

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

NCI STAFF WORKING GROUP LEANS TOWARD STARTING CCOP WITH COMMUNITY HOSPITALS AS LEAD FUNDING AGENCIES

NCI executives are leaning toward the conclusion that the Community Clinical Oncology Program will be started with guidelines that will preclude "research bases" (university centers, cooperative groups) from competing with community hospitals as the lead institutions in the program. If that is the final decision, it will be a major victory for the Assn. of Community Cancer Centers, whose representatives have battled to develop CCOP as a community controlled program.

It also would be a defeat for Charles Moertel, chairman of the Community Activities Subcommittee of the Div. of Resources, Centers & Community Activities Board of Scientific Counselors. And it could (Continued to page 2)

In Brief

MARGARET SLOAN, PIONEER IN INTERNATIONAL MEDICINE COLLABORATION, DIES; HAMMER TO ADDRESS AACI

MARGARET SLOAN, chief of the Occupational Medicine Branch in NCI's Div. of Resources, Centers & Community Activities, died Dec. 10 at her home in Rockville, Md. She was 66. A pioneer in the development of collaboration in medical sciences with the USSR, she joined NCI in 1961, "Dr. Sloan's invaluable scientific judgment resulting from the wealth and diversity of her professional experience provided a unique contribution to cancer research in this country and abroad," Director Vincent DeVita said.... ARMAND HAMMER, chairman of the President's Cancer Panel, will address the Assn. of American Cancer Institutes Jan. 24 at the opening session of the organization's semiannual meeting at UCLA. DeVita and DRCCA Director Peter Greenwald are on the agenda Jan. 25. A scientific presentation by the USC Comprehensive Cancer Center is scheduled for June 26, and the Second Annual Scientific Symposium of the UCLA Jonsson Comprehensive Cancer Center will follow adjournment of the AACI meeting. ... "DECADE OF DISCOVERY: Advances in Cancer Research 1971-1981," which commemorates the 10th anniversary of the National Cancer Act, is now being distributed by NCI's Office of Cancer Communications. The book was produced by NCI at the direction of the National Cancer Advisory Board. NCAB Chairman Henry Pitot said the 1971 Act "increased the pace of cancer research to such a degree that for cancer, the 1970s became an unparalleled decade of discovery." For free copies, write to OCC, NCI, Bethesda, Md. 20205. ... CONG-RESSMAN JACK BRINKLEY (D.-Ga.) has introduced a joint resolution commending Solomon Garb for his "invaluable leadership role in the fight against cancer." The resolution acknowledges Garb's role in securing passage of the National Cancer Act and in his own clinical cancer research.

Vol. 8 No. 1

Jan. 1, 1982

© Copyright 1982 The Cancer Letter Inc. Subscription \$125 year North America/\$150 yr elsewhere

Post Reporter Responds to Criticism Of Cancer Series

... Page 2

NCI Advisory Group, Other Cancer Meetings ... Page 4

RFPs Available, Sources Sought ... Page 5

COOPERATIVE AGREEMENTS WILL BE CCOP FUNDING MECHANISM; WORKSHOPS PLANNED

(Continued from page 1)

ultimately be a severe blow to those cooperative groups which have used the existing Cooperative Group Cancer Control Program to develop ties with community hospitals and significantly increase the number of patients from communities enrolled in group clinical studies.

The Cooperative Group Cancer Control Program, funded now at about \$5 million a year, will be phased out as CCOP is implemented.

Moertel has argued that cooperative groups and university centers should be permitted to compete for CCOP awards. Under the plan advocated by ACCC and which NCI staff appears to favor, awards would be made to community hospitals or consortia of hospitals which would then negotiate with one or more research bases through which patients would be entered on national protocols and which would provide certain support activities. The community institutions would be in the driver's seat, free to determine which groups or centers they would work with.

"We're probably going to put the money directly into the communities and have them channel it into research bases," an NCI executive told *The Cancer Letter*.

The door has not been closed entirely on groups and centers as lead institutions in the program. After initial awards have been made and some experience has been gained, consideration may be given to permitting research bases to compete on their own for at least some of the subsequent awards.

When the split over the guidelines developed at the last DRCCA Board meeting, it appeared that Moertel's subcommittee would be given another chance to resolve the differences. Instead, an NCI working group was established to develop final recommendations to present to the DRCCA Board at its Jan. 14-15 meeting and to the National Cancer Advisory Board at its Feb. 1-3 meeting.

The working group consists of Jane Henney, acting NCI deputy director; Peter Greenwald, DRCCA director; John MacDonald, director of the Cancer Therapy Evaluation Program in the Div. of Cancer Treatment; William DeWys, chief of the Clinical Investigations Branch in DCT; Donald Buell, program director for medical oncology and community activities in DRCCA; and Harry Handelsman, DRCCA project officer for the Cooperative Group Cancer Control Program.

The working group also has decided on the funding mechanism for CCOP-cooperative agreements. If approval from both Boards is obtained, a request for applications (RFA) will be issued in March, with the first awards probably going to the NCAB for approval in October. NCI has been deluged with requests for information on CCOPs, with the result that a series of workshops is being planned for various locations around the country. The first will be held in Los Angeles Jan. 26, at St. Vincent's Medical Center, starting at 10 a.m. It will be open to anyone interested in the program.

POST REPORTERS RESPOND TO CRITICISM OF SERIES ON CANCER DRUG DEVELOPMENT

Jonathan Neumann and Ted Gupp, the *Washington Post* reporters who wrote the widely criticized series on anticancer drug development and testing, were invited by *The Cancer Letter* to respond to the torrent of criticism directed at them and the series which was published over several issues of the newsletter. They chose to do so by submitting excerpts from a letter written by Neumann to members of the Wilkins family, who had objected to aspects of the series. Those excerpts follow in full, as submitted by Neumann:

This is in response to your long letter to the Washington Post. First, I think you should know that your letter was well read and that people here took it seriously. In addition, I'd like you to know that I sympathize with all of your feelings—including your anger and frustration—and I appreciate the clear and thoughtful tone of your letter. Regardless of the "facts" or debating points of the articles, I am still a human being and I can feel the hurt and pain you express in your letter—as I felt the anguish you expressed in our telephone conversation.

Because I know you are deeply concerned about all the issues surrounding the Post series, I want to answer some of the points you raised in your letter.

At one point you asked: "Have the reporters, and the Post, honestly and intelligently considered the impact of their presentation on the people who must make these life and death type decisions?"

The answer to that question is yes. I fully respect that you might not agree with our answers to the questions about the "impact" of the stories. But I'd like you to know that we not only fully considered those issues—but that for months before publication, those issues were one of our primary considerations. The publication of the stories was not casual or haphazard. It was based on a year of reporting, interviewing and studying documents. It became evident early on in the reporting that the stories—no matter how they were presented would have an "impact" because of the sensitive and compelling nature of the subject. Our only interest throughout was that the truth be told and that the "impact" be responsible, as far as we could control it. We have always hoped, of course, that the results of the stories would be beneficial—although, as always, the results of our stories are not for us to determine, but for the community at large to decide.

You said in your letter that you felt our stories were "biased" and "slanted" and "uninformed." Again, I fully understand why you feel that way. But I know and understand myself—and my motives—even better. I have always thought that to be biased means to reach an opinion before the facts are in; to prejudge or unfairly reach an opinion without information. In the case of the cancer series, there is simply no possibility that Ted Gup or I (the authors of the series) entered the reporting with a bias. We were ignorant when we started. We knew nothing of experimental drugs or of clinical research methods—or of most aspects of cancer research. One thing we learned quickly was that there are so many different "schools" or perceptions or biases in the world of cancer treatment. I don't even know now what all the different biases are (I doubt anyone does). One thing I did conclude, however, was that our stories, when published, should stick as closely as possible to facts and quotes—and avoid opinionated sentences as much as possible. I believe we did that.

Many of the critical letters to the Post have said, in effect, that the Post's bias was "obvious." I must say honestly that this thought perplexes me. If the bias is so obvious, how come I don't know what the bias is? I would guess that the bias referred to would be: that we are biased against drugs; or, that we are biased against doctors; or, that we are biased against research; or, that we are biased in favor of laetrile or the other "alternative" cancer therapies; or that we had some personal feelings (possibly based on family experiences with cancer) coming into the story, thus tainting our opinions. I think it is reasonable to assume that those are the "obvious" biases we have been accused of. However, none of them are true.

If I came out of the year of reporting on cancer research with a personal opinion about experimental drugs (or a "bias" about the subject), I would say it is this: there are some serious, critical questions that need to be asked about our nation's cancer drug research efforts. These questions are not being addressed and considered in any substantial way now. The questions include: has the "well gone dry" among the types of chemical compounds being selected as experimental drugs? Are these chemicals being selected primarily because there is nowhere else to turn in this program-but not because there is any reasonable hope that these chemicals will cure cancer? Could there be better and more reliable animal tests to determine whether these chemicals should be introduced for human trials? Currently, a major flaw of animal tests for efficacy is that they are often "overpredictive" not "underpredictive"; that means that chemicals often show more activity (although not much activity) in animal systems than in humans. Statistically, we therefore know that we are continually introducing chemicals to humans with little or no chance of efficacy. Can't we devise better animal systems, and thus prevent a great deal of unnecessary human suffering in clinical trials? Can monitoring of human experiments be substantially improved so that doctors in every hospital testing a new drug can know of adverse reactions to the drug at other hospitals--thus preventing predictable organ damage and human suffering? Can firm guidelines be established (there are none at all now) to determine when to stop testing a drug-to determine both when a drug does not work against cancer and when a drug is too toxic for human use?

I suppose you will read that list of questions and say: "Those are important issues. Why didn't the Post write the stories that way, instead of being so sensationalistic?"

Cancer research-like many other areas-is very complicated and is very political. You may not know this, but numerous doctors and researchers across the country and in Washington have, in fact, been asking those questions for several years. Those questions are largely left unanswered-or, more to the point, they are not taken seriously by many leading cancer researchers. In many cases, these questions are considered to be merely the "biases" of one of the many interest groups I referred to earlier. If we had published a story simply listing those questions, the series would have gone unnoticed -and the questions would have gone unaddressed. In addition, when you analyze it, those questions alone are more "biases' than the facts we printed. Journalism is a very difficult business; we try to publish facts, not questions or conclusions. As for our chief responsibility-informing the general public-why would anybody care about those questions if they did not know the hard realities that gave rise to them?

I think if you read through our entire series again (which I

am not asking you to do) you will find that about 98 percent of it is straightforward reporting of case histories of drug tests. The other two percent is summarizing of the tests and what people say about them. You won't find our personal opinions anywhere—other than the clear opinion that we feel this material should be known publicly. That, in fact, is our major opinion about this material.

584 C.

As to the idea that we were "slanted" or "selective" in our presentation, I am convinced that any rational and openminded person who studies all of the available reports of drug experiments in the United States for the past 10 years would have to see that the facts show that there has been very little efficacy with new drugs discovered in the past 10 years, and that there have been serious side effects and suffering among those on the experimental drugs. Further study of the records -comparing the results of the past decade with the previous decade and the one before that—would also inevitably show that virtually all of the commercial anticancer drugs were discovered before 1970, and, despite the enormous screening and testing effort of the past decade, virtually no better drugs have been found. The conclusion is not that anyone has done something wrong; there is no need for defensiveness. What is needed is a hard look at the question: have we hit a dry well? Have we looked in the same place for too long?

The points I just made have not been addressed substantially by the leaders of cancer research in this country. I think, in fact, it is fair to say that by emphasizing these points, I am looking at experimental research in a different context than most cancer doctors view it. This may be why Vincent DeVita, head of the National Cancer Institute, and others have said that the Post has a "tragic misunderstanding" of the context of all this material. I quarrel with the use of the word "tragic" and the concept of a "misunderstanding." I am aware that Dr. DeVita's context is different than the one we present in the series. It is not that we misunderstand the context. You can look at the same facts in different contexts. Sometimes it is necessary to do so in order to make progress.

If there was a "slant," then, to our stories, it was that we presented the material as we saw it-not as the National Cancer Institute and many cancer doctors would like us to see it. This is not to say that we printed our opinions of the facts. On the contrary, it is to say that we printed the facts without coloring them with the emotional opinions (however well intentioned they are) by cancer doctors. You asked in your letter: "Why not an article that has as a theme that says "Experimental Drugs offer us hope in the war on cancer, however faint, problem plagued and frustrating." If we did that, our story would have been necessarily biased and based on opinions and hopesbut not on facts. Yes, the story would have made many more people happy. But would it have helped or even offered to solve any problems in the long run? I think not. As it is, I think the facts show that our stories are true and are not misleading. The truth is hard to accept—but I think it should be faced. To write the stories in the tone you suggest, I believe, would be unfair to the preponderance of facts.

I think it is also important to point out that Ted Gup and I have received hundreds of phone calls and dozens of letters from doctors and patients who have thanked us for writing the series—and have said they see the stories as a public service. There are also several doctors and scientists at the National Cancer Institute and the Food and Drug Administration who say that the stories were "long overdue"—that major problems in the experimental drug program have been ignored for years. Again: no one is challenging the idea of research or of human experimentation, nor the "sound ethical and rational foundation" for research, as you referred to in your letter. What is being questioned is what is happening in practice—not the underlying theories.

In your letter you referred to the reaction of others to our

stories. I'd just like to say that while I understand the anger and emotion from some of the medical oncologists who have felt they are coming under attack, I also believe that their resoundingly defensive responses have been unfortunate and irresponsible. It's one thing to disagree; it's quite another to lose one's composure and hurl words like "sadist" and "murderer" and "killer." Ted Gup and I have been labeled with those words by some few and we have been similarly attacked in letters, publications and testimony in Congress offered by some health administrators and cancer doctors. You might notice that in many letters from medical oncologists we are accused of numerous "inaccuracies." But specific examples of inaccuracies are not given. That is because, as the doctors know, our series was very accurate. If there are errors of fact, the errors were not in our reporting but in the collection of data by the National Cancer Institute. All of the data in our series comes straight out of official NCI documents and hospital records. While some people may not like what we published in the Post, the point is that we always stayed with the facts without embellishment or exaggeration; we never insulted anyone with silly phrases or accusations; and we always documented what we wrote. The medical oncologists who have failed to consider the import and substance of our series would do well to think calmly and to back up their claims before attacking the Post. Their profoundly emotional and nonfactual method of response to the serious ethical and medical questions raised in the articles poses yet another serious question about their objectivity and credibility in a scientific field that demands rational thinking.

Finally, I'd like to apologize for any hardships I might have caused you—even indirectly—by working on these articles. If you feel that our stories implied that your son was a "guinea pig" I am deeply sorry. I never thought that or meant to imply it. I thought that your quote in our article explained very vividly and clearly what your feelings were and why you opted for experimentation. I was also thinking of you and your family when I quoted Mrs. Linda Bost as saying: "You can't say that they (the patients who died in experiments) were wasted or even guinea pigs. . What was learned in those experiments might be used to help others. You've always got to hold on to that hope."

I pray that you and everyone else always does hold on to that hope. But at the same time, let's push forward with our eyes open and with the truth—not just our hopes—as our guide.

NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR JAN., FEB., FUTURE

3rd Conference on Human Tumor Cloning-Jan. 10-12, Univ. of Arizona Cancer Center, Tucson. Optional primer course Jan. 10, invited and competitively selected papers Jan. 11-12. Sydney Salmon and Jeffrey Trent are cochairmen. Contact Mary Humphrey, Conference Coordinator, Univ. of Arizona Cancer Center, Tucson 85724, phone 602-626-6044. From Gene to Protein: Translation into Biotechnology-Jan. 11-15, Konover Hotel, Miami Beach. 14th Miami Winter Symposium sponsored by the Univ. of Miami and Papanicolaou Cancer Research Institute. Frontier areas of genetic experimentation, including translation of lab processes into practical applications. Contact Miami Winter Symposium, P.O. Box 016129, Miami 33101, phone Sandra Black, 305-547-6265. Gynecologic Oncology Group-Jan. 14-16, Omni Hotel, Miami. Business meeting. Contact John Kellner, Group Manager, GOG Headquarters, 1234 Market St., Suite 430, Philadelphia 19107, phone 215-854-0770.

NCI Div. of Resources, Centers & Community Activities Board of Scientific Counselors–Jan. 14-15, NIH Bldg. 31, Rm 4, 8:30 a.m. both days, open. Current Concepts in Human Immunology and Cancer Immunomodulation—Jan. 18-20, Montpellier, France. Contact Dr. B. Serrou, Laboratoire d'Immunopharmacologies des Tumeurs, Centre Paul Lamarque, B.P. 5054, 34033 Montpellier Cedex, France.

First Venezuelan Course on Basic Oncology–Jan. 18-22, Caracas. Contact Dr. Enrique Pimentel, Centro Nactional de Genetica Humana y Experimental, Apartado Postal 50.587, Caracas 1050A, Venezuela.

Breast Cancer Task Force–Jan. 19-20, NIH Bldg 31 Rm 6, 8:30 a.m. both days, open.

Assn. of American Cancer Institutes—Jan. 24-26, UCLA Jonsson Comprehensive Cancer Center, semiannual meeting. Symposium on Childhood Cancer: Impact on Family—Jan. 29-30, Brooklyn. Contact Dr. Kalman Flomenhaft, Downstate Medical Center, Box 32, Brooklyn, N.Y. 11203.

National Cancer Advisory Board—Feb. 1-3, NIH Bldg 31 Rm 6, open Feb. 1, 8:30 a.m.–5 p.m. and Feb. 3, 8:30 a.m.–adjournment.

Frontiers in Hematology/Oncology-Feb. 1-5, Sugarbush Inn, Warren, Vermont. Sponsored by Albany Medical College and St. Mary's Hospital Cancer Treatment Center. Contact Linda Bonacquisti, Program Coordinator, Div. of Oncology, Albany Medical College, Albany, N.Y. 12208, phone 518-445-5361. NCI Div. of Cancer Treatment Board of Scientific Counselors-Feb. 8-9, Old Prudential Bldg., M.D. Anderson Hospital, Houston. Open Feb. 8, 8:30 a.m.-4:30 p.m., Feb. 9, 8:30 a.m.adjournment.

Soft Tissue Sarcoma–Feb. 11, Roswell Park continuing education in oncology. Contact Gayle Bersani, Cancer Control Coordinator, RPMI, 666 Elm St., Buffalo, N.Y. 14263, phone 716-845-4406.

Cancer Clinical Investigation Review Committee–Feb. 22-23, NIH Bldg 31 Rm 6, open Feb. 22, 8:30–9:30 a.m.

First International Conference on the Modulation and Mediation of Cancer by Vitamins—Feb. 23-26, Arizona Health Sciences Center Auditorium, Tucson. Sponsored by the Univ. of Arizona Cancer Center. Contact Mary Humphrey, Univ. of Arizona Cancer Center, Tucson 85724.

Second Annual Postgraduate Course of Current Approaches to Radiation Oncology, Radiobiology, and Clinical Physics– Feb. 24-26, San Francisco. Contact Extended Programs in Medical Education, UC School of Medicine, San Francisco 94143, phone 415-666-4251.

NCI Div. of Cancer Cause & Prevention Board of Scientific Counselors—Feb. 25-26, NIH Bldg 1, Wilson Hall, 9 a.m. both days, open.

16th Annual Clinical Symposium–Feb. 26-27, St. Jude's Children's Research Hospital, Memphis. Contact Associate Director for Clinical Research, St. Jude Children's Research Hospital, Box 318, Memphis, Tenn. 38101.

Conservation Surgery and Radiation Therapy in the Treatment of Operable Breast Cancer—Feb. 27-28, Sheraton Fisherman's Wharf, San Francisco. Seventeenth Annual San Francisco Cancer Symposium. Contact West Coast Cancer Foundation, 50 Francisco St., Suite 200, San Frnacisco 94133, phone 415-981-4590.

phone 415-981-4590. UCLA Symposia on Molecular & Cellular Biology: B and T Cell Tumors, Biological & Clinical Aspects—Feb. 28-March 6, Squaw Valley, Calif. Contact Molecular Biology Institute, UCLA, Los Angeles 90024.

FUTURE MEETINGS

Cancer Control and the Primary Physician—March 3, Summit, N.J. Sponsored by College of Physicians & Surgeons of Columbia Univ., Overlook Hospital, and American Cancer Society N.J. Div., open to physicians, nurses, and other health care professionals. Topics will include cancer statistics in New Jersey, screening, pain control, role of nutrition, comprehen-

The Cancer Letter Page 4 / Jan. 1, 1982

sive care of the cancer patient, psychosocial support, hospice and home care, and rehabilitation. Contact Cordis Griffith, Dept. of Medical Education, Overlook Hospital, Summit, N.J. 07901, phone 201-522-2085.

Eighth Annual Symposium on Diagnosis and Treatment of Neoplastic Disorders—Medical, Surgical and Radiotherapeutic Aspects—March 18-20, Johns Hopkins Univ. Medical Institutions. The course will focus on new approaches in cancer treatment, therapy of specific malignancies, and management of the complications of cancer. The program will include minisymposia on breast cancer, chronic myelocytic leukemia, Hodgkin's disease, and female germ cell tumors. Biological response modifiers, hyperthermia, radioimmunoglobulin therapy, new anticancer drugs, and in vitro testing will be discussed. Contact Program Coordinator, Continuing Education, Turner Auditorium Rm 22, 720 Rutland Ave., Baltimore, Md. 21205, phone 301-955-5880.

Western States Conference on Cancer Rehabilitation: Psychosocial, Physical, and Economic Interventions—March 25-27, Fairmont Hotel, San Francisco. A comprehensive interdisciplinary conference on the care of people living with cancer. Research advances and their practical applications will be presented. Contact Northern California Cancer Program, Carrie Ewing, PO Box 10144, Palo Alto, Calif. 94303, phone 415-497-7431.

Oncology Update 1982-April 3, Biltmore Hotel, Los Angeles. Sponsored by Northridge Hospital Foundation Medical Center. Presentations will be made on alternatives in primary management of breast carcinoma, emotional and psychological factors that impact lives of cancer patients, results now achieved with newer chemotherapeutic agents, and the role of highly specific antibodies in management of the cancer patient. Contact Sandra Rozzen, NHMC Medical Education Dept., 18300 Roscoe Blvd., Northridge, Calif. 91328, phone 213-885-5311. Genetic Mechanisms in Chemical Carcinogenesis—April 5-6, Univ. of North Carolina School of Medicine, Chapel Hill. The sixth annual Cancer Research Symposium will focus on chromosomal lesions in cancer, molecular mechanisms in carcinogenesis, and genetic differences in carcinogen metabolism. Contact Mimi Minkoff, Cancer Research Center, Box 30, MacNider Bldg., Chapel Hill 27514, phone 919-966-3036. Seventh Annual Congress of the Oncology Nursing Society-April 23-25, Stouffer's Riverfront Hotel, St. Louis. Sen. Daniel Inouye of Hawaii will be the keynote speaker. Contact Oncology Nursing Society, 701 Washington Rd., Pittsburgh, Pa. 15228, phone 412-344-3899.

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. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

RFP N01-CM-25600-58

Title: Production of hybridomas secreting antibodies reactive specifically with human cytokines

Deadline: Jan. 28

The Biological Response Modifiers Program, Div. of Cancer Treatment, NCI, seeks contractors with

the expertise necessary to produce monoclonal antibodies reactive with various human cytokines. Up to six cytokines yearly will be provided by the BRMP, and the contractor will provide the BRMP with antilymphokine secreting hybridomas, and semi-purified immunoglobulin derived from the various hybridomas.

For the purpose of this procurement a broad definition of cytokine will be used to include all agents with known immunological or growth regulatory functions. Representative examples include interleukin 1, interferon, lymphotoxin, products of suppressor T cells, products of helper T cells, etc. **Contract Specialist:** Mary Armstead

RCB, Blair Bldg. Rm. 212A 301-427-8737

RFP NCI-CM-27512-26

Title: Hyperthermia quality assurance program **Deadline:** Approximately Feb. 20

The Div. of Cancer Treatment, NCI, requires an organization possessing the facilities and capabilities necessary to perform the following:

1. Task A: Develop criteria, guidelines, procedures, and ancillary equipment for a quality assurance program in hyperthermia.

a. The contractor shall develop for the major heat generating modalities (radiofrequency, microwave, and ultrasound) and for appropriate thermometry systems to be used therewith the following:

1) Criteria for calibration and standardization of equipment and for its use in heat generation or for temperature measurements.

2) Guidelines for thermal treatment planning (time and temperature distributions in and around the treatment volume), for periodic calibration of heat generating and thermometry systems, and for testing of equipment with phantoms.

3) Procedures for calibration and standardization of heat generating devices and of thermometry systems.

4) Ancillary equipment and theoretical tools such as realistic and dynamic phantoms to simulate the various parts of the human body and theoretical models to complement studies with phantoms, large animals, and humans.

b. In developing these criteria, guidelines, procedures, and the ancillary equipment for carrying out the hyperthermia quality assurance program, the contractor shall consider but not be restricted to the following factors:

1) Development of phantoms for testing heating equipment to include:

a) The heating efficiency, the depth of penetration and beam widths of heating patterns, as well as the estimated net power required for thermal effectiveness.

b) EM radiation leakage of shortwave and micro-



wave applicators to reduce exposure to the patient and to the equipment operator.

2) The limitations of phantoms in simulating the acoustical and electrical properties of the human body at specific frequencies, temperatures, and pressures.

3) Specifications to standardize the composition of phantoms to facilitate accurate intercomparisons among institutions.

4) Safety of operators, patients, and other personnel in or near the treatment area.

5) Interstitial or intracavitary devices as well as external applied heating devices.

6) Instruments for the proper use of phantoms.

7) The basic physics of specific applicators and their appropriateness for heating tumors in various anatomical sites.

8) In vivo and/or in vitro thermal, electrical, and acoustical characteristics of various types of tumors as a function of frequency, time, spatial orientation, pressure, and temperature.

9) A calibration standard for thermometry systems with an accuracy of 0.01° C in order to insure accuracy of clinical measurements to 0.1° C.

10) Guidelines for checking calibration equipment against a central standard developed by NCI.

11) Guidelines for use of nonperturbing thermometers for various EM fields and their use (or the use of other thermometers) with ultrasound heat generating devices.

12) Evaluation and possible use of a thermographic camera to spatially map the surface temperature on phantoms.

2. Task B: Implement and conduct a hyperthermia quality assurance program.

a. The contractor shall implement and conduct a hyperthermia quality assurance program based upon the guidelines and procedures developed in Task A to include:

1) Periodic checking of thermometry and associated equipment to verify temperature distributions.

2) Examining and monitoring techniques used by institutions to determine temperatures.

3) Evaluation of temperature information recorded in clinical applications of hyperthermia.

4) Evaluation of safety procedures used at institutions.

5) Develop an inventory of equipment characteristics (such as three-dimensional power density distributions) for institutions or groups of institutions which can be used to evaluate data recorded during the treatment of patients.

6) Conduct on-site examinations of heating equipment and techniques at institutions.

7) Assist individual institutions in implementing their own quality assurance procedures.

8) Prepare educational materials for the proper use of phantoms, heating devices, thermometry

equipment, and thermal treatment planning tech- *#* niques.

9) Provide guidelines for proper shielding of treatment areas.

10) Provide guidelines for verification of thermal treatment plans.

b. The contractor shall be prepared to provide these services to clinical cooperative groups, cancer centers, and individual investigators for projects funded by NCI and to other investigators upon approval by NCI.

c. The contractor shall participate in workshops held by NCI in conjunction with contracts awarded under RFP NCI-CM-17480-22: Phase I Evaluation of Equipment for Hyperthermic Treatment of Cancer.

It is anticipated that this project will have a duration of five years: Task A—years 1-2, and Task B years 3-5. The contractor shall provide four staff years per year in performing this project. **Contract Specialist:** Carolyn Swift

> RCB, Blair Bldg. Rm. 228 301-427-8737

RFP N01-CP-25604-59

Title: Resource for human esophageal tissue cell from donor with epidemiological profiles

Deadline: Feb. 22

NCI is interested in organizations having both the technical capability and the interest to study various aspects of chemical carcinogenesis in specific human tissues. These studies involve the following:

1. Obtainment, storage, transporting to NCI, cultured human esophageal tissue following surgical re-

SOURCES SOUGHT Synopsis No. 52

Title: Operation of a low temperature repository Deadline for qualification statements: Approximately Jan, 15

NCI is seeking small business sources (500 emsection and/or immediate autopsy.

2. Provide epidemiological profiles on all tissue donors and patients.

3. Provide the morphological, cytochemical and immunocytochemical characteristics of epithelium in normal, premalignant and malignant states.

4. Provide the morphological, cytochemical and immunocytochemical characteristics of epithelium in normal, premalignant and malignant states of tissue and cells maintained in culture.

5. Using established methods and those to be provided by NCI to develop epithelial cells from organ cultures to be stored in the contractor's facility and delivered periodically to the NCI.

A four year effort is anticipated in the effective pursuit of this project.

Contract Specialist: J. Roland Castle RCB, Blair Bldg. Rm. 2A07 301-427-8764 ployees or less) with the ability to carry out a project for the operation of a low temperature repository for biological materials. Interested organizations will be expected to:

1. Provide suitable floor space sufficient for the installation and storage of refrigerators/freezers and all items necessary for a repository. This would include approximately 50 cubic feet of -20° C space, 600 cubic feet of -70° C space and 100 cubic feet of liquid nitrogen storage. Government owned freezers are available for this storage project.

2. Maintain and operate facilities for the storage of packages and bulk biological materials at temperature designated by the project officer; supply electrical power to accommodate the refrigerator/freezers; supply the liquid nitrogen to the liquid nitrogen freezers; and house the units in an air conditioned facility with the capacity to maintain a room temperature of 72° F +/- 2° F when all equipment is operational.

3. Maintain security of all storage facilities. Furthermore, it is critical that a connection to a central temperature alarm system be available, that it is monitored 24 hours a day and that necessary personnel are notified.

4. Maintain and operate standby facilities for use in the event of loss of refrigeration capacity of any repository area including the maintenance of standby refrigeration equipment and the operation and maintenance of a standby generator.

5. Pick up and distribute specimens to and for NCI investigators upon request in Bethesda, Frederick, and as specified by the project officer. In those cases where materials are to be furnished by investigators outside the NIH, the offerors shall mail empty vials to the investigators and receive the mailed specimens.

6. All distributed material shall be shipped under conditions which will maintain the necessary storage temperature; shall keep up to date with all regulations, including U.S. and foreign customs regulations, concerning transport of biologicals, particularly etiologic agents; assure that proper packaging procedures are followed including proper labelling of the shipments; and provide all required labels.

7. Send notification cables/telegrams to all foreign and domestic investigators receiving a frozen or refrigerated shipment and send telegram confirming receipt of shipment.

8. Make arrangements to pick up incoming shipments from specified local airports. As the incoming shipments usually represent a substantial financial investment, personnel shall be available at any given time to receive the arriving package and return it to the repository for storage at required temperatures.

9. In those instances where processing of a specimen is required (e.g., sera separation from a blood sample), the offeror will use standardized procedures, as determined by the investigator, for the required processing and/or subaliquoting of the sample.

10. Catalog and maintain an inventory control system for all materials using procedures established by NCI. This system should be an accurate reflection of the number, type and location of the samples as well as the withdrawal and shipment schedule. In addition, the offeror shall maintain a previously developed computerized data system which provides storage of clinical, laboratory and inventory data. The operation of this system requires the use of preestablished data collection mechanisms and a communications terminal that is able to interface with the IBM 3033 in use at the NIH computer center. The offeror should be responsible for monitoring the completeness of the data associated with the specimens in the automated system and assist in collecting this information when incomplete. Automated reports summarizing the data should be available upon request. This requires a person capable of querying the data base. Forms for summarizing the data will be provided.

11. Provide to individual investigators every six months a list of inventoried materials which have been in the repository for a maximum of three years. The offeror will work with the individual investigators in removing unwanted materials (sunset clause).

12. In those instances where the samples are picked up at the NIH reservation or the Frederick Cancer Research Facility, the offeror shall pick up the samples within 24 hours of the request, and store the samples at the proper temperature two hours after pickup.

13. In those instances where the samples are to be delivered to the NIH reservation or FCRF, the offeror shall make delivery within 24 hours of the request.

14. In those instances where the samples are picked up at the airport, the offeror shall pickup and store the samples at the proper temperature no more than two hours after the samples have arrived.

Organizations will be evaluated on their capability to provide the above services as evidenced by the following types of information which must be provided:

Resumes of experience and capability should cover (1) the name, professional qualifications, and experience of scientist(s) and technical personnel in work relevant to the workscope; (2) availability and description of facilities required to perform the project; (3) current capacity for operation of a repository, distribution facility and manual and automated inventory systems; (4) ability to respond to requests in a timely manner; (5) adequacy of plans for initiation and phase-in of work.

This is not a request for proposal. Interested organizations qualifying as small businesses are invited to submit a resume of experience and capability based on the information provided above. NCI will evaluate qualification statements and will issue an RFP to those firms judged to be qualified. Responses should be submitted in 20 copies to: Contract Specialist: J. Steve Metcalf

RCB, Blair Bldg. Rm. 114 301-427-8888

SOURCES SOUGHT Synopsis No. 52

Title: Current Cancer Research Project Analysis Center (CCRESPAC)

Deadline for qualification statements: Jan. 19

NCI is seeking small business sources capable of responding to a potential request for proposals to provide support services to the International Cancer Research Data Bank Program (ICRDB).

This new procurement will consist of five main activities:

Collection and processing of descriptions of cancer research projects.

Annual updating of project descriptions.

Preparation of technical documents known as "Special Listings."

Regeneration of special searches in response to requests for information from scientists, clinicians and administrators.

Qualification criteria:

A. The use of the offeror's inhouse computer (or very easy and guaranteed access to a computer with high priority as needed) is a requirement of this RFP. Because of the need for daily online interaction with a working file for data input, updating and retrieval, and because of the size of the file to be maintained online, the use of the Div. of Computer Research & Technology, NIH, computer system is not appropriate for this contract.

B. Because the data is cycled several times between scientists, staff responsible for input and preparation of publications, and the computer files, and because of the need for almost daily interaction with the project officer on all aspects of the project, it is essential that the following major components of this project be performed within the same organizational component:

1. Collection and updating of project descriptions (including the related correspondence).

2. Selection, analysis, organization and final arrangement of projects and records for Special Listings.

3. Building and updating the CANCERPROJ database.

4. Computer systems required for 1-3 above. Important notes regarding personnel listed in the response to this announcement:

A complete C.V. must be supplied for each profes-

sional staff member who would be available to spend 20 percent or more of his/her time on this project. The CV must show degrees (with date awarded and major subjects); biomedical courses taken; subsequent experience (showing time spans and an outline of duties at each location); and relation of the individual to the organization (full time, part time, free lance, consultant, etc.).

A chart must be provided showing range of minimum and maximum time each professional staff member would be available for this project. The staff members who would perform each of the following essential functions must be clearly identified in the response to this announcement:

-The project officer and any backup toplevel administrative staff.

-The staff who would be involved in collection and updating of project descriptions.

-The staff who would carry out editing, indexing, and input functions.

-The staff who would provide scientific expertise for preparation of special listings.

-The computer staff who would be responsible for developing interactive systems for building and updating the data base, and for preparing the photocomposition tapes for Special Listings.

An organization chart showing reporting relationships between individuals in each of the categories listed in the previous paragraph.

This contract will require extensive face to face interaction between the project officer and the contractor's staff. During the complex startup phase of this new activity, the project officer and other ICRDB staff will need to meet with the contractor's staff frequently. In addition to these meetings, deliveries of tapes, drafts of special listings, and frequent pickup and delivery of materials at both the contractor's office and the ICRDB office will require many additional trips to ICRDB offices at 5333 Westbard Ave., Bethesda, Md.

Organization experience for reprogramming or writing new programs similar to those needed to carry out this workscope must be discussed, as existing programs and systems will need significant revision.

Sample copies of documents produced by photocomposition by the offeror must be provided.

This is not a request for proposal. Submit six copies of capability statements and supporting documentation to:

Contract Specialist: Barbara Mercer RCB, Blair Bldg. Rm. 327 301-427-8877

The Cancer Letter _Editor Jerry D. Boyd

Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means (electronic, mechanical, photocopying, recording or otherwise) without the prior written permission of the publisher. Violators risk criminal penalties and \$50,000 damages.