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After Year-Long Review, Varmus Removes "Reasonable Pricing" Clause From CRADA

NIH Director Harold Varmus Tuesday removed the controversial "reasonable pricing" clause from the Public Health Service model Cooperative Research and Development Agreement.

"An extensive review of this matter over the past year indicates that the pricing clause has driven the industry away from potentially beneficial

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In Brief

Comis Named ECOG Chairman; Long Joins Capitol Associates; Chabner Day In Shelbyville

ROBERT COMIS was named chairman of the Eastern Cooperative Oncology Group at the group's annual meeting last week. Comis is the clinical director of the Jefferson Cancer Center in Philadelphia. . . . **ED LONG** has left his position as minority staff director of the Senate Appropriations Subcommittee on Labor, HHS & Education to join Capitol Associates, a government relations firm that represents a number of cancer organizations. Long was named vice president, congressional relations. . . . **"WELCOME TO SHELBYVILLE**, Home of Bruce Chabner," read the signs on the road leading to Shelbyville, IL (pop. 5,000) during the month of April. The town where NCI's former Div. of Cancer Treatment director was born honored Chabner's retirement from the Institute last week by declaring April 7 "Bruce Chabner Day." Meanwhile, in Bethesda, the day was marked by a symposium in Chabner's honor, with scientific presentations by his former clinical fellows. Chabner is the new head of the Div. of Hematology and Oncology at Massachusetts General Hospital, Harvard Univ., and clinical director of the hospital's cancer center . . . **THE RESCISSION PACKAGE** passed by the Senate last week proposes a $79 million cut in intramural construction for NIH. The House version of the rescission bill proposed a $50 million cut from NIH intramural construction and $20 million from extramural construction projects administered through the National Center for Research Resources. . . . **PROBATION** is over for the National Surgical Adjuvant Breast & Bowel Project. NCI Acting Director **Edward Sondik** earlier this week ended the year-long probationary status of the cooperative group. Sondik's action followed the group's recent submission of a paper containing a reanalysis of the lumpectomy trial. The reanalysis was submitted to the

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Industry Applauds Removal Of CRADA Pricing Clause

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collaborations with PHS scientists without providing an offsetting benefit to the public," Varmus said in a statement.

"Eliminating the clause will promote research that can enhance the health of the American people," he said.

Clause Adopted After AZT Controversy

The reasonable pricing clause was adopted in 1989, in response to the high price of the drug AZT. However, the impact of the clause was brought into question three years later, in the course of a Congressional challenge to the CRADA that resulted in the development of the drug Taxol.

Observers connected to the drug and biotechnology industries applauded Varmus's decision:

● "I applaud the move, though it was long overdue," said Bruce Ross, a former senior vice president at Bristol-Myers Squibb Co., who defended the Taxol CRADA in Congressional hearings two years ago.

"The Taxol experience was a great benefit to the American people, but the examination of Taxol pricing scared off a number of potential collaborators on other equally important projects," Ross, a consultant to oncology companies, said to **The Cancer Letter**.

● "Dr. Varmus' decision is clearly correct as a matter of law and public policy," said Dan Kiser, an attorney with Fox, Bennett & Turner, a Washington firm that negotiated--and subsequently defended--the CRADA for the development of Taxol. "There is no doubt that the use of the clause, and the resulting politicization of the collaborative research process, acted as a deterrent to important government-industry collaborations in a number of therapeutic areas, including cancer and AIDS. Removal of this obstacle should generate new interest in collaborative research efforts."

● "Today's announcement by NIH is a clear victory for patients awaiting new treatments and cures, and a major step forward for biomedical progress," Carl Feldbaum, president of the Biotechnology Industry Organization, said in a statement.

"The removal of the CRADA reasonable price clause makes it possible for biotechnology companies to cooperate more effectively in taking a breakthrough from basic research to a new drug," Feldbaum said.

Wyden Suggesting Statement Of Principles

Meanwhile, Rep. Ron Wyden (D-OR), who headed an inquiry into the development of Taxol, has suggested that NIH replace the reasonable pricing clause with a statement of principles the government would pursue in negotiations with the industry.

"Ron is discussing these issues with Dr. Varmus," a congressional source said to **The Cancer Letter**. "Ron is suggesting that NIH adopt a statement of negotiating principles, which would include seeking assurance of co-ownership of technologies as well as assurance of royalty revenues from development of drugs or devices, as provided in the statutes."

Year-Long Review of CRADA Program

The action by Varmus comes after a year-long evaluation of the CRADA program. As *NIH* examined the effect of the pricing clause, it drew on advice from scientists, industry collaborators and patient groups.

In the end, NIH officials concluded that:

● The clause discourages the execution of exclusive licenses and CRADAs and inhibits the ability of PHS scientists to gain access to research materials and expertise from the private sector, even outside the context of a license or a CRADA.

● The vast majority of CRADAs result in new scientific knowledge, not new products. No CRADA product has been developed under an exclusive license.

● CRADA did not assure the industry

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collaborators a monopoly position in the marketplace. In several cases, technologies developed through the CRADA program resulted in issuance of licenses to different companies. Thus, the companies would be likely to compete in the marketplace.

"The clause attempts to address the rare breakthrough product at the expense of a more open research environment and more vigorous scientific collaborations," Varmus said.

"One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment," he said.

Though the CRADA program exists throughout the federal government, only one other agency, the Bureau of Mines, includes a reasonable pricing clause in its license agreements.

The now defunct clause required "a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public... Exclusive commercialization licenses granted for [NIH] intellectual property rights may require that this relationship be supported by reasonable evidence."

Advisors Begin Writing Report On NCI Intramural Program

The National Cancer Advisory Board's Ad Hoc Working Group on NCI Intramural Programs has begun writing a report that is expected to have a major impact on the structure of the Institute.

The working group was scheduled to meet this week to begin writing its report to the NCAB, concluding a six-month investigation into the *intramural program*. The draft report is to be released at the NCAB's next meeting, May 15-17.

Sources said the report is expected to address the following issues:

- Several members of the committee have recommended a separation of the intramural and extramural programs within the NCI's divisions. Sources said the committee has not reached consensus on the structure to recommended.
- Consolidation of the four program divisions into three divisions.
- The need to upgrade and strengthen support for the NIH Clinical Center, and the importance of translational research in the NIH research agenda.
- The need for better communications throughout NCI.
- The need to reduce bureaucracy that impedes the conduct of studies.
- The continued need to support the NCI drug development program. Sources said the committee is sympathetic to the view that cancer drug development cannot be done entirely by the pharmaceutical industry.
- Lack of opportunities for young intramural investigators to test their ideas.

Sources said working group co-chairmen Michael Bishop and Paul Calabresi have received more than 100 personal letters from NCI scientists discussing these issues, particularly the problems of communication and control of the research agenda.

Russian-American Conference On Breast Cancer Canceled

The First Russian-American Breast Cancer Conference was canceled last week, as US co-sponsors cited lack of cooperation by the Russian side.

The conference was scheduled to begin in Moscow on June 7.

"Despite all our efforts to organize this program from the US, it became very clear that the conference could not be successful without the diligent support an cooperation of the [Russian Academy of Medical Sciences Cancer Research Center]," conference co-chair Barrie Cassileth wrote in a letter to Nikolai Trapeznikov, director of the cancer center.

The research center was to be the site of the conference that was planned to acquaint physicians from the former Soviet republics with the international standards of breast cancer detection and treatment.

The sponsors of the conference included NCI, the US State Department and the National Alliance of Breast Cancer Organizations.

"During my recent visit to Moscow, I was given various assurances of cooperation," Cassileth wrote in a letter dated April 6. "However, we have not been able to receive satisfactory or timely information and action needed for the conference to proceed.

"In addition, costs that were agreed upon in writing when I was in Moscow were subsequently escalated beyond reality," Cassileth wrote.

It appears that informing Trapeznikov about the cancellation will require ingenuity.

The telephones at the offices of the cancer center director and his deputy are not being answered, and the dedicated fax line is on the blink, Cassileth said.

In Brief

Sondik Removes Probation For NSABP As Reanalysis Is Submitted To NEJM

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New England Journal of Medicine. "It's an indication of progress," **Norman Wolmark**, chairman of the group, said to **The Cancer Letter**. "I am pleased that NSABP will now be able to focus on its main objective in proceeding with clinical trials in breast and bowel cancer." **Ronald Herberman**, former acting chairman, who is serving as the principal investigator for biostatistics, said, "We are very pleased to have the full confidence of the NCI once again, and to carry out the important missions of NSABP." . . . **INDIANA UNIV.** Cancer Center was selected to receive a $500,000 Bristol-Myers Squibb Unrestricted Cancer Research Grant. The five-year grant will enhance the center's clinical research, said director **Stephen Williams**. Supervisor of the grant will be **Lawrence Einhorn**, distinguished professor of medicine at the university. . . . **ANNUAL REPORT ON CARCINOGENS**, (7th), 1994, Volumes 1 and 2, is available from the National Technical Information Service, tel: 202/487-4650, for $105 plus handling. Quote order no. PB95-109781KVF. The report provides data on more than 175 substances that are believed to cause cancer. . . . **INSTITUTE OF MEDICINE** is accepting nominations for the Gustav O. Lienhard Award. The award, a medal and $25,000, recognizes individuals for outstanding achievement in improving health care services in the US. Support for the award is provided by the Robert Wood Johnson Foundation. The emphasis of the award is on creative or pioneering efforts that have appreciably improved personal health services rather than on the science base of health care. To encourage consideration of the widest possible range of candidates, there are no eligibility limits with respect to the education and profession of individuals who may be nominated; however, their achievements should be national in scope. The nomination letter should include a detailed description of the nominee's accomplishments meriting this award and should not exceed five pages in length. Also included should be a one-sentence citation explaining how the nominee's overall accomplishments or specific achievements have made a national contribution to the area of personal health care services. A selected biography of up to 15 entries should be included. Nominations must be postmarked by June 16 and sent to Cynthia Abel, Lienhard Award Committee, Institute of Medicine, 2101 Constitution Ave. NW, Washington, DC 20418. . . . **THE DON SHULA FOUNDATION** has granted $270,000 to the American Society of Clinical Oncology to fund a special three-year Career Development Award, as well as two Young Investigator Awards in 1995-96. The recipient of the DCA is Jose Baselga, of Memorial Sloan-Kettering Cancer Center. The recipients of the Young Investigator Awards are Heinz-Josef Lenz, of the Kenneth Norris Jr. Comprehensive Cancer Center, and Craig MacArthur, of Washington Univ. The grants represent a continuation of support begun by the foundation in 1993. The foundation has granted nearly $360,000 to ASCO to fund basic and clinical cancer research, with the emphasis on breast cancer. Shula started the foundation in 1990; the following year, his wife Dorothy died of breast cancer. The foundation, based in Miami, FL, may be reached at 305/621-4744. . . . **CITY OF HOPE** National Medical Center and Beckman Research Institute have recruited two new executives. **Marsha Emmer Addis** was named vice president for research administration and cancer center associate director for administration. **Gwen Oki** is the new director of research subjects protection. Addis was deputy director for administration at Univ. of California, Los Angeles, Jonsson Comprehensive Cancer Center. Oki was a research administrator at Childrens Hospital Los Angeles. . . . **YALE CANCER CENTER** has designated the week of April 23-29 to begin a cancer prevention and nutritional education program aimed at Connecticut youth. Titled "The Seeds of Prevention," the program will distribute 50,000 seed packets of carrots to all third-grade students in the state's public and private schools. "The program focuses on preventive medicine in its most basic form," said Vincent DeVita Jr., center director. "The Seeds of Prevention will encourage our young people to begin early understanding the value of gardening and growing healthful foods, along with the beneficial link

between good nutrition and the prevention of cancer." In addition to the seeds, 2,500 lesson plans will be provided to teachers covering subjects related to cancer prevention, good nutrition, healthy eating and gardening. Every student will receive a newsletter with nutritional information, carrot recipes and gardening advice.

Breast Cancer Action Plan Issues RFA For Small Grants; Other Initiatives Coming Soon

The HHS Office on Women's Health has released the first Request for Applications for distribution of *funds set aside in the* NCI budget to fund initiatives developed as part of the National Action Plan on Breast Cancer.

The RFA will provide $3 million in total costs per year for two years to fund about 40 small grants in breast cancer research and outreach activities.

Review of the applications will be conducted jointly by NCI extramural reviewers and members of the National Action Plan working groups, said Suzanne Haynes, of the OWH.

"It is very exciting because consumers are intimately involved for the first time in making recommendations for how money is being spent," Haynes said to **The Cancer Letter**.

The National Institute on Aging has agreed to add as much as $300,000 to the RFA to fund applications related to aging and breast cancer, Haynes said.

Pace of Action Plan Picking Up

Later this month, the office will announce a program that will provide $2 million in administrative supplements to existing federal grants to address the six priority areas of the Action Plan, Haynes said. Also, intramural researchers will compete for another $1.5 million from the Action Plan, she said.

"I am very pleased by the pace at which the National Action Plan is proceeding recently, and I think we are on track," said Fran Visco, co-chairman of the plan, president of the National Breast Cancer Coalition, and a member of the President's Cancer Panel.

"I look forward to the response to this request, but at the same time I want to make clear that we recognize that it is our role to really design a plan with short and long term goals within each of the six priority areas, and we will be driven by that plan, and not simply by the desire to spend money."

The text of the RFA follows:

RFA CA-95-016

Title: **National Action Plan On Breast Cancer Innovative Small Grant Program**

Application Receipt Date: June 14

The National Action Plan on Breast Cancer is a public-private partnership created to eliminate the epidemic of breast cancer. The Public Health Service's Office on Women's Health, which coordinates the implementation of the NAPBC, and NCI invite applications for Small Grants (R03) in breast cancer research and outreach activities to address several priority areas in the NAPBC.

This program is designed to support the implementation of six high priority areas for breast cancer that were derived from the "Proceedings of the Secretary's Conference to Establish a National Action Plan on Breast Cancer." These six activity areas are: information dissemination, national biological resource bank, consumer involvement, breast cancer etiology, clinical trials accessibility, and breast cancer susceptibility genes issues.

One goal of this initiative is to provide support for novel, creative pilot research and outreach projects that, if successful, will yield exceptionally important new information on breast cancer. A second goal is to support developmental, exploratory, or pilot projects that could serve as the basis for more comprehensive well-defined future research and outreach project applications in the area of breast cancer.

Funds to support this Small Grant program will be administered through the NCI. Approximately $3 million in total costs per year for two years will be committed to fund applications submitted in response to this RFA. It is anticipated that approximately 40 awards will be made.

Inquiries: Susan Blumenthal, Deputy Assistant Secretary for Health (Women's Health), Co-Chair, The National Action Plan on Breast Cancer, ATTN: Suzanne G. Haynes, Office on Women's Health, USPHS, Hubert Humphrey Building Rm 730-B, 200 Independence Ave. SW, Washington, DC 20201, tel: 202/690-7650, fax: 202/690-7172.

RFA Available: Cooperative Group For Breast Cancer MRI

RFA CA-95-014

Title: **Multi-Institutional Cooperative Group For Clinical Evaluation Of Magnetic Resonance Imaging In Breast Cancer**

Letter of Intent Receipt Date: May 9

Application Receipt Date: June 9

The Diagnostic Imaging Research Branch (DIRB) of the NCI Div. of Cancer Treatment invites applications from consortia of institutions for Cooperative Agreements (U01) to study the role of Magnetic Resonance Imaging (MRI) in improved detection and staging of breast cancer.

The NCI is seeking talented scientists from academic, non-profit and for-profit research organizations who will interact with other members of the Consortium, and with DIRB in a concerted way to evaluate and optimize new approaches to breast cancer diagnosis.

One consortium of multiple institutions, called "Multi-Institutional Cooperative Group for Clinical Evaluation of MRI in Breast Cancer," will be funded. Scientific approaches taken by the Cooperative Group will be broad and will reflect the creativity and capabilities of the Group participants.

The purpose of this RFA is to stimulate cooperative efforts through phase II clinical trials for facilitated evaluation of sensitivity, specificity and local staging accuracy of breast MRI compared to conventional radiologic approaches in about 3,000 women with abnormal or non-diagnostic x-ray mammograms for whom biopsy is required.

MRI data in detection and staging of breast cancer may be compared to that of ultrasound (US) and other imaging modalities.

Histopathologic evaluation of MRI-detected lesions will be done for every patient, either by MRI-guided biopsies in combination with follow up imaging studies in patients with probable benign disease and/or women with breast cancer selecting breast conservation therapy (e.g., when some of the detected lesions may not be found in the lumpectomy tissue samples), or by examination of mastectomy specimens.

A sufficient number of patients must be available in each participating institution for successful completion of the proposed clinical trial.

Each participating institution must have experience with clinical studies in breast MRI (at least 100 previous examinations) and must demonstrate the plan for histopathologic evaluation of MRI-detected lesions.

In addition, it is expected that the study participants will establish a database that would enable the Group to address vital questions such as:

Can MRI reduce the number of diagnostic procedures, such as breast biopsies, in women with benign conditions? Can MRI reduce the number of repeated lumpectomies, and/or other potentially avoidable therapeutic procedures in women with early stage disease?

It is anticipated that this phase II trial, focused on evaluation of diagnostic value of MRI and its role in optimization of breast cancer detection and staging in women undergoing biopsy, may, at its completion suggest the need for phase III clinical trials to validate:

(a) the impact of MRI data (e.g., improved staging accuracy through improved definition of local anatomic tumor extent) on cost-effectiveness of breast cancer management in women with early-stage disease as well as, (b) the role of MRI as a screening tool in reducing mortality of general (asymptomatic) population of women with "radiodense" breast tissue and patients at high genetic risk for breast cancer. Particular emphasis will be placed on accrual of women younger than 50 and/or minority women with "radiodense" breast tissue.

It is anticipated that one award will be made for approximately $1.5 million total costs per year for four years to a single consortium consisting of several participating institutions to ensure accrual of about 3,000 women over a period of four years.

Inquiries: Faina Shtern, Div. of Cancer Treatment, NCI, Executive Plaza North Rm 800, Bethesda, MD 20892, tel: 301/496-9531, fax 301/480-5785, email: shternf@rrp.nci.nih.gov

NCI, EORTC Offer Support For Scientists In Former USSR

Program Announcement: **Career Development Awards for Young Cancer Researchers in the Newly Independent States of the Former USSR**

Application Deadlines: May 15 and Nov. 15

Starting Dates: Oct. 1 and April 1

NCI in cooperation with the European Organization for Research and Treatment of Cancer

provides a limited number of small grants of up to $10,000 per year for up to three years to outstanding scientists from the NIS who have at least three years, but not more than 10 years of postdoctoral cancer research experience, for cancer related research at their home institutions. Initially, nominations for these awards will be solicited from foremost cancer research institutions in the various countries of the former USSR.

The objective of this program is to encourage cancer research by outstanding young scientists of the NIS during this period of transition to a market economy. These small awards will provide funds:

1. For a monetary incentive of up to $50 per month paid to the awardee. Awardees will be expected to devote at least 80 percent time to research.

2. To purchase supplies, materials and possibly small equipment items necessary to conduct cancer research in the NIS scientist's laboratory.

3. To involve up to two named collaborators or assistants in the project. Such persons must be junior to the awardee in education and/or experience, have lower current salaries, and not be related to the awardee by blood or marriage. Their incentive will be up to $30 per month.

All biomedical and behavioral research topics supported by the NCI are eligible for inclusion under this program.

The incentive allowance (paid quarterly) will supplement the awardee's official salary and that of his/her assistants. An account will also be established against which the awardee can order supplies, materials, perhaps some small equipment—only under very special circumstances—and a limited number of journal subscriptions.

Successful candidates who establish collaborations with American NCI-supported scientists may also apply for travel and subsistence costs for visits to the collaborating laboratory under the Short Term Scientist Exchange Program of the Office of International Affairs, NCI.

Materials to be submitted by nominating institutions parallel those of the Research Career Development Award submitted by American candidates and applicant organizations.

Although these awards are for up to three years, the second and third year are conditional upon the receipt by NCI/EORTC of a satisfactory progress report each year, and upon the availability of funds.

Nomination materials are to be submitted by the above deadlines to the EORTC/NCI Liaison Office in Brussels and to the Office of International Affairs at NCI.

The nominees and their research programs will be reviewed and evaluated by the EORTC Candidate Selection Committee for merit. The selected nominees files will be forwarded to NCI for the final action by the NCI Executive Committee.

Inquiries: EORTC/NCI Liaison Office, 83 Av. E. Mounier, Bte. 12, 1200 Brussels, Belgium, tel: (32)(2)772-22-17, fax (32)(2)770-47-54, and Office of International Affairs, NCI, Building 31 Rm 4B47, Bethesda, MD 20892, tel: 301/496-4761, fax 301/496-3954.

NIH To Hold Public Forum On NRSA Tuition Policies

NIH has established a Tuition Payment Task Force to facilitate public input and develop individual recommendations concerning NIH policy on tuition reimbursements on institutional National Research Service Award research training grants (T32).

The task force met April 10 to plan a Public Forum on Tuition Reimbursements, scheduled for June 5, in the Auditorium of the Natcher Building (Building 45) on the NIH campus.

The task force will consider testimony from participants, and immediately following the forum each of the members will develop recommendations addressed to the NIH Deputy Director for Extramural Research.

The public forum may be of interest to directors of NRSA research training programs, trainees supported by those programs, officials at institutions receiving NRSA research training support, organizations representing academic institutions, and other interested parties.

All interested individuals are welcome to attend, limited to space available. Discussion of issues concerning the cost of graduate education and the appropriate Federal share of those costs will provide a basis for Task Force deliberations.

For information on attending the public forum, contact Ernest Marquez, Chief, Office of Review, National Institute of Nursing Research, Building 45, Room 3AN-12E, 45 Center Drive, MSC 6302, Bethesda, MD 20892-6302, tel: 301/594-5965, fax 301/480-8256.

RFPs Available

RFP N01-CM-57245-08

Title: **Cancer Therapy Evaluation Program Information And Management And Computer Support**

Deadline: Approximately June 15

NCI is seeking support for the computer system of the Cancer Therapy Evaluation Program. This effort will support all computer systems of CTEP. This shall include support of the CTEP Personal Computer and Server-LAN including recommendations for information management problem resolution, implementation and maintenance of these systems. Additionally, the contractor will maintain and enhance several key large data base systems which exist within CTEP.

These systems include: The CTEP Information System (CTEP-IS), the PMB Inventory Management System (PMB-IMS), the Adverse Experience Reporting System (AERS), Annual Data Updates (ADU), Quarterly Data Updates (QDU), CTEP-LAN, PMB-LAN, the Clinical Trials Monitoring Branch-Information Management System (CTMB-IS), and the Regulatory Affairs Branch (RAB) Cooperative Research and Development Agreements (CRADA), and the Clinical Trials Agreement (CTAs) data base systems. Additional support of CTEP includes providing programming and data management support for the Biometrics Research Branch (BRB) staff, as needed in the performance of projects. This requires a familiarity with statistics equivalent to attainment of a Master's degree, good knowledge of SAS, graphics (SAS or other language), and Fortran. The government expects to make one award. This award will have a maintenance portion with annual options to complete several new software enhancements, developments, and system implementations.

This award shall be incrementally funded for a five year period requiring 15 Full Time Equivalents (FTEs)/ year for a total of 95 FTEs for the base work with optlons for an additional 6 FTEs/year for 30 optional FTEs over the 5 years. This is a total Small Business set-aside. All responsible small businesses conforming to the size standard of $18 H annual receipts (Standard Industrial Classification #7376) may submit a proposal which shall be considered by the agency.

Contract specialist: Todd Cole, RCB, Executive Plaza South, Rm 603, Bethesda, MD 20892, tel: 301/496-8620.

RFP NCI-CN-75063-29

Title: **Surveillance, Epidemiology And End Results Quality Control Unit**

Deadline: Approximately Aug. 2

The NCI Div. of Cancer Prevention and Control, Surveillance Program is interested in soliciting proposals from organizations for maintaining a quality control unit (QCU) for the Surveillance, Epidemiology and End Results (SEER) Program. The purpose of the QCU is to assess and insure the completeness, accuracy and timeliness of data that are available to the NCI through the SEER Program and from other cancer registries for the purpose of measuring progress in cancer control. A secondary purpose of the QCU is to reduce the variability in data collection procedures through education and communications. A third purpose of QCU is to provide a research and evaluation component that focuses on the assessment of the quality of surveillance data and efficiency of existing surveillance systems to assure that they continue to serve the NCI program needs.

Contracting Officer: Clyde Williams, RCB, Prevention and Control Contracts Section, Executive Plaza South, Rm 635, Bethesda, MD 20892, tel: 301/ 496-8603.

RFP NCI-CM-57238-30

Title: **Synthesis of Bulk Chemicals and Drugs for Preclinical and Clinical Studies**

Deadline: Approximately July 17

The Pharmaceutical Resources Branch, Developmental Therapeutics Program, of NCI's Div. of Cancer Treatment anticipates making award(s) of cost-reimbursement, incrementally funded contracts, for a base period of three years, with two one year option years beginning on or about April 1, 1996. The objective of this project is for the preparation of chemicals and bulk drugs needed by the program for preclinical and clinical studies. This contract will provide and operate a materials preparation laboratory for the synthesis of varying amounts of materials, not readily available from other sources in the quantity and/or quality needed by NCI.

The scale of the work to be performed under this solicitation requires a functional large-scale facility with at lease one (20-100 gallons) glass-lined reactor, and several glass reaction vessels (50 and 100 litres) with the necessary supporting equipment and laboratories.

The project may be proposed on two levels. Level I offerors shall provide 2.75 to 3 technical staff years, per year, with completion and deliveries of the targets of 8 to 12 assignments, excluding reports. Level II offerors shall provide 5.5 to 6 technical staff years, per year, with completion and deliveries of the targets of 15 to 25 assignments, excluding reports.

The proposed principal investigator should be trained in organic or medicinal chemistry, preferably at the PhD level, from an accredited university or possess equivalent experience, and have extensive experieince in the conception and execution of chemical syntheses, scaleups and synthetic process development. The SIC code is 8731. Offerors who qualify only as a small business are encouraged to submit proposals.

Contract specialist: Elsa Carlton, RCB, Executive Plaza South Rm 603, 6120 Executive Blvd MSC 7220, Bethesda, MD 20892-7220, tel: 301/496-8620.