, Group B to a broader group through cancer centers, and Group C to practicing physicians.

"Within existing regulations, the system is working as smoothly as it can," DeVita said.

Mauer listed what he felt was a consensus of the group on "special attributes of clinical research in cancer centers:

"1. Many studies are now in long term followup, and you need a stable base for continuing observation and followup.

"2. Protocol development in centers is characterized by a logical sequence and review of data, offering the opportunity for sequential approaches.

"3. Data analysis has a consistency of quality and better opportunity for quality control.

"4. Opportunity for related studies, such as pain control and other supportive services, clinical and in the laboratory.

"5. A lot of data is collected that has nothing to do with whether A is better than B but with patterns, treatment complications, biology of cancer, long term treatment complications.

"6. The opportunity for multidisciplinary or multimodal interrelationships, specialties and subspecialties, pathologists as well as chemotherapists, radiotherapists and immunologists.

"7. Beyond the initial treatment protocol, there are the second line studies, for new agent studies.

"8. Studies are being carried out in an environment where related and unrelated scientific disciplines exist, where investigators can go for help when the need arises.

"9. Studies are being reviewed and reported in an environment with a variety of disciplines, with comment by people in basic cancer research as well as other clinical disciplines.

"10. Research is in a setting where educational opportunities can be provided."

"The common denominator of programs in centers is the spark, the bright spark, occurs in a milieu where it can be developed," Carter said.

"That's terribly important," Freireich agreed. "Original, innovative ideas tend to occur in centers where they can be carried out."

DeVita described his philosophy of cancer treatment research:

"My major function is to get the money that is devoted to treatment out to the people who can use it best with the least amount of restrictions and maximum flexibility. I'm dedicated to the proposition that no single person should direct research in clinical or preclinical areas."

DeVita brought up the controversy over whether review of clinical research applications in the traditional R01 investigator initiated grant mechanism by NIH Div. of Research Grants study sections offers fair and adequate review.

"I can give you anecdotal examples of grants that have been disapproved, that should have been approved, because of some element, cost for example. But I can't document it. You can find examples of that in all study sections, for all types of grants."

DeVita's staff is doing a survey of grant approvals and disapprovals by DRG study sections in 1978 fiscal year. About 18% of all R01 applications have been for clinical treatment research, 10% for preclinical treatment research and 72% for all other types of research. DeVita said the survey shows so far that the percentage of approvals, disapprovals and grants awarded have been approximately the same for all three groups.

DeVita said that he feels the problem may not be with study sections, but that the R01 mechanism "is not ideal for clinical research."

Rosenberg said the long term project at Stanford he had described was funded primarily under the program project (P01) mechanism, although other mechanisms were used at times. Other committee members agreed that the program project was a good mechanism for providing funding of a long term multidisciplinary research.

Mauer pointed out that "protocols flow in sequence. The next one cannot be anticipated until results of the current study are known. At the end of three years with many studies, patient entry has just been closed. Ten year followup may be required, while grants are awarded for three years, or five years. There is a likelihood that a study section would not regard the study at that point (renewal time) as having shown anything significant."

"The mechanism that intrigues me," DeVita said, "is the consortium grant." Cautioning that that is a mechanism that might not ever be made available, DeVita explained it would involve a grant to a single

institution, with "subgrants" to others, with flexibility to move them around and an extended funding period.

"Clinical investigation needs a lot of flexibility," DeVita said. "We need a mechanism in which the investigator presents a general plan and then is permitted to do what he needs to do. The program project is close. A consortium grant would be ideal. You would have the nucleus, and could change people if you needed to. The R01 grant is the wrong mechanism.

"Program projects, consortium grants, career awards all have that flexibility. That's the kind of thing we hope to bring up in the clinical trials review. It's not going to be centers vs. Cooperative Groups."

David Joftes, chief of the Review & Referral Branch in the reorganized Div. of Cancer Research Resources & Centers (to be renamed Div. of Extramural Activities), defended DRG study sections and the R01 mechanism.

"You have focused on the wrong aspect of what happened at Stanford," Joftes told the committee. "There was one constant there—high quality. Also there was interdisciplinary research in a real sense. You can put grant applications before the wrongest kind of study section, and if the science is good, they'll find a way to fund it. Many of the applications that are disapproved by study sections involve the same old drugs that don't work."

"I don't agree with you," DeVita said.

"Based on your history, today's promising drug is tomorrow's failure," Joftes continued. "Some applications bring in drugs that are no more than cellar sweepings from Harlem. You need true multidisciplinary research. How many basic scientists are on the Task 10 Committee? Review after review show basic science and clinical science in parallel, not working together."

DeVita, still at the podium, turned to Emil Frei, Harvard, who had his hand up. "Tom, will you save me from some remarks I shouldn't make?" DeVita said.

Frei argued that advances in cancer treatment "are extraordinary, but we need better public relations. Dan Greenberg (a Washington science writer) has convinced the public there has been no progress in therapeutic research when it is an area in which advances are coming more rapidly, with more leads to follow, than any other area of biomedical research."

DeVita turned again to Joftes. "What you have said, Dr. Joftes, indicates an extraordinary lack of knowledge of clinical research."

"That may be true, but you've got to deal with people like me," Joftes said.

Henderson, after asking Joftes if he had been on program project reviews, commented that "the major percentage of budgets deal with fundamental questions. Most every place I go, I see a tremendous and successful effort to get other disciplines involved."

"It's not happening frequently enough," Joftes said. "It appears to reviewers that they are paying lip service to it, but few basic scientists are involved.

"I'm a far more sympathetic devil's advocate than you'll find on the street in Bethesda," Joftes continued. "Those are the people you'll have to deal with."

"I'll take my chances with the people on the street in Bethesda," DeVita replied.

DeVita attempted to put to rest the concern by Cooperative Group members over the proposal he said previously he would make at the clinical trials review that the groups be reorganized along geographic lines.

"I'm not about to reorganize anything," he said. "Any member of a Cooperative Group can move, and his grant will move with him. But we won't put a map on the wall and force anyone to move. If no one wants to become geographic, we won't force you to. We have no intention of going to any group and say, you'll be a three part group. If you do it, you'll do it yourself."

Carter pointed out there are eight review mechanisms for clinical research—center core grants ("perhaps the most essential"), Cooperative Group grants, program project grants, contracts, request for applications (RFAs, which include Cancer Research Emphasis Grants), organ site program grants, R01, and cancer control grants and contracts.

Applications responding to RFAs and the R01 grants are the only ones reviewed by the DRG study sections. Organ site grants are reviewed by the appropriate organ site task force committee. All others are reviewed by committees appointed and supervised by NCI—the Cancer Center Support Grant Review Committee (core); Clinical Cancer Investigation Review Committee (Cooperative Groups); Clinical Program Project Review Committee; contract review committees; and cancer control grant and contract review committees.

"Do we need a new one?" Carter asked.

John Durant, Univ. of Alabama, is both director of a comprehensive cancer center and chairman of a Cooperative Group. He suggested that it appears the percentage of grants awarded to principal investigators without MD degrees has been increasing, and this parallels the makeup of study sections. "Inevitably this will lead to misunderstanding of clinical grants. Is the clinical talent spread too thin? Are they not being asked to serve on study sections?"

"We're sensitive to suggestions on the makeup of groups going on site visits," Joftes said. "And you can't say the CCIRC is composed of PhDs."

"I'm talking about R01s, and almost all review of those applications is by reading the papers submitted," Durant said.

DEA Director Thomas King said that vacancies on study sections are announced, and that suggestions for filling them were welcomed.

"Dr. Durant has hit on the core of the problem," Freireich said. "Every study section is predominantly drawn from the cadre of people who leap up and say that clinical research is applied, it's not science. The guts of the review process depends on the selection of reviewers, and we've assigned that to people far removed from the clinic. We need some study sections dominated by clinical scientists."

"I'm not a bit prejudiced against clinical research," King said.

"Dave Joftes is," Freireich said.

"Jay, ask Tom who I'm recommending as the new executive secretary of CCIRC (to replace retiring Clair White)," Joftes said. King responded that it was a clinician.

Laszlo commented that in reviewing program project and core grants, as well as R01s, "people frequently cast the deciding votes who do not understand the need for a nutritionist or other specialists and facilities."

"That is the fault of the system," Joftes said. "Knowing that, there are some things you can do. Take the time on site visits to make sure that others on the team understand these things. And when we notify you of who is on the team, let us know if you feel there's a hole on it."

Mauer suggested that a new clinical study section be formed within NCI, a "CCIRC B" which would be assigned to review R01 grant applications in clinical research.

"I'll tell you what would happen," Carbone said. "They'll say there's $31 million available (the amount funding the Cooperative Groups this year), the groups will get half and the rest would go to the R01grants."

DeVita described the present system, with the NCI reorganization, of allocating funds for grants. All R01 grants compete against each other, irrespective of which division or program to which they are assigned. They compete for the total amount of money in the grants pool. The $31 million assigned to the groups and funds earmarked for center core grants, cancer control grants, organ site programs, and construction are not included in the R01 pool.

"Shouldn't the Cooperative Group funds be open to competition, and not be a line item?" Freireich asked.

"That would be hard to do," DeVita said.

"The groups are very well organized," Freireich said. "The chairmen meet with you and Upton. This group (centers) is struggling."

"You're doing pretty well," DeVita said.

"As long as you say 40% of the budget (DeVita had noted that DCT's budget for clinical treatment research was $75 million) is over here administratively, we've got a problem."

Freireich had mentioned that the groups budget has been permitted to grow about 10% as a cost of living increase. But DeVita said, "There is no real reason why the group budget has to grow. It could shrink. That money could go back to other programs. Of course, if money really gets tight, everyone will go down."

Jerome DeCosse, CCIRC chairman, pointed out that the groups have been in a "remodeling and renewal process. Some groups have disappeared (phased out by CCIRC), some are smaller than they were. I think we've gotten better. We are trying to emphasize science and quality.

"I do have a problem with confirmatory studies as of value to research," DeCosse continued. "That's control. It is a conjunction of the CCIRC and cancer control."

"I've heard an idea that is original," Freireich said. "The Cooperative Groups have proven that cancer control can be practiced through the groups. Let's use the groups as the leading edge to get good Cooperative Group research funded with cancer control money, and free up the $31 million to do good cancer clinical research. That would get cancer control funds back into the clinical research area. What's the control budget, $30 million?"

"Try $84 million," DeVita said. The FY 1979 budget for the Div. of Cancer Control & Rehabilitation is $69.7 million.

"God, if we could only get half that," Freireich said.

"The cancer control legislation has regionalization written all over it," Frei said. "The same is true for clinical research. The groups are talking about regionalizing. The only answer is regionalizing."

Carter ended the meeting with a summary of the discussions and recommendations for position statements by AACI:

"If innovative clinical research is to be carried out in cancer centers, we need core support, increased availability of program project support, increased availability of R01 support, a special study section to review the R01 grants, and longer grant award periods."

Cancer Center Program Director William Terry suggested that the committee, if it feels a new study section is needed, "you should not be inhibited by our administrative problems. Make it clear that you feel a new study section is needed for review of cancer clinical research."

Carter agreed. "Leave it up to NCI to determine if it will try to get a new study section in DRG, phase out an existing one and replace it, or set up a new one within NCI."

NCI CONTRACT AWARDS

Title: Preparation of 28 compounds
Contractor: Midwest Research Institute, $75,235.

OMB TO ASK $29 MILLION CUT IN NCI SPENDING FOR CURRENT FISCAL YEAR

The Office of Management & Budget is planning a recision request to Congress to cut $160 million from the amount appropriated to NIH for FY 1979. The recision would trim NCI's appropriation from $942 million to $912.7 million.

A recision request has to be approved by both houses of Congress. If either house disapproves, or if no action is taken within 45 days after the request is made, it is disallowed.

The White House will submit the recision when it sends the FY 1980 budget to Congress, probably in the third week of January. It could be early March before NCI will know what its spending level will be for the fiscal year. With the second round of grants to be acted upon by the National Cancer Advisory Board in January, many of those approved then for funding probably will not be awarded until April—and not even then, if the recision is approved by Congress.

The Administration will ask the same amount, $912.7 million, for NCI for 1980.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. Some listings will show the phone number of the Contract Specialist, who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Their addresses, all followed by NIH, Bethesda, Md. 20014, are:

Biology & Diagnosis Section — Landow Building
Viral Oncology & Field Studies Section — Landow Building
Control & Rehabilitation Section — Blair Building
Carcinogenesis Section — Blair Building
Treatment Section — Blair Building
Office of the Director Section — Blair Building

Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

SOURCES SOUGHT

RFP NCI-CM-97248

Title: *Monitoring of immunologic competence in cancer patients*
Deadline: *Dec. 15 (for submission of resumes)*

Only one organization is known which can perform the effort above. This organization is the Litton Bionetics Inc. LBI has developed unique technical capabilities for growth conditions for various tissue culture cell lines as well as computer storage of data and retrieval systems. This organization also provides facilities for frozen sample storage and maintenance of samples.

Specifically, the required services include providing courier service for pickup and delivery of blood serum and tissue samples, separating serum and lymphocytes from blood cyropreservation of lymphocytes, operating and maintaining serum and lymphocyte bank, maintaining culture lines, performing a panel of in vitro assays of human immune competence and interacting for computer retrieval of tissue culture, serum, and lymphocyte works. The organization must be located in close proximity to the NIH so that once or twice daily pickups of samples are possible with minimum biological traumatic effect to the specimens.

If any organization feels that it has the demonstrated technical capabilities required to perform the aforementioned work, the submission of a brief, but concise, summary of capabilities is invited. This summary should include a complete resume of the proposed personnel outlining their experience in performing immunologic assays and tissue culture of mammalian tissue. Plans for maintaining proper catalogue and retrieval systems and general organization of workscope should be included as well as detailed research equipment and facility.

Responding organizations must clearly indicate their ability to pickup and deliver samples within 30 minutes of receipt with minimum degradation. Information submitted must be pertinent and specific in the technical area under consideration. Unnecessarily elaborate brochures are neither required nor desired. Resumes must be submitted in 5 copies.

Contract Specialist: Helen Lee
Cancer Treatment
301-427-8125

RFP NCI-CM-97268

Title: *Phase II studies in gastrointestinal cancer*
Deadline: *Approximately Feb. 2*

NCI is seeking an organization with a multidisciplinary team to: (1) Systematically investigate new and established chemotherapeutic agents; (2) develop new combinations and multidisciplinary treatment approaches; and (3) perform detailed pharmacologic evaluations of single and combined agents in gastrointestinal (GI) cancer. The primary objective will be to evaluate new therapies emanating from the NCI Drug Development Program for subsequent testing by other NCI grant and contract supported investigators.

The successful offeror must have a program in which a minimum of 40 patients per year with either pancreatic or gastric cancer and an additional 40 patients with colorectal cancer can be entered on studies. The multidisciplinary team shall consist of collaborators with expertise in diagnostic gastroenterology, surgery, radiation oncology, pharmacology, medical oncology and immunotherapy.

The contractor must have adequate knowledge of nutritional derangements related to GI cancer and its treatment and have capabilities to provide hyperalimentation or other supportive care measures to control nutritional imbalances. The facilities shall be

adequate for approximately 10 in-patients, space for out-patient visits, laboratories and offices.

Contracting Officer: Stephen Gane
Cancer Treatment
301-427-8125

RFP NCI-CM-97239

Title: *HL-A typing and matching for platelet and leukocyte transfusions*

Deadline: *Approximately Feb. 9*

Support service for determination of HL-A phenotyping on 4,000 peripheral blood samples per year as well as computerized storage and retrieval of HL-A types and names of donors and patients. These services will include sample pickups, analysis for HL-A determination, and delivery of samples and result data to NCI investigators within 48 hours of receipt.

The results of all data must be stored on a computer file. The computer file must also provide a minimum of 30,000 HL-A types and names of donors and patients. The computer system must allow retrieval of all HL-A type data as well as names of donors and patients and other serological information as required. These services must be available five days a week excluding weekends and holidays.

The contractor must have the following capabilities: 1) Possess a panel of cells of known HL-A identity. 2) Able to perform HL-A typing of tissue culture cells on a small number of tissue culture cells. 3) Possess serological reagents for human leukemia cells. 4) Possess a panel of HL-A specific antisera. 5) Provide for detection of anti-HL antibodies in the sera of patients. It is anticipated that the contract will be awarded for three years.

Contract Specialist: Helen Lee
Cancer Treatment
301-427-8125

RFP NO1-CN-95432-05

Title: *Develop effective methods for modifying smoking behavior in special at-risk populations*

Deadline: *Approximately Feb. 15*

The Div. of Cancer Control & Rehabilitation of NCI plans to develop, test and evaluate methods for effectively modifying the smoking behavior of specific, well defined at-risk populations and to document the methodology and validation in a form which provides for effective replication in similar situations.

Some examples of some at-risk groups which might be considered are industrial workers exposed to carcinogens that interact with smoking to increase the risk of cancer, teenage females who continue to smoke in spite of an overall downward trend in the use of cigarettes, women on the pill, etc.

Respondents to this RFP should be able to: (1) Develop a study design which would include a problem statement and analysis, specification and description of statistical techniques to be used for data analysis. (2) Design, develop and evaluate smoking cessation interventions to meet the specific needs of the special at-risk group. (3) Test and validate interventions on representative samples of the selected group. (4) Followup and document impact of the program on the behavior of the participants. (5) Develop final report which would include protocols detailing how to plan and implement an effective smoking cessation program for a specific at-risk population.

The scientific and technical portions of the proposals submitted in response to the RFP will be the major factors in selecting contractors to conduct this study. Experience and expertise in the design and evaluation of smoking cessation programs will also be important elements in the selection process.

Contract Specialist: James Prather
Control & Rehabilitation
301-427-7984

RFP NO1-CN-95431-05

Title: *Cross validation of smoking cessation programs*

Deadline: *Approximately Feb. 15*

The Div. of Cancer Control & Rehabilitation of NCI plans to fund prospective evaluations of the most widely utilized smoking cessation programs to obtain objective, reliable data on the effectiveness of these programs.

Respondents to this RFP shqulde be able to: (1) Determine the study design and scientific methodology for revaluating and comparing the effectiveness of these programs. (2) Provide a set of protocols detailing the objectives, content, methodology, followup and cost of the programs selected for evaluation. (3) Conduct, or work with an organization to conduct, each of the smoking cessation programs to be evaluated. (4) Assess the impact of the programs upon the knowledge, attitudes and behavior of the participants. (5) Obtain followup measures of smoking rates three, six, nine and 12 months after completion of formal cessation interventions. (6) Prepare an analysis and final report that provides objective, valid data on the effectiveness of the programs.

The scientific and technical portions of the proposals submitted in response to this RFP will be the major factors in selecting contractors to conduct this study. Experience and expertise in the design and evaluation of smoking cessation programs will also be important elements in the selection process.

Contract Specialist: James Prather
Control & Rehabilitation
301-427-7984

RFP NO1-CN-95435-02

Title: *Professional education in cytology related to bladder, lung, colorectal cancer and cervix*

Deadline: *Feb. 15*

NCI intends to issue an RFP to obtain the services

of organizations capable of expanding educational programs of cytology and cytopathology in bladder, respiratory and colorectal cancer. Multiple awards are planned for a three year period.

The RFP focuses on educational programs to overcome the shortage of well qualified professionals in those fields.

NCI expects to support several selected highly qualified cytology schools and other teaching groups or programs to increase significantly, through a three-year period of support, the number, proficiency, continuing professional education and quality control of cytotechnologists and cytopathologists with specific relevance to patients with possible bladder, lung or colorectal cancer. Geographic locations are important in order to distribute training and continuing education centers across the country. The attempt will be made to support at least one training center in several general regions. Offerors will compete only with other offerors in regions which will be identified in the RFP.

Contract Specialist: Susan Yablon
Control & Rehabilitation
301-427-7984

RFP NO1-CN-95434-05

Title: *Development of a course on prevention, focusing on cancer, for undergraduate medical students and/or residents*

Deadline: *Feb. 15*

The Div. of Cancer Control & Rehabilitation of NCI is seeking proposals for the development of a course on cancer prevention for undergraduate medical students and/or residents. The focus of the course should be to teach this group of health professionals how to use prevention approaches and methods in clinical practice, specifically as they relate to cancer, and to critically evaluate new research findings in the literature on cancer prevention.

The contractor will be required to: (1) Using the expertise of an interdisciplinary group of health professionals, develop a course in cancer prevention for undergraduate medical students and/or residents which will be given as an elective. (2) Field test and evaluate the course in cancer prevention and make revisions, as necessary. (3) Develop a course in cancer prevention which can be replicated by other medical schools and/or residency programs. A mandatory option for a longitudinal followup of the undergraduate medical students and/or residents in order to assess the long term benefits of the course will be included in this procurement.

RFP NO1-CN-95433-05

Title: *Development of a course on prevention, focusing on cancer, for nurse practitioners or physicians assistants*

Deadline: *Feb. 15*

The Div. of Cancer Control & Rehabilitation is seeking proposals for the development of a course on cancer prevention for nurse practitioners or physicians assistants. The focus of the course should be to teach this group of health professionals how to use prevention approaches and methods in clinical practice, specifically as they relate to cancer, and to critically evaluate new research findings in the literature on cancer prevention.

The contractor will be required to: (1) Using the expertise of an interdisciplinary group of health professionals, develop a course in cancer prevention for nurse practitioners or physicians assistants which will be given as an elective. (2) Field test and evaluate the course in cancer prevention and make revisions, as necessary. (3) Develop a course in cancer prevention which can be replicated by other nurse practitioner or physicians assistant programs. A mandatory option for a longitudinal followup of the nurse practitioners or physician assistants in order to assess the long term benefits of the course will be included in this procurement.

Contract Specialist for above two RFPs: H. McEwan
Control & Rehabilitation
301-427-7984

RFP 78-S-15 (Subcontract)

Title: *Long-term carcinogenesis bioassay, using rodents*

The requirement is for inhalation studies on five chemicals. Offerors should have experience in long term rodent studies and testing. A board-certified veterinary or medical pathologist with experience in laboratory animal rodent pathology, an HT/ASCP registered technician (or equivalent), chemist, and toxicologist must be available for the program. Facilities for testing and maintaining animals in stringently controlled, clean conditions are necessary.

A pre-proposal conference will be held on a date to be announced. Attendance is to be by written request only. The deadline date for receipt of completed proposals is to be announced. Those companies interested in receiving a copy of RFP 78-S-15 should send a request.

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1776 E. Jefferson St.
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Attn: Subcontract Administrator
301-881-2305

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