THE CANCER LETTER

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PROTECTION COMMISSION ASKS HEW TO ADOPT ENTIRE REPORT AS POLICY FOR HUMAN SUBJECT RESEARCH

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has recommended to HEW that its report based on the deliberations of its 1976 Belmont Conference be adopted in its entirety as a statement of HEW policy.

(Continued to page 2)

In Brief

UPTON STILL PONDERING LOCATION OF CENTERS, OTHER PROGRAMS; MOVES COULD INVOLVE DCCR

FINAL MAJOR step in NCI's reorganization is still being pondered by Director Arthur Upton. Centers, organ site, training and construction programs are still not assigned to a program division. Options include: (1) Putting them all into one new division; (2) combining centers with the Div. of Cancer Control & Rehabilitation; (3) combining centers, organ site, training and construction with DCCR; (4) splitting out some of DCCR's present programs and assigning them to other divisions, with or without any or all of the unassigned programs going into DCCR; (5) none of the above. Upton is considering the ramifications of those options, listening to advice and opinions from his staff and others, including representatives of the Assn. of American Cancer Institutes and the Assn. of Community Cancer Centers. . . . **GAO REPORT** on NCI's Carcinogenesis Testing Program will be out soon. . . . **TWO MEMBERS** of the NCI Research Contracts Branch staff have retired—Richard Colton, assistant chief for operations, and William Caulfield, deputy chief of the Viral Oncology & Field Studies Section . . . . **FLORIDA CANCER** Council is pushing a bill in the state legislature, the Cancer Control & Research Act, which would establish and finance programs in detection, epidemiology, treatment and rehabilitation. Herbert Kerman, Daytona Beach physician, is chairman of the council. . . . **TENTATIVE AGENDA** for the National Cancer Advisory Board meeting May 24-25 includes a review of Div. of Cancer Cause & Prevention programs by Director Gregory O'Conor, and discussion of the roles of related agencies in cancer activities, including OSHA, NIOSH, Consumer Product Safety Commission, and Environmental Protection Agency. . . . **CANADIAN ASSN.** of Radiologists 42nd annual meeting June 24-28 in Vancouver will include, in addition to presentation of scientific papers, the Annual Oration, by Roy Filly, San Francisco, on "Comparison of ultrasonography, computed tomography, and gallium-67 scanning for detection of abscess;" a joint diagnostic and therapeutic session on radiation protection; the Gordon Richards Memorial Lecture by Harold Johns, Toronto, on "Impact of physics on therapeutic and diagnostic radiology;" and the Royal College Lecture, by Derek Harwood-Nash, Toronto, on "Pediatric neuroradiology: a perspective."

PRACTICE-RESEARCH BOUNDARIES, BASIC PRINCIPLES SOUGHT AS HEW POLICY

(Continued from page 1)

The Belmont Report summarizes basic ethical principles and guidelines for research involving human subjects developed by the commission. The report was published in the April 18 issue of the *Federal Register.* HEW asked for comments on the recommendation that it be adopted as department policy.

"Three principles or general prescriptive judgments that are relevant to research involving human subjects are identified in this statement," the report says. "Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects.

"These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects."

The statement included three primary considerations:

• **Boundaries between medical practice and research.** "For the most part, the term 'practice' refers to interventions that are designed solely to enhance the wellbeing of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term 'research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge, expressed for example in theories, principles and statements of relationships. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

"When a clinician departs in a significant way from standard or accepted practice," the report continues, "the innovation does not, in and of itself, constitute research. The fact that a procedure is 'experimental' in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees to insist that a major innovation be incorporated into a formal research project.

"Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."

• **Basic ethical principles.** The report cites three which are "particularly relevant to the ethics of research involving human subjects—respect for persons, beneficence, and justice."

"Respect for persons incorporates at least two ethical convictions—first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy."

The report further defines 'autonomy' and discusses individual freedom and self determination as they relate to participation in trials. "Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequences. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations. . . .

"Beneficence is often understood to cover acts of kindness or charity that go beyond strict obligation," the report says. "In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. . . .

"Justice—Who ought to receive the benefits of research and bear its burdens? This is a question of justice. . . . An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."

The report noted that during the 19th and early 20th centuries, the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients.

"The selection of research subjects needs to be scrutinized in order to determine whether some classes, such as welfare patients, racial and ethnic minorities, or persons confined to institutions are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

"Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the

beneficiaries of subsequent applications of the research.

• **Applications.** When the general principles are applied to the conduct of research, considerations include informed consent, risk/benefit assessment, and the selection of subjects.

"Informed consent—Controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension, and voluntariness." The report explains in some detail the commission's understanding of each of those elements.

"Assessment of risks and benefits—This requires a careful arrayal of relevant data, including in some cases, alternative ways of obtaining the benefits sought in the research. . . . For the investigator, it is a means to examine whether the proposed research is properly designed. For the review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For the prospective subjects, the assessment will assist the determination whether or not to participate." The report discusses in detail the nature and scope of risks and benefits.

"Selection of subjects—Social justice requires that a distinction be drawn between classes of subjects that ought and ought not to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects, such as adults before children, and that some classes of potential subjects such as the institutionalized mentally infirm or prisoners may be involved as research subjects, if at all, only on certain conditions."

The comment period will close July 17. Send them to F. William Dommel Jr., Asst. Director for Regulations, Office for Protection from Research Risks, NIH, 5333 Westbard Ave., Rm 303, Bethesda, Md. 20205. The phone number is 301-496-7005. All comments received will be available for inspection at that address.

NCI EPIDEMIOLOGIST-STATISTICIANS DISPUTE BROSS CLAIM ON X-RAY HAZARD

Roswell Park statistician Irwin Bross has claimed development of a "new statistical methodology" to reanalyze data from a leukemia study, data which he says now demonstrate that previous risk estimates underestimate radiation hazards by a factor of 10 (*The Cancer Letter*, Feb. 23).

John Boice and Charles Land, of NCI's Environmental Epidemiology Branch, disputed Bross' claim in a recent publication (*American Journal of Public Health*, February 1979).

"Although we agree that medical x-rays should not be performed without reason and that certain host factors may increase susceptibility to radiation effects, we feel that the conclusions of the article (e.g. that a dose-effect curve was demonstrated in the one rad range) are not justified by the analysis or data reported," Boice and Land wrote.

"The statistical model used by Bross, et al, appears unsuited for analysis of the (leukemia study) data. Precise estimates of 'risk' are obtained only by incorrectly treating estimated values as known constants, and results are not consistent with a large body of data from epidemiologic studies. Furthermore, to our knowledge the 'new statistical methodology' has never been presented in a journal devoted to statistical methods and has not, therefore, received the kind of critical peer review required before such a technique can be accepted as useful and valid.

"In addition, no radiation dosimetry was performed, and the casual way in which radiation doses were assigned ignores factors that could radically change the shape of any dose-effect relationship."

PAULING DISPUTES CONTENTION THAT HIS APPLICATIONS LACKED ESSENTIAL DETAILS

To the Editor:

In ***The Cancer Letter*** for 22 Sept. 1978, page 4, there was published an article saying that Mr. Benno Schmidt, chairman of the President's Cancer Panel, had said that I had not really made any grant applications to the National Cancer Institute, but only a request for funds, and that I had refused to put the request in the form of an application. There was then published in ***The Cancer Letter*** for 23 March 1979 a correction by Mr. Schmidt, who said that in fact his statement was in error and that I had submitted five research grant applications since 1973, that they were in the proper format, and that they were accepted by the Div. of Research Grants for review. He then said that the statement that my applications were not grant applications "was an erroneous interpretation on my part of information which I had been given verbally to the effect that Dr. Pauling's poor priority scores and disapprovals stemmed from the absence in his applications of essential details, documentation, and controls."

The statement about the absence of essential details, documentation, and controls is false. The descriptions of the proposed investigations and their background occupied a total of 400 pages in the five applications, with a total of 800 references to the literature, not including those in the bibliographies of the investigators. There was a detailed discussion of the controls to be used in the studies. Much of the discussion and about half the references have been published in our recent review articles: Ascorbic Acid and Cancer: A Review, E. Cameron, L. Pauling, and B. Liebovitz, *Cancer Research* 39, 663-681, March 1979; and Ascorbic Acid as a Therapeutic Agent in

Cancer, E. Cameron and L Pauling, *J. Internat. Acad. Prev. Med.* 5, 8-29, 1979. Mr. Schmidt seems to have been misled by the sources of his information.

Linus Pauling
Menlo Park, Calif.

DCT BOARD WORRIED THAT COMMUNITY PHYSICIAN SUCCESS WILL HURT RESEARCH

The review of clinical trials by the Board of Scientific Counselors of NCI's Div. of Cancer Treatment was focused primarily on the Cooperative Groups, their impact on the treatment of cancer and their place in further clinical research.

Discussion at the two day meeting touched on other issues—group vs. single institution studies, needs in various modalities and disciplines to achieve further progress, various ways to support and carry out clinical research. Portions of that discussion follow:

Denman Hammond, chairman of the Childrens Cancer Study Group, made a presentation on contributions of the Cooperative Groups to pediatric oncology. Among the noteworthy accomplishments, Hammond pointed out, is that in some studies now, childhood leukemia patients are achieving two year survival at a rate of 80-90%, and complete remission induction is obtained with 95% of patients.

Board member Sharon Murphy, St. Jude Childrens Hospital, agreed that studies mentioned by Hammond "demonstrate the power of the group approach. . . . But what do we do in the next generation?" She noted that with some subgroups of patients, survival has reached a plateau, and it is not clear that further improvements can be made by manipulating doses. Improved understanding of cell biology, especially in the poor risk subgroups, is needed, she said.

Murphy suggested that "we may need a concentration" of children "where we would have a critical mass of specialists to study prognostic factors, help understand underlying phenomena."

Hammond agreed that "one of the facts that is emerging is that more aggressive chemotherapy is not the answer." He said the groups are moving into studies such as pharmacological uptake, and surface marker factors. "We must have enough patients in each subgroup, and we need the groups to get those numbers."

Responding to criticism that the Cooperative Groups engage in too many duplicative and overlapping studies, Hammond said there is "now such good communication between the groups, facilitated by NCI staff, that we rarely do not know what others are doing."

"De we need one, two, three or four pediatric groups?" DCT Director Vincent DeVita asked.

"Three is a good number," Hammond said. "I would like to see the posture of some pediatric institutions strengthened. I would be opposed to any monolithic nationwide group."

Responding to questions by Board members Enrico Mihich, Roswell Park, and Sydney Salmon, Univ. of Arizona, on biological parameters and biological and chemical tests, Hammond said, "I couldn't have planted two better questions. . . . There are a variety of tests that need doing, and we are getting closer to fuller understanding. Unfortunately, contracts for phase I pediatric testing of chemotherapeutic agents have been canceled. One can superficially say that you can get all the information on toxicity from adults. That is not true. You can't say that children are just small adults. It was very important to the pediatric Cooperative Groups to have a member institution doing phase I pediatric testing. I would like to suggest that the Board look at this, to see if we can't overcome whatever objections there were."

Salmon pointed out that most biological marker studies are not being supported by the Cooperative Group mechanism. "They are simply done by member institutions on their own. We would like to have every member institution capable of doing these tests, for group wide studies."

Hammond suggested that funding mechanisms "must permit a little more response time. Three to five years is too limited. We need a better mechanism to adopt quickly to clinical leads and needs. We need a better tie in for phase 1 studies. We could have longer grants and still have intermittent review."

Hammond noted that the average duration of funding for NCI grants is 2.6 years, while at the National Institute of Heart, Lung & Blood Diseases, it is five years.

DeVita responded that more flexible mechanisms of cooperative agreements and consortium grants would be proposed (***The Cancer Letter,*** April 6). On the phase 1 and 2 contracts, "we made a procedural mistake. We competed them as a package and pediatric lost out in the competition. We can compete them separately."

Charles Coltman, Univ. of Texas (San Antonio), presented a review of lymphoma research conducted by Cooperative Groups, which he said has made "clear contributions" in establishing the activity of many agents, confirmed the value of MOPP and other combinations, and is presently examining other regimens for less toxicity.

Coltman pointed out a paradox that has developed. "Our success has become a detriment to clinical research. The transferral of tools to community physicians has allowed them to treat successfully without contributing data to studies."

Henry Kaplan, Stanford Univ., has been seen by some Cooperative Group members as their chief adversary on the Board. Kaplan has been critical of the groups on occasion and has questioned some of their claims they have made concerning their contributions.

"It was interesting to read through these extensive documents," Kaplan said. "Dr. Coltman and his colleagues are to be congratulated for the mountain of

material on lymphomas. We should be obliged to use their material as a benchmark in assessing the rest of the material presented to us.

"The most important question we have to answer," Kaplan continued, "is the extent to which Cooperative Groups played a role in confirming initial studies and concepts from various institutions—no one has ever questioned the value of this role—and the extent of their own initiatives. It is not necessary, in my mind, for them to have been initiators, to have broken new ground. I never perceived that charge for them. However, the material presented here claims some achievements (as initiators) that is not entirely valid."

Kaplan said a claim by Coltman that the first study combining chemotherapy and radiotherapy was initiated by a Cooperative Group in 1965 was in error. "The record clearly shows that in 1951 a study combining radiotherapy and nitrogen mustard to treat localized Hodgkin's disease was initiated independently by David Karnofsky at Memorial and by myself at Stanford, and there was another by Hancock in England in 1957.

"The real question is, how can we come to grips with a valid assessment of Cooperative Group contributions?" Kaplan continued. "Obviously, they have made enormous contributions in confirming pilot studies and working out treatment schedules. But the record has been distorted with inaccurate statements."

"I thank Dr. Kaplan for setting the record straight," Coltman said.

Board member James Holland, who is also chairman of Cancer & Leukemia Group B, disputed Kaplan on one point. "In 1963, I inquired of him and Dr. Rosenberg (about combinations) and got the answer that it was too risky to undertake." Holland claimed that pertinent material was not published until 1969. "Your allusion that (Coltman's claim) was incorrect and puffery is not correct."

"Dr. Holland presented a rejoinder to my concern, but he changed the statement," Kaplan said. "I will quote again, since he has difficulty comprehending." He emphasized that "our reservations were on radiotherapy used with chemotherapy, not with chemotherapy combinations. Our conviction was based more on the lack of curative ability than the hazard. That changed with MOPP."

As for Holland's 1963 letter, which Kaplan said he had forgotten, "I couldn't have survived all these years without a selectively faulty memory."

Murphy was concerned about the impact of "community physicians applying the tools effectively. How will that affect group wide studies?"

"It could have a severe impact," Coltman said. "I think we could allow community physicians to participate in studies more with us. Community oncologists are using combination chemotherapy in adjuvant settings. We need to attract them into working with us in controlled clinical trials."

Paul Carbone, chairman of the Eastern Cooperative Oncology Group and director of the Univ. of Wisconsin Comprehensive Cancer Center, said he felt the issue of community physicians keeping patients out of research protocols because they can effectively treat them was "a straw man. . . . You and I, Henry, all of us here, have trained these people. Now we're saying they can't treat patients, they have to bring them back to centers. We need better communications, to work with those people, to get them involved. I'm not pessimistic. I think we can work with them."

Kaplan said he was concerned about radiation dose levels in many studies. "Perhaps that is indicative of the problem of communication between the Cooperative Groups and, shall we say, uncooperative groups. One of the new concepts that has emerged in Hodgkin's disease was a deliberate attempt to reduce radiotherapy, replace with MOPP or other chemotherapy, with the view to reduce late effects of radiation. Yale has excellent results with low dose radiation plus chemotherapy close to MOPP. In 1967-70, I saw a 21 month old child with stage 3B Hodgkin's and a four-year-old with stage 3B. We realized that if we treated them successfully with high dose radiotherapy, it could impair their growth. We decided on an impromptu combination of low dose radiation and MOPP. Both are alive and well and within one centimeter of the standard height."

Kaplan said Stanford now treats children under 6 with 1500 rads plus MOPP, and up to 2500 rads for children 11-14, plus MOPP. Eight year survival of all children, in all stages, is 96%.

RALL, FDA CHIEF ON PANEL FOR PUBLIC ISSUES SYMPOSIUM AT AACR MEETING

David Rall, director of the National Institute of Environmental Health Sciences and head of the new National Toxicology Program, will chair a symposium on public issues at the 70th annual meeting of the American Assn. for Cancer Research in New Orleans.

The symposium will be held on May 17, the second day of the meeting, at 8:30 p.m. in the New Orleans Hilton.

Donald Kennedy, who announced last week that he will leave as commissioner of the Food & Drug Administration to accept a position at Stanford Univ. will be on the panel to discuss regulatory policy. I. Bernard Weinstein, Columbia Univ., will discuss the science of testing for carcinogens. Ann Marie Norberg, a member of Congressman Andrew Maguire's staff, will present the legislative point of view.

L.W. Wattenberg, Univ. of Minnesota, will chair a symposium on "Prevention of Cancer—Some Recent Strategies." S.S. Mirvish, Eppley Institute, will speak on ascorbic acid inhibition of the formation of carcinogenic N-nitroso compounds; W.R. Bruce, Univ. of Toronto, will talk on dietary factors; Wattenberg

will discuss inhibition of chemical carcinogenesis; Michael Sporn, NCI, will make a presentation on retinoids; and B.S. Blumberg, Institute for Cancer Research, will talk on hepatitis B virus and prevention of cancer of the liver.

Joseph Simone, St. Jude Children's Hospital, will deliver the Richard and Hinda Rosenthal Foundation Award Lecture on "Childhood Leukemia as a Cancer Research Model."

Roswell Boutwell, McArdle Laboratory, will deliver the G.H.A. Clowes Memorial Lecture on "Biological and Molecular Mechanisms of Tumor Promotion."

Hugh Creech, long time AACR secretary-treasurer who is winding up his year as president of the organization, will make the Presidential Address on the topic, "Responsibilities of AACR."

Vincent DeVita, director of NCI's Div. of Cancer Treatment, will present the 10th annual David A. Karnofsky Memorial Lecture on "Consequences of the Chemotherapy of Hodgkin's Disease" at the 15th annual meeting of the American Society of Clinical Oncology, which will precede the AACR meeting by two days, also in New Orleans.

NEW PUBLICATIONS

"Nutrition and Cancer," published quarterly by the Franklin Institute Press, Box 2266, Philadelphia 19103, Gio Gori, editor; $48 year U.S., Canada and Mexico; $56 elsewhere.

"Statistical & Epidemiological Data on Urologic Editor, UICC, 3 rue du Conseil General, CH 1205, Geneva.

"Cancer—A Manual for Practitioners," published by the American Cancer Society Massachusetts Div., edited by Blake Cody. Contact local ACS divisions or the Mass. Div., 247 Commonwealth Ave., Boston 02116.

NCI's Office of Cancer Communications will send copies of its publication order form to those requesting it. The form contains eight titles of general information on the National Cancer Program; nine for health professions, plus individual chapter reprints on eight cancer sites and seven bibliographies of education materials that are available; nine titles for program planners and communicators; and 27 titles of public and patient education materials. Send for a copy of the order form before requesting any of the publications, which are available at no charge.

ADVISORY GROUP, OTHER CANCER MEETINGS FOR MAY, JUNE

Clearinghouse on Environmental Carcinogens Data Evaluation/Risk Assessment Subgroup—May 1, NIH Bldg 31 Rm 10, 9 a.m., open.
International Society of Clinical Biostatisticians—May 2-3, Institut Jules Bordet, Brussels.
EORTC Symposium on Progress & Perspectives in Lung Cancer Treatment—May 3-5, Brussels.
Breast Cancer Task Force— May 3-4, NIH Bldg 31 Rm 10, 1—5 p.m. May 3; 8:45 a.m.—adjournment May 4, open.
Tumor Immunology Committee— May 7-8, NIH Bldg 31 Rm 9, open May 7, 9—9:30 a.m.
The Changing Scene of Childhood Cancer—May 9, Yale Comprehensive Cancer Center, Hartford, Conn.
Immunotherapy of Cancer: Success or Failure?— May 10 Roswell

Large Bowel Cancer Project Review Committee—June 7-8, Prudential Bldg., Houston, open June 7, 7:30 p.m.—8 p.m.
Cancer of the Colon & Rectum: 1979— June 10, Roswell Park continuing education in oncology.
Clinical Cancer Education Committee— June 11-12, NIH Bldg 31 Rm 6, open June 11, 8:30—9 a.m.
American Cancer Society Board of Directors—June 11-15, Registry Hotel, Minneapolis.
Hodgkin's & Non-Hodgkin's Lymphoma: Multifocal Aspects in the Clinical Spectrum—June 14-15, Sheraton Brandywine Inn, Wilmington, Del.
Cancer Control Intervention Programs Review Committee—June 14-15, Landow Bldg Rm A, open June 14, 8:30—9 a.m.
Charged Particle Radiotherapy—June 24-28, Canadian Assn. of Radiologists, Vancouver; 42nd annual meeting.
Clinical Cancer Investigation Review Committee—June 25-27, NIH Bldg 31 Rm 8, open June 25, 8:30—10 a.m.

NCI CONTRACT AWARDS

Title: Metropolitan Surveillance Epidemiology End Results Program, continuation
Contractor: Emory Univ., $100,000.

Title: Large scale production of oncogenic or potentially oncogenic viruses
Contractor: Electro-Nucleonics Laboratories, $693,886.

Title: Support services for studies on role of viruses and experimental oncogenesis and human cancer, continuation
Contractor: Hazleton Laboratories, $806,292.

Title: Study of genetic and immunologic factors in viral leukemogenesis, continuation
Contractor: Albert Einstein College of Medicine of Yeshiva Univ., $68,575.

Title: Immunological and biochemical studies of mammalian viral oncology, continuation
Contractor: Meloy Laboratories, $833,161.

Title: Studies of Marek's disease herpesvirus, continuation
Contractor: Life Sciences Inc., $499,490.

Title: Study of propagation and serioepidemiology of EB virus, continuation
Contractor: Children's Hospital of Philadelphia, $52,160.

Title: Housing and maintenance of a chimpanzee breeding colony, continuation
Contractor: Southwest Foundation for Research and Education, $25,000.

Title: Research on mouse typing and diagnostic reagents, continuation
Contractor: Microbiological Associates, $520,709.

Title: Metropolitan Atlanta SEER Program, continuation
Contractor: Emory Univ., $608,928.

Title: In vitro cell culture screening of new materials for cytotoxicity
Contractor: Univ. of Florida, $525,635, andArthur D. Little Inc., $285,322.

Title: Study of the rythmometry on Japanese and North American female volunteers of dif ferent age groups
Contractor: Univ. of Minnesota, $58,191.

Title: Studies on possible viral etiology of human malignancies, continuation
Contractor: Baylor College of Medicine, $185,790.

Title: Population based cancer epidemiology research center in Iowa, continuation
Contractor: Univ. of Iowa, $1,125,840.

Title: Research on spontaneous and virus induced neoplastic transformation, continuation
Contractor: Meloy Laboratories, $828, 697.

Title: Development of the Connecticut cancer epidemiology program, continuation
Contractor: Yale Univ., $421,000.

Title: Studies of pediatric tumor resource, continuation
Contractor: Johns Hopkins Univ., $52,972.

Title: Studies of immunoprevention of spontaneously occurring neoplasms, continuation
Contractor: Microbiological Associates, $260,000.

NEW COMMUNITY ONCOLOGY PROGRAM RFP AVAILABLE; CONFERENCE SCHEDULED

The RFP for the new Community Hospital Oncology Program has finally been completed and will be available early in May (see RFPs Available). NCI's Div. of Cancer Control & Rehabilitation plans to fund as many as 30 contracts, for a total of up to $10 million a year, in three categories. A preproposal conference is scheduled for June 18.

A preproposal conference for RFP N01-CP-95616, carcinogenicity studies in rodents (***The Cancer Letter***, April 13), has been scheduled for May 2 at NIH, Bldg 31 Room 4, at 9 a.m.

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. Address requests to the contract officer or specialist named, NCI Research Contracts Branch, the appropriate section, as follows:
Biology & Diagnosis Section and Viral Oncology & Field Studies Section—Landow Building, Bethesda, Md. 20014; Control & Rehabilitation Section, Carcinogenesis Section, Treatment Section, Office of the Director Section—Blair Building, Silver Spring, Md. 20910.
Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP N01-CN-95457-45

Title: *Community Hospital Oncology Program*
Deadline: *July 31*

An RFP is available from the Div. of Cancer Con-

trol & Rehabilitation soliciting contract proposals to field test a model for the multidisciplinary clinical oncology program approach to community cancer program development. It is the intent of DCCR to conduct the test in three categories of community cancer care settings. These categories are: (a) multi-hospital cooperative (community-wide) programs; (b) small community programs; and (c) single hospital programs.

The purpose of these community hospital oncology programs is to provide scientific evidence that implementation of the COP model in a community will improve the scope and quality of cancer care for cancer patients over that received prior to development of the program.

Contract Specialist: Estelle Cohen
Control & Rehabilitation
301-427-7984

RFP NCI-CP-FS-91025-65

Title: *Etiologic study of respiratory cancer in coastal Texas*

Deadline: *June 1*

The Environmental Epidemiology Branch of NCI is planning a case-control interview study of the environmental determinants of lung and larynx cancer in the coastal Texas area (a six-county area including Houston and Galveston). This will be an investigation into the influence of smoking, occupation, ethnicity, and general environment on the high respiratory cancer mortality rates in this area. Only one contract award will be made.

The contractor shall serve primarily as a field-operating research/service collaborator on this in-house study undertaken and designed by the Environmental Epidemiology Branch. The contractor must have:

1. Expertise in conducting extensive structured interview stu lies in the field through personal face-to-face interviews in Texas.

2. Expertise in abstracting medical records and in locating patients or their next-of-kin for interview.

3. A highly experienced project director, experienced interviewers, a full-time field management specialist, computer equipment and facilities, and data processing personnel with experience in handling epidemiologic data.

4. An ongoing close working relationship with Texas state and local health officials and the Texas medical community to ensure accurate identification of cases and controls, as demonstrated by previous collaborative studies.

5. Close familiarity with the population and industries of coastal Texas so that the contractor may assist NCI staff in the final detailed design of this study.

Among other duties, the potential collaborator is expected: (1) To assist in the design phase of the project. (2) To identify appropriate respiratory cancer cases and controls among residents of the coastal Texas area. This will include some cancer cases diagnosed as early as 1975. (3) To interview the anticipated 3,000 subjects using an approved detailed field studies questionnaire after obtaining appropriate informed consent. Each interview will last approximately one hour. (4) To abstract hospital charts of the cases to obtain required information. (5) To computerize and summarize the data and collaborate with the NCI staff in analyzing the resulting data.

Contracting Officer: Sydney Jones
Viral Oncology & Field Studies
301-496-1781

RFP NCI-CP-FS-91034-65

Title: *Support services for occupational studies*

Deadline: *Approximately June 5*

The Div. of Cancer Cause & Prevention of NCI, Environmental Epidemiology Branch, is seeking technical (nonprofessional), managerial, and clerical support for its occupational studies program.

Prospective contractors must have experience and expertise in all phases of occupational studies such as the design of data collection documents, abstracting, interviewing, keying and editing of data, recording, tracing of members of established cohorts, procuring of death certificates, creation and manipulation of computer files, and generation of basic statistics. The personnel required include five fulltime, permanent persons (data collection manager, systems analyst, two computer programmers and one clerk-typist) and four person-years of part-time help. The contractor must have, at the time of submission of a proposal, permanently established offices within 50 miles of the NIH off-campus Landow Bldg., 7910 Woodmont Ave., Bethesda, Md. 20205, in which the Environmental Epidemiology Branch is located.

In accordance with Section 15 of the Small Business Act, it is hereby determined that 100% of this procurement will be a Small Business Set-Aside. In order to qualify as a Small Business for this procurement, responders must have gross earnings of $12 million or less over the last three years.

Contracting Officer: Sydney Jones
Viral Oncology & Field Studies
301-496-1781

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