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Joseph Simone Accepts Chief Physician Job At Memorial Hospital, Succeeding DeVita

Joseph Simone, director of St. Jude Children's Research Hospital since 1983, has accepted the position of physician in chief at Memorial Hospital, vacant since Vincent DeVita stepped down from that job last year. The appointment, which will be effective July 1, was announced by Paul Marks, president and chief executive officer of Memorial Sloan-Kettering Cancer Center. "We are very fortunate to recruit Dr. Simone, who has an outstanding record of leadership at St. Jude and who is such an accomplished clinical investigator," Marks said. "This is a time of enor-

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In Brief

Yarbros To Move From Missouri To Illinois; Canellos Elected Fellow Of Royal College

JOHN YARBRO, director of the Div. of Hematology & Medical Oncology at the Univ. of Missouri School of Medicine in Columbia, has accepted the position of director of the regional cancer center in Springfield, IL. The center is part of Memorial Medical Center, a 600 bed teaching hospital headed by Robert Clarke, president and CEO. Yarbro's wife, **Connie Henke Yarbro**, will be director of nursing resource development for the hospital. Both will continue their publishing ventures; John Yarbro publishes "Seminars in Oncology," and Connie Yarbro publishes "Seminars in Oncology Nursing." John Yarbro will fill the vacancy created last April when Gale Katterhagen resigned to take a job in California. The Yarbros will begin their new jobs March 1. . . **GEORGE CANELLOS,** chief of the Div. of Medical Oncology at Dana-Farber Cancer Institute, has been made a fellow in the Royal College of Physicians of Great Britain. . . . **KAREN HASSEY DOW** has been appointed editor of "ONS Nursing Scan in Oncology," a new bimonthly publication of the Oncology Nursing Society. Dow, a nurse specialist at Beth Israel Hospital in Boston, is a member of the editorial board of "Cancer Nursing." . . . **2,740 NURSES** who took the Oncology Nursing Certification Exam last fall passed, or 80 percent. Of those, 1,748 nurses passed the exam for the first time, 799 renewed their credentials and 193 were repeating the exam. Next date for the exam is May 12. . . . **CLARIFICATION:** NCI Director Samuel Broder was quoted in the Feb. 7 issue of **The Cancer Letter** as saying that NIH patient travel should be cut along with the staff travel budget. That is not correct. What he said was that patient care travel should be allocated separately from the staff travel budget and thus should not count against the total allocated to staff.

Simone Accepts Chief Physician Job At Memorial Hospital, Effective July 1

(Continued from page 1)

mous optimism at Memorial Sloan-Kettering Cancer Center, as new insights into the biological bases of cancer are enabling us to devise effective approaches for early diagnosis, treatment, and even prevention of the disease. Dr. Simone brings a wealth of valuable experience to this key position,, and as we move into the new era in cancer care, we welcome his stewardship of Memorial Hospital."

"Dr. Simone is known for his great compassion, keen clinical acumen and proven leadership ability," said James Robinson, chairman of the MSK Boards of Overseers and Managers. "We are pleased he is bringing his enormous expertise in patient care to the role of physician in chief of Memorial Hospital."

Simone said, in accepting the appointment, "I have been a great admirer of Memorial Sloan-Kettering for a long time. They have made huge strides over the past decade, but with the great resources of professional talent in place, it is very clear that there are no limits to future accomplishments. I am most gratified to join their effort and their single focus on the control and cure of cancer."

There may be a few who are thinking, "Haven't we heard this before?" It was only a little more than three years ago when similar expressions emanated from MSK news releases, with the names DeVita and NCI in the places now occupied by Simone and St. Jude. It was a blockbuster story then, involving as it did the departure of DeVita from his glittering career at NCI, culminating in the directorship. And then, as now, there were many who had reservations about whether a strong and successful individual could come in and work with the strong and dynamic Marks, who had a reputation for not being the easiest person in the world to get along with.

"That wasn't the issue with Vince," Marks told **The Cancer Letter** last week. He stood by his statement, issued then (**The Cancer Letter**, May 31), that DeVita gave up the physician in chief position "to return to the clinical research activities that had been his focus in the past." Marks added last week, "I know, that's hard for you guys to believe, but that's the way it was." He denied reports that DeVita resigned when Marks would not go along with changes DeVita wanted to make. "That was not accurate," Marks said.

DeVita remains at Memorial, holding an endowed chair in clinical oncology and as professor of medicine at Cornell Univ. Medical College.

'We See Eye To Eye'

Marks said that he has had "long philosophical discussions with Joe. We see eye to eye on major new directions and on new initiatives we can take."

Simone also expressed confidence that he and Marks can have a productive relationship. "I've talked to a lot of people and I've spent a great deal of time with Paul. In my judgment, I can do the job. It's a challenging job, and a great place for clinical cancer research."

Marks said that he "really enjoyed the process of trying to attract Joe to Memorial, and I'm pleased that we were able to do so. He has a lot of ideas about our program and directions in which we can go. There's no place like Memorial for pursuing those ideas."

The last three physicians in chief at Memorial have all been among the top people in their respective specialties--Ted Beatty, a surgeon; Samuel Hellman, radiation therapy; and DeVita, medical oncology. "They each made enormous contributions here," Marks said. "I'm confident Joe will, too."

Simone is one of the country's leading pediatric oncologists, having played a major role in the development and refinement of curative treatments for childhood leukemia. He received his MD from Stritch School of Medicine at Loyola Univ. in Chicago and completed his residency at Presbyterian-St. Luke's Medical Center. After a fellowship in pediatric hematology at the Univ. of Illinois, he joined St. Jude in 1967. He was named chief of hematology in 1969, chief of hematology-oncology in 1973, and, in 1983, he was appointed director, succeeding Alvin Mauer, who had resigned to head the Univ. of Tennessee Cancer Center in Memphis.

Simone has been a member of the Pediatric

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Oncology Group and had been elected to succeed Teresa Vietti as chairman when her term expires in the fall of 1993. Simone said that his new job will preclude his serving as chairman or as a member of the group, and that he had submitted his resignation. POG will schedule a new election to select Vietti's successor.

Simone has assumed national leadership roles in clinical research and cancer centers. He has served as chairman of NCI's Clinical Cancer Investigation Review Committee, which reviews cooperative group grants, and of NCI's Cancer Center Support Grant Review Committee. He is president elect of the Assn. of American Cancer Institutes.

ELM Wins ACCC Management Contract Recompetition Over ORC

ELM Services Inc. won the first recompetition of the Assn. of Community Cancer Centers management contract, locking in the job for another five years.

ELM, based in Rockville, MD, has managed ACCC since 1978 under a year to year agreement without a competitive renewal process. Lee Mortenson, ELM founder and president, has been ACCC executive director since that time and will continue in that capacity, one of the provisions of the contract.

ELM won renewal of its contract in what was described as strong competition from a team put together by Oncology Resource Consultants Inc., a Washington D.C. firm headed by Kathy Bowing Avis.

ACCC was founded in 1974 and initially contracted with CDP Associates for management services. Mortenson was a member of CDP's staff during part of that period and spent much of his time working with ACCC. When CDP relinquished the contract in 1978, Mortenson started ELM and was awarded the management job by the ACCC board.

Avis was also a member of the CDP staff and was a founding member of ACCC.

Lloyd Everson, current ACCC president, said the board determined last year that the management contract should be recompeted. About 10 firms requested copies of the RFP, but the only serious proposals presented to ACCC's contract review committee were those of ELM and ORC.

Work to be performed under the contract includes membership list maintenance, membership billing, financial reporting and record keeping, support for two national meetings, chapter and state society management, support for board and committee meetings, management and preparation of four issues a year of the association's journal, preparation of the annual delegates roster, cancer DRG reports, support for the association's Industry Advisory Council, and ACCC representation and liaison with other oncologic societies.

ORC Proposal

In the ORC proposal, former ACCC President David Johnson would be the executive director. Johnson was president and CEO of Deaconess Hospital, Evansville, IN, and related companies from 1965 until 1986. He headed Eyecare of America in Evansville for two years, and currently is president of the American Protestant Health Assn. in Schaumburg, IL. He served on the ACCC board for 10 years.

In addition to her work with CDP, Avis held management positions with the West Coast Cancer Foundation and Salick Health Care Inc. She founded ORC in 1990 with partner Nancy Bookbinder.

The ORC proposal involved subcontracts with the health law group of McDermott, Will & Emery, and with Health Sciences International, Lewin/ICF, specialists in health planning, health communications and publishing, data base management, and health policy.

Robert Clarke, ACCC president-elect and chairman of the Contract Review Committee, said in a letter to Avis and Bookbinder that their proposal "was extremely well prepared, and we were very impressed with your representatives." Current President Lloyd Everson told them that their "grasp of the issues was superb."

However, the committee recommended and the board agreed to award the contract to ELM.

"ELM has done an outstanding job," Clarke told **The Cancer Letter**. Membership growth, both individual and delegate (institutional), has been excellent, and development of ACCC activities and services have reached a level of sophistication in recent years "beyond anything we expected" in the association's earlier years.

Everson told **The Cancer Letter** that the competition "set a good precedent," and indicated that it would be repeated when ELM's contract ends in five years, although that will be up to those board members at that time. "It's healthy for the organization, for the membership to know, that this was competed in the open."

Clarke's committee was a cross section of ACCC's membership, including physicians, nurses, and administrators, and a mix of new and old members, Everson said. "In watching the process, I tried to remove myself and make sure the board and committee played major roles. Those people took the job seriously, and I think they did it well."

President's Budget Vs. NCI's Bypass: A Tale Of Missed Opportunities

What would be the impact of the President's proposed fiscal 1993 budget for NCI of a little over $2 billion--an increase of only 1.5 percent above the FY92 appropriation--if it were accepted by Congress with no changes?

Look no further than NCI's FY93 bypass budget for a listing of the scientific opportunities that might be missed with a nearly flat budget (copies are available from NCI's Financial Management Branch, Bldg. 31 Rm 11A18, Bethesda, MD 20893, phone 301/496-5803).

NCI is required by law to submit every year to the President a document that outlines the accomplishments of the National Cancer Program and the resources needed, in the Institute's professional judgement, to take advantage of scientific opportunities in the prevention and treatment of cancer. Framers of the National Cancer Act of 1971 intended this document to be the only budget request for the Institute, bypassing the NIH and HHS bureaucracy. However, every Administration since the Act's inception has ignored the bypass budget, using instead HHS budget figures to prepare the President's budget request, which is submitted to Congress.

At Congressional appropriation hearings each spring, the NCI director must defend the President's request, and usually only discusses the bypass budget when asked to do so by a sympathetic congressman whose staff has taken the time to at least glance through the nearly 400-page document.

For FY93, the bypass budget called for $2.7 billion that NCI could spend wisely--$700 million more than the President's request released last month (**The Cancer Letter,** Feb. 7).

"The bypass budget provides an outline for making important, practical advances now, without sacrificing the search for ultimate solutions in the future," NCI Director Samuel Broder wrote in an introduction to the bypass budget.

"An underlying principle of the bypass budget is to restabilize those mechanisms that have shown significant decline when measured in 1980 constant dollars," according to the document's "executive summary." "Basic research, through research project grants, remains the highest budget commitment; and support for intramural research will continue for high priority basic research and clinical investigations in cancer and AIDS."

The bypass budget took the President's FY 1992 request of $1.8 billion and gave NCI a hypothetical 5 percent inflationary increase ($81.5 million) to continue the same level of effort. Then, the document added the following initiatives and their incremental increases (for comparison, the President's FY93 request is also listed):

Research project grants: $259.457 incremental increase, for a total of nearly $1.15 billion. This would:

--Fund awards at full recommended levels

--Support 50 percent of competing applications.

--Solicit proton beam therapy research proposals.

--Solicit applications on the development of a cancer vaccine, in conjunction with research and development contracts.

--Solicit research on AIDS related lymphomas.

Under NCI's projections using the President's FY93 budget, $953 million would go to research project grants.

Cancer centers: $80.429 million increase, for a total of $199.3 million ($176.8 million for centers, $22.5 million for SPOREs). This would:

--Increase funding to those centers currently funded below peer review recommended levels.

--Fund competing centers at recommended levels.

--Fund approximately six new centers, including centers focused on pain and minority issues.

--Provide funds to cover comprehensiveness, including enhanced outreach activities.

--Expand SPORE grants in breast, prostate, and lung cancer.

The President's budget would provide $125.4 million to cancer centers, and $17.5 million for SPOREs.

Clinical cooperative groups: $38.170 million increase, for a total of $106.7 million. This would:

--Increase number of patients accrued to 25,000.

--Expand minority participation in clinical trials.

--Expand high priority clinical trials including tamoxifen and its impact on breast cancer and a clinical trial in the over age 65 group.

--Fund clinical trials on AIDS related lymphomas.

The President's budget would provide $77.9 million for cooperative groups.

Cancer prevention and control: $111.407 million increase, for a total of $204.6 million. This would:

--Expand chemoprevention/nutrition programs, including research affecting women's health.

--Expand minority research efforts using the minority based Community Clinical Oncology Program.

--Accelerate public health initiatives.

--Develop programs relative to the behavior and psychological aspects of cancer.

--Further develop initiatives detailing the impact of

cancer on the aging population, as well as low income and rural populations.

--Expand studies on pain associated with cancer.

--Enhance program on organ sparing and surgical reconstruction.

The President's budget would actually decrease funding for prevention and control from the FY92 level, to $91 million.

Training/Education: $45.693 million increase, for a total of about $101.8 million. This would:

--Target efforts toward the recruitment of minorities in oncological research.

--Expand cancer education programs through the R25 mechanism and National Research Service Awards.

The President's budget would provide only about $60 million for training and education programs.

Construction: $80.16 million incremental increase, for a total of $86 million. This would:

--Support extramural construction projects across the cancer research spectrum.

--Repair, improve and expand the facilities at Frederick Cancer Research & Development Center.

--Obtain two-year obligation authority.

The President's budget would provide no funding at all for construction.

Research & development contracts: $135.299 million increase, for a total of $333.7 million. This would:

--Enhance information dissemination activities through the Cancer Information Service.

--Further develop cancer vaccine efforts.

--Evaluate state of the art patterns of care in CCOPs.

--Expand activities in drug development for both AIDS and cancer, epidemiology studies, and smoking and tobacco initiatives.

The President's budget would provide $203 million for R&D contracts.

Intramural research: $89.735 million incremental increase, for a total of $448.2 million. This would:

--Provide additional personnel and support expenses associated with high priority intramural research projects conducted by the major operating divisions and the Frederick Cancer Research & Development Center.

--Support the NIH Management Fund, including activities at the NIH Clinical Center.

The President's budget would provide $372.7 million for intramural research.

Research management and support: $22.39 million increase, for a total of $117.8 million. This would:

--Support information dissemination activities, including focus on the low literate individual and minority populations, through publications and other educational initiatives.

--Increase international collaboration.

The President's budget would provide $95.7 million for research management and support.

Other projects: $20.524 million increase.

Altogether, NCI requested $964.770 million more than the President's FY92 request, for a total FY 93 bypass budget of $2.775 billion. This is $765 million more than the President's FY93 request.

NCI highlighted the following "Special Areas" for high-priority research:

▶**Women's health issues:** "Among the many diverse areas of high priority for NCi in cancers in women, those of surpassing importance are:

--"The development and implementation of prevention clinical trials for breast cancer, examining the role for tamoxifen chemosuppression in certain postmenopausal and high risk women. NCI will also examine the efficacy of prevention strategies with dietary reductions of daily fat intake and/or supplementation of micronutrients such as calcium and vitamin A derivatives.

--"The accessibility and delivery of health care to women who, for reasons of age, race, education, or most importantly poverty and lack of resources, are medically underserved.

--"The clinical development, procurement and availability of promising new therapies, for example, taxol, a chemically complex natural product with a unique mechanism of action and important activity in refractory or relapsing ovarian and breast cancer."

NCI would spend a total of $480 million on research on cancer in women and $20 million on AIDS in women under the bypass budget.

▶**Cancer and poverty:** "The reduction of disproportionately high cancer death rates found in minority and medically underserved groups continues to be a major focus of NCI. These populations include Black Americans, Hispanics and Native Americans (American Indians, Alaska Natives, and Native Hawaiians) as well as low income groups." The bypass document outlines proposed increases in funding of research project grants, cancer centers, cooperative clinical research, cancer education and training, intramural research, cancer prevention and control, that would address the problem of cancer and poverty. The bypass budget requests a total of $90 million to fund research in this area.

▶**Cancer and the population age 65 and over:** "Persons age 65 years and older constitute only 12 percent of the population; yet, they develop 58

percent of all new cases of cancer and account for two-thirds of all cancer deaths.... NCI believes that the lower death rates found among younger Americans reflect advances in treatment, earlier detection, and the impact of smoking prevention and cessation since the release of the Surgeon General's report in 1965 and the establishment of the National Cancer Program. The high and increasing rates among persons age 65 and over represent a concern and a challenge. The proportion of the elderly population in America is growing and is expected to increase by 10 percent to 35 million persons by the year 2000. That these rates are increasing suggests that there will be an even greater burden from cancer in the elderly community over the next decade. Nevertheless, because reduction in mortality rates have been seen in younger Americans, coupled with the fact that with each succeeding year, more signs appear that cancer mortality rates are beginning to stabilize and decrease among persons age 50 through 65, NCI believes these trends represent a measure of progress.

"NCI's goal is to gain a clearer understanding of the causes underlying the disparity in cancer mortality rates between older and younger Americans and to determine the best ways to provide quality prevention, early detection, and prompt treatment of cancer as well as to assist those with cancer in their recovery and rehabilitation. It is clear that some aspects of prevention will involve interventions at much earlier ages if we are to successfully change such behaviors as smoking, poor diet, and excessive sun exposure which lead to increased risks of cancer."

The document did not specify the amount requested for this area, apparently since it cuts across almost everything the Institute does.

►**Information dissemination:** Expansion of NCI's information dissemination programs "depends upon the additional resources requested as part of the 1993 bypass budget. For example, in 1993 the Institute will restructure the Cancer Information Service under a new series of contracts that will assure that all citizens are served by a regional office. To complement this effort, additional resources are needed to expand the CIS outreach capacity. Such an expansion is essential if the CIS is to serve as the major outlet of NCI's national cancer education programs.... By 1993, NCI's emerging program to reach people of low literacy will need new resources as it finishes it first year of implementation. Plans are also underway to develop Hispanic and Appalachian Leadership Initiatives on Cancer modeled on the successful National Black Leadership Initiative on Cancer."

The amount requested for these activities is included in the Research Management & Support request of an additional $22 million.

►**Cancer vaccines:** NCI will undertake the following additional or expanded scientific activities under the bypass budget:

--Biological carcinogenesis--emphasis on basic and applied studies to identify viral or viral induced antigens that elicit protective immunity and that form the basis for vaccine preparation. Animal models will be developed to determine the immune response to viral induced tumors and to test the safety and efficacy of proposed vaccines.

--Tumor biology--research to identify at the molecular level potential autoantigens on tumors and clone genes encoding such differentiation antigens will be expanded.

--Tumor immunology--research will identify important epitopes that induce desirable protective responses. This program will initiate efforts to construct recombinant vaccines and test them in animal models. Increased emphasis on development of methods to overcome immune tolerance to tumor antigens and to enhance immune responses of the host.

--Epidemiology and biostatistics--recruit registers of patients who have recovered from cancer and perform sero-epidemiologic studies to dissect their immune response to identify factors important for survival.

Specific amount for this area is not specified in the bypass document.

►**Novel approaches to cancer therapy:** The bypass budget notes that, "The triad of surgery, radiation, and chemotherapy, which has served as the foundation of cancer treatment for the past 40 years, is now being expanded to include biological response modifiers, growth factor inhibitors, genetic based therapies, and agents specifically designed to reduce the toxicity of therapy." The document lists some new targets for cancer therapy: therapeutic agents such as taxol and camptothecin derivatives, growth factor inhibitors, trans-retinoic acid, dominant oncogenes, tumor suppressor oncogenes, monoclonal antibodies, and cancer vaccines.

Emphasis also would be placed on novel radiation therapy modalities such as proton beam therapy, radioisotopes, and photodynamic therapy.

Studies in gene transfer therapy would be continued; and other studies would focus on multidrug resistance, colony stimulating factors, and autologous bone marrow transplantation.

American Assn. for Cancer Research recently formed a committee to study and comment on the

FY93 bypass budget, as a result of remarks AACR President Harold Moses made at a meeting of the National Cancer Advisory Board last fall (**The Cancer Letter,** Dec. 6). Moses criticized the bypass budget as an "unusable document" that is ignored by Congress and the Administration, and is developed with little input from the extramural research community.

Since that meeting, AACR has been in communication with NCI Director Samuel Broder a number of times, and Broder invited the organization to comment on the bypass budget and become involved in planning the FY94 request.

The AACR committee consists of Moses, Bernard Weinstein, Lee Wattenberg, Edward Bresnick and Richard O'Reilly.

Advisors Ok Continuation Of NIAID's Women & Infants Study; 3 RFPs

Advisors to the National Institute of Allergy & Infectious Diseases have given concept approval to expansion and continuation of NIAID's mulitcenter Women & Infants Transmission Study for another four years at a total cost of $28 million.

NIAID's Combined Division Advisory Committee also gave concept approval to recompetition of three support contracts.

Following are the concept statements:

Women and infants transmission study. RFP continuation, first year cost $7 million, four years; total $28 million.

The objectives of WITS II are to: 1. assess the effect of pregnancy on HIV disease in women, including the impact of therapeutic anti-retroviral treatment; 2. delineate the timing and factors related to mother-infant transmission; 3. assess new methods for early diagnosis of HIV infection in the neonatal period; and 4. evaluate the impact of various therapeutic modalities on the natural history of chronic HIV infection among infants and children, including survival, morbidity, and quality of life.

WITS II is a continuation of the multicenter Women & Infants Transmission Study (WITS I). Currently over 330 pregnant women and 230 infants are enrolled in WITS I; the estimated final enrollment for WITS I is about 500 pregnant women and 400 infants. The renewal centers will be funded by contractual arrangements.

Data collected under WITS II will expand the data collected under WITS I to provide a large enough body of data to answer critical scientific questions about perinatal HIV transmission and early diagnosis. Two to three centers will intensively study timing of transmission and early diagnosis of infant HIV infection while the remaining sites will continue longitudinal follow up of the children already enrolled in WITS I. The data collected to answer the unique research questions in WITS II will be linked with data from other U.S. government supported projects to address important questions on pediatric HIV research which can only be answered with large numbers of patients. WITS II will also complement the Women's Interagency Health Study by providing data on the effects of pregnancy on the natural history of HIV disease among women.

These studies will provide critical clinical and epidemiological information on perinatally transmitted HIV and early diagnosis of HIV disease among infants born to HIV positive women. Applicants will be required to demonstrate the ability to recruit annually a minimum of 50-60 seropositive mother-infant pairs during the prenatal period. The applicants must be linked to existing programs which provide counseling and testing services for HIV infected pregnant women and which provide the social services and the comprehensive clinical, obstetric and pediatric care that are needed for the participants and their families. The applicants must also demonstrate clinical, epidemiologic, immunologic, and virologic expertise in HIV disease for prenatal, intrapartum and postnatal obstetric and gynecologic assessments of women, and for clinical and neurodevelopmental assessments of neonates, infants, and children.

AIDS research and reference reagent program. Recompetition of an RFP, first year cost $1 million, five years.

The objectives of the AIDS Research and Reference Reagent Program are: to acquire state-of-the-art reagents for AIDS-related research and to make these reagents available to qualified investigators throughout the world; to encourage and to facilitate technology transfer through publication of methods, and provision of standardized panels and protocols; to support DAIDS sponsored research grants, cooperative agreements, and contracts through reagent purchase, allocation, and transfer; to communicate needs of AIDS investigators for collaborative partners; and to participate as an AIDS Collaborating Center of the World Health Organization.

The Repository was established in January 1988. The first catalog, published in 1988, listed 62 reagents from 20 contributors. The Repository has grown considerably and now contains 322 reagents from 142 contributors. Contributors and users include scientists from the NIH, academic and nonprofit institutions, and from the private sector. During the past four years the Repository has provided 13,000 reagents to over 1,000 laboratories. The Repository publishes a catalog annually, and a catalog update/newsletter periodically. More than 80 publications in 1992 catalog cite the Repository as a source of essential reagents.

The Repository is a unique resource and provides renewable reagents to the AIDS research community. Approximately 25% of Repository activities involve other grantees i.e., collaborators in DAIDS cooperative agreements, ACTG investigators, and DAIDS contractors. As a collaborative center of the World Health Organization, the Repository is a major provider of reagents to AIDS investigators worldwide. The Repository also provides storage space, and technical assistance for reagents from the Div. of Microbiology and Infectious Diseases.

The current contract expires in January 1993.

Storage, repackaging, and distribution of investigational agents for AIDS. Recompetition of an RFP, first year cost $990,000, five years, one award.

Objective of this project is to support the AIDS clinical trials effort and regulatory responsibilities by storing, packaging, labelling and distributing drug products to the clinical sites according to regulations governing investigational drugs.

The Div. of AIDS, through the Treatment Research Operations Program, has centralized its investigational drug distribution system by establishing a repository to receive, store, package, label, distribute and dispose of investigational agents to the AIDS Clinical Trials Group, the Community Program for Clinical Research on AIDS, and Vaccine Evaluation Units. The repository

performs this function in accordance with Federal regulations governing investigational agents.

This contract provides for the storage, packaging, labeling, purchasing and distribution of clinical drug products in support of NIAID sponsored trials within the AIDS Clinical Trials Group, the Community Program for Clinical Research on AIDS, and the Vaccine Evaluation Program and their collaborating sites.

The contractor will receive study products from various sources, repackage and label them as required, store and ship them under specified conditions to authorized investigators. Under certain circumstances, study agents may be purchased. Manual and computerized data processing systems will be used for accountability, distribution records and other repository functions. The contractor will be responsible for inventory maintenance, providing adequate systems to ensure the proper storage, safety and stability of drug products, processing and, when appropriate, disposing of returned drugs.

Virology quality assurance. Recompetition of an RFP, first year cost $760,000, five years, one award.

Objectives of this project are: 1) To provide a quality assurance program for existing and newly developed virologic measures being utilized in DAIDS sponsored trials. 2) To facilitate standardization of virologic assay techniques. 3) To develop and maintain virology performance standards.

The Div. of AIDS sponsors a multitude of research projects, many of which rely on virologic assays to follow disease progression and to evaluate the potential efficacy of therapeutic interventions. Currently, the Virology Reference Laboratory, through its quality assurance and methods development activities, implements standardized assays and stringent performance standards which, together, facilitate comparability of data obtained from laboratories participating in multicenter studies.

The Virology Quality Control Program, through development and implementation of standardized assays and the monitoring of performance standards, will continue to facilitate the scientific efforts of the Clinical Research Program. Examples include development of virologic surrogate markers, mechanism and clinical significance of antiviral drug resistance, and other studies which will be useful in the evaluation of potential therapies for HIV disease.

This project would provide a quality assurance program for virologic assays in DAIDS-sponsored multicenter studies, including ACTG, WITS, HATS, AVEU, etc. In addition, through this contract, new technology and methodology can be developed, evaluated, and implemented in a standardized manner.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CP-21103-13
Title: Cancer following bone marrow transplantation
Deadline: Approximately April 7

NCI's Radiation Epidemiology Branch is seeking organizations capable of performing a study entitled, "Cancer following bone marrow transplantation." The purpose of this contract is to study cancer risk among a larger cohort of patients receiving a bone marrow transplant. The objectives of the study will be to evaluate the influence of immunosuppression and therapy with whole body irradiation and chemotherapy on the risk of new leukemias and lymphomas among bone marrow transplant patients, and to quantify the change in risk over time.

The association of cancer risk will be evaluated in light of the intensity of immunosuppression, degree of HLA match, therapy with total body irradiation or alkylating agents alone and in combination, and the effect of fractionated versus single dose TBI. In addition, factors associated with the risk of second solid tumors will be explored. A small biochemical component will examine the usefulness of the glycophorin-A (GPA) assay in identifying increased mutation rates in the surviving stem cells following high dose TBI, and to address issues surrounding stem cell survival. It is desirable that offerors be able to assemble a cohort of at least 2,000 bone marrow transplant patients.
Contracting officer: Sharon Miller
RCB Executive Plaza South Rm 620
301/496-8611

RFA Available: Construction Grants

RFA OD-92-02
Title: Extramural research facilities construction projects
Letter of Intent Receipt Date: March 10
Application Receipt Date: April 27

The Dept. of Health & Human Services appropriation for fiscal 1992 provides $7.5 million in the budget of the NIH director's office for extramural facilities construction grants to be awarded competitively. NIH announces the availability of an RFA for the construction of facilities of urgent national importance for biomedical research and/or services to support such research.

The main objective of this construction program is to facilitate the conduct of biomedical research by providing funds for construction of new facilities and for the purchase of associated fixed research equipment essential for the operation of these facilities. Support may be requested for the construction of new facilities and for additions or renovations to existing facilities to meet the biomedical research and/or support needs of an institution or of a research group that utilizes the resources of that institution. The purpose of the proposed facility must be within the scope of one of the statutes authorizing the awards. Those statutes authorize construction grants that would benefit the fields of cancer, vision, heart, lung, blood, and AIDS research.

Domestic, non-Federal, public and private nonprofit institutions, organizations and associations that conduct or support biomedical research are eligible to apply for these construction grants (C06).

This one time solicitation based on the fiscal 1992 appropriation provides $7.5 million for this initiative. It is anticipated that four to five awards will be made. Up to 50 percent of the allowable costs of a project may be awarded, not to exceed $2 million. Prior to grant award, the applicant must provide an assurance of required matching funds and that additional funds will be secured to meet any projected costs in excess of the award amount. Requests of less than $500,000 will not be accepted. No indirect costs or continuation costs will be awarded.

Letter of intent may be sent to and copies of the complete RFA received from:

Kenneth Brow, Chief, Research Facilities Branch, Div. of Cancer Biology, Diagnosis & Centers, NCI, Executive Plaza North Rm 300, Bethesda, MD 20892, phone 301/496-8534.