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Administration To Request 3.9% Increase For NIH; 1.3% Raise For NCI In FY97

President Clinton later this month is expected to request a $12.4 billion appropriation for NIH in fiscal 1997, an increase of $442.5 million, or 3.9 percent, over the current year's budget.

The Administration request would include $2.28 billion for NCI,

(Continued to page 2)

In Brief

BRCA 2 Gene Sequence Published; CALGB To Mark 40th Anniversary

MYRIAD GENETICS researchers, in an article in Nature Genetics, describe the complete sequence of BRCA2, a tumor suppressor gene that produces susceptibility to breast cancer, and mutations that disrupt production of the BRCA2 protein. **Sean Tavtigian**, of Myriad, is the lead author of the March 1 article, "The BRCA2 Gene and Mutations in 13q-linked Kindreds." A consortium of 51 scientists from Myriad, University of Utah, the CHUL Research Center and Laval University, the University of Pennsylvania and the University of Toronto's Hospital for Sick Children participated in the discovery. BRCA2 is believed to be responsible for about 40 percent of early-onset, hereditary breast cancer. Myriad, based in Salt Lake City, UT, said it expects to introduce a genetic test for BRCA1 later in 1996, and a combined BRCA1 and BRCA2 test during 1997. . . . **CANCER AND LEUKEMIA GROUP B** marks the 40th anniversary of its founding this spring. The three former group chairmen, **Emil Frei III**, **James Holland** and **O. Ross McIntyre,** are scheduled to address the plenary session of the group's semi-annual meeting May 4 in Miami Beach. The group was founded in 1956 as the Acute Leukemia Group B. Its name was changed in 1976. For meeting registration, contact CALGB, tel: 312/702-9171. . . . **UNIVERSITY OF MICHIGAN** Comprehensive Cancer Center appointed **Eric Fearon** and **James Mule** as co-directors of the center's new Cancer Genetics and Gene Therapy program. Fearon is the center's associate director for basic research. Mule, formerly with NCI, is scientific director of the center's Bone Marrow Transplantation Program. . . . **LA JOLLA** Cancer Research Foundation has been renamed The Burnham Institute in honor of Malin and Roberta Burnham of San Diego, CA. The change was recommended by the Board of Trustees. Malin Burnham, board chairman for 12 years, recently made a $5 million donation to the institute. The institute is one of 10 basic science centers that receives an NCI Cancer Center Support Grant.

President's FY97 Budget

NIH Would Redirect $123M To Fund New Clinical Center

(Continued from page 1)

an increase of $35 million, or 1.3 percent, over fiscal 1996.

The request for NCI would include $2.06 billion for cancer research, an increase of 1.73 percent, and $220.5 million for AIDS research, a decrease of $3.66 million, or 2.33 percent, from FY96.

The figures were outlined in Office of Management and Budget documents dated Feb. 14 and obtained last week by **The Cancer Letter**. The figures could change before the Administration publicly releases the FY97 budget request later this month, sources said.

Increase For Research Project Grants

The request would include a 3.7 percent increase in NIH funding for research project grants. The amount would enable NIH to fund 6,720 grants, an increase of 100 competing grants over FY96.

Each institute would be expected to support a 2.6 percent increase in research project grants, excluding Small Business Innovation Research grants.

Under the budget request, the Administration proposes to fund the construction of a new NIH Clinical Center in FY97, at a cost of $310 million. According to the documents, the Administration included $187 million for the project, and expects NIH to redirect $123 million from other programs to support the remaining costs of the construction.

Redirection Questioned

Some professional societies and medical research advocates say they are concerned about the redirection of funds for the Clinical Center construction in one fiscal year, and are suggesting that the Administration spread the amount over several years.

Although advocates say they support the building of a new clinical center, they do not want it to come at the expense of other NIH programs.

According to the OMB documents, the increase for NIH would amount to 1.64 percent when the funds for the Clinical Center construction are excluded.

On Capitol Hill

Cancer Advocacy Groups Seek 6.5% Increase For NCI

Testifying before the House Labor, HHS & Education Appropriations Subcommittee last week, several cancer advocacy groups called for a 6.5 percent increase for NCI in fiscal 1997.

The increase sought by the groups that testified last week would amount to $150 million.

"With health care costs for cancer in excess of $104 billion annually, it is astounding that the US invests less than 2 percent of this amount in research on prevention, treatment, and a cure for cancer," said Margaret Foti, president of the National Coalition for Cancer Research.

"Clearly, no private, product-oriented enterprise would settle for a 2 percent investment in R&D," Foti said at the hearing Feb. 28. "Rather, there would be a 5 or even 10 percent investment in the future."

An Incremental Increase Sought

NCCR member organizations said they were seeking an incremental increase, though their ultimate goal was to secure NCI funding at the level of the Bypass Budget, an assessment of scientific opportunities which the NCI director submits to the US President.

"Our ultimate goal as a nation is to fulfill the promise of cancer research and achieve the Bypass Budget request of $2.977 billion for FY 1997," said Myles Cunningham, president-elect of the American

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Cancer Society and a surgeon at St. Francis Hospital in Evanston, IL.

The Institute's current operating budget is $2.25 billion.

Push Grant Funding To 25th Percentile

According to testimony submitted by NCCR, a 6.5 percent increase would allow NCI to fund approved grants to the 25th percentile, pushing up the payline from the current target level of the 23 percentile.

Also, the increase could allow NCI to expand support for training, clinical trials and other translational research programs.

"Given the [4.7 percent] projected biomedical inflation rate in the coming year, any increase significantly less than 6.5 percent would be, in effect, a cut in research funding," NCCR said in a statement.

The coalition also urged against earmarking for "site- and gender-specific research... unless additional funds are provided for these priorities."

NCI-DOD Agreement Praised

Paul Bunn, president of the Association of American Cancer Institutes, said the recent agreement between NCI and the Department of Defense to give military personnel and their dependents access to clinical trials represents a model for government intervention on behalf of clinical researchers and the cancer centers (see story, page 5).

"Patients cannot be expected to pay for routine care costs, nor can research funding from government or industry," Bunn, director of the University of Colorado Cancer Center, said to the subcommittee.

"We are pleased that the DOD has recently dealt with the issue by [covering] research costs," Bunn said. "We would hope this would be extended to the rest of the population."

ACS Offers Recommendations

ACS, too, offered several specific recommendations, including a $30 million appropriation for the Office on Smoking and Health, another $30 million for the National Program of Cancer Registries operated by the Center for Disease Control and Prevention, a $200 million appropriation for the CDC Breast and Cervical Cancer Control Program, and another $5 million for the CDC effort to develop strategies for promoting cancer screening.

NCI Increases Grant Funding By $74 Million, Raises Centers, Cooperative Groups, Training

NCI expects to spend $1.026 billion to fund research project grants this fiscal year, an increase of $74 million, or 7.8 percent over last year, Institute Director Richard Klausner said last week.

The amount projected for grants funding represents 45.6 percent of the Institute's fiscal 1996 operating budget of $2.25 billion.

"Our priorities are to use our budget to maintain the engine of discovery and to ensure that those discoveries benefit patients," Klausner said to the National Cancer Advisory Board at its meeting Feb. 27.

The increase will enable the Institute to fund R01 grants to the 23rd percentile, compared to the 15th percentile last year (**The Cancer Letter**, Feb. 9, 1995). Paylines for other grant mechanisms also would increase.

NCI would provide $274.5 million to fund competing research project grants, an increase of $52.9 million from last year. The budget for noncompeting grants would be $717.7 million, an increase of $19 million from last year.

$11 Million Increase For Cancer Centers

Under the FY96 budget, the Cancer Centers Program would receive $166.9 million, an $11 million increase from last year. About $3 million to $6 million of the increase would be set aside to fund competitive core grant supplements in heritable cancers or cancer genetics, and training and education for genetic counselors. About $2 million to $5 million would fund research in AIDS-related malignancies.

Other highlights of the FY96 budget include:

--Research Career Program would receive $16.7 million, compared to $15.6 million last year. NCI would fund 208 trainees this year, compared to 197 last year.

--Cancer Education Program would receive $9.4 million, compared to $8.3 million last year.

--Clinical Cooperative Groups would recieve $89.2 million, compared to $75 million last year.

--Minority Biomedical Research Program would receive $2.4 million, compared to $2 million last year.

--Other research, a category that includes scientific evaluation and conference grants, would receive $5.9 million, compared to $4.7 million last

year.

--National Research Service Awards training program would receive $41 million, compared to $38.5 million last year.

--R&D contracts would receive $158.3 million, compared to $205.4 million last year. The decrease reflects approximately $30 million of cuts in contract spending as well as recoding some contract funds to other budget categories.

--NCI intramural research program would receive $405.2 million, compared to $373 million last year.

--Research management and support would receive $100.8 million, compared to $96.4 million last year.

--Cancer prevention and control would receive $225 million, compared to $192.2 million last year. The amount is required by law to be 10 percent of the Institute's budget.

--Extramural construction funding would receive $3 million, compared to $8 million last year.

NCAB Approves New Awards Honoring Howard Temin

NCI has established a new grant mechanism designed to stabilize the early independent careers of cancer researchers.

The Institute plans to set aside up to $1.5 million in fiscal 1997 to fund 10 Howard Temin Extended Support Awards, named in honor of the late Nobel laureate and member of the National Cancer Advisory Board.

The NCAB, at its meeting Feb. 27-28, unanimously approved the new grant mechanism.

"We felt there was a particular need to attract the best young people into cancer research," NCI Director Richard Klausner said to the NCAB Planning and Budget Subcommittee. In honoring Temin, NCI also hoped the award would carry a certain prestige, Klausner said. The "Temin scholars" would be invited to meet annually in Bethesda.

The K01 grant would provide up to five years of support and act as a "bridge" as a senior fellow moves from a mentor's laboratory to establish an independent laboratory. Under the new award, up to three years may be spent in a mentor's laboratory.

The grant would provide a salary of up to $75,000, and for all other expenses, $20,000 while the candidate is working in a mentored environment, and $50,000 when the candidate establishes an independent research position.

The grant would be portable, moving with the scientist to a different institution. Awardees also would be eligible to apply for concurrent NIH grant support.

Eligible candidates must have a doctorate and have completed at least three years of postdoctoral research, have demonstrated highly productive research activity and the potential for establishing an independent research program. Candidates must provide three letters of recommendation from established cancer researchers.

All current NCI career awardees in their last two years of support who meet the eligibility criteria are encouraged to apply, the Institute said.

NCI may release the Request for Applications for the new grants later this month, said Vincent Cairoli, chief of the NCI Cancer Training Branch. Investigators interested in application information should contact the branch at 301/496-8580.

BMT Appropriate For Some Breast Cancer Patients, Blues Advisory Panel Says

A panel of breast cancer experts advising the Blue Cross and Blue Shield plans last week said high-dose chemotherapy with autologous bone marrow transplantation is an appropriate treatment option for some patients with stage IV breast cancer.

The Blues' Technology Evaluation Center said the latest studies demonstrate that high-dose chemotherapy with ABMT "offers some benefit in the treatment of metastatic breast cancer."

Also, the panel said, the mortality from the procedure has decreased dramatically, and is now approaching the risk of conventional chemotherapy.

However, the Medical Advisory Panel convened by the Blues also found that the benefit appears to be no greater than conventional therapy, the evaluation center said in a statement dated Feb. 29.

Recommendation For Reimbursement

The treatment could be reimbursed when administered as first therapy following the diagnosis of metastatic breast cancer or as first treatment for metastatic disease that has recurred after a period of complete remission, the advisory group said.

The results of high-dose chemotherapy with bone marrow transplantation in women with refractory

disease are discouraging, the panel noted.

The recommendation is not binding for the 63 independent, locally operated insurance plans.

Panel: No Proven Advantage For BMT

Craig Henderson, a member of the advisory panel and professor at the University of California at San Francisco, said it is unproven whether high-dose chemotherapy with ABMT has any advantage over standard chemotherapy.

"[It] is not clear that high-dose chemotherapy with ABMT is the best treatment for any group of patients, that it will cure any patient that would not be cured by any other treatments, or that it will prolong survival to a greater extent than commonly used conventional dose chemotherapy," Henderson said in a statement.

Words of caution notwithstanding, it remains to be seen what effect the recommendation will have on the medical practice. Frequently, patients regard ABMT as their best chance of a cure, and many sue their insurers when coverage for the procedure is denied.

Susan Gleeson, vice president of the Blues' Technology Evaluation Center, said the procedures should be carried out by "experienced centers with good outcomes and low mortality rates, and that they meet the most recent accreditation standards for bone marrow transplant centers."

Standards for accreditation of marrow transplantation programs were developed recently by the American Society for Blood and Marrow Transplantation and the Foundation for Accreditation of Hematopoietic Cell Therapy.

Peters: Panel's Recommendation Not Enough

The evaluation center's recommendation does not go far enough, said William Peters, director and CEO of the Barbara Ann Karmanos Cancer Institute in Detroit.

"The recommendation says that [the Blue Cross and Blue Shield plans] can cover it for patients with metastatic breast cancer, but for patients who are enrolled in clinical trials for primary breast cancer, they are still not covering it," Peters said to **The Cancer Letter**. "And that's where the biggest benefit is most likely to be seen."

Peters, a long-time advocate of the insurance reimbursement for the procedure, said that, ideally, the treatment should be provided in the context of clinical trials.

As it stands, insurance companies have in effect contributed to raising the patient expectations about the procedure, and, consequently, its widespread use, Peters said.

"A lot of this could have been prevented many years ago by the insurance companies working with the academic centers," Peters said. "We got to this point because patients were being told that they couldn't get state of the art care at the best centers in the country, but they could get out-of-date treatment at their local place. And patients aren't going to tolerate that. So they filed suits.

"It is incumbent upon the insurance industry to figure out a way in which they can help their subscribers get access to the best treatment at the best centers," Peters said.

Two New Studies Shaped Conclusions

According to Blue Cross and Blue Shield officials, the two recent papers that played a role in shaping the panel's conclusions reported the results of a study in South Africa (Bezwoda et. al., Journal of Clinical Oncology 13:2483-2489, 1995) and a study at Duke University (Peters et. al, Proceedings of the American Society of Clinical Oncology 14:347, 1995).

The Blues technology assessment program is a collaboration with Kaiser Permanente, Southern California Region.

NCI, DOD Sign Agreement On Clinical Trials Access

NCI and the Department of Defense signed an interagency agreement that will give military personnel and their families access to cancer clinical trials.

The agreement, signed March 5, includes a three-year demonstration project that allows beneficiaries of TRICARE/CHAMPUS, the DOD health program, to participate in NCI-sponsored phase II and phase III clinical treatment trials. In the past, DOD regulations have limited reimbursement for medical care delivered as part of a clinical trial (**The Cancer Letter**, Feb. 9, 1995).

"We regard this agreement as a milestone in the long quest to resolve the conflict between policies of the insurance industry and the need to foster clinical research," said Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers.

DOD provides medical services to about 8.3 million beneficiaries through its 120 military hospitals and through care purchased from civilian providers.

"DOD supports NCI's efforts to ensure that progress against cancer continues," said Stephen Joseph, the Assistant Secretary of Defense for Health Affairs. "We have an interest and a responsibility to participate in the appropriate evaluation of improved therapeutic approaches for our patients."

Lee To Discuss Similar Program With HCFA

Philip Lee, HHS assistant secretary for health, said he planned to meet with top officials at the Health Care Financing Administration to explore the feasibility of launching a similar demonstration project through that agency. HCFA has authority over the Medicaid and Medicare programs.

"We will be sitting down with [HCFA Administrator] Bruce Vladeck to see if this is a possibility under HCFA to enter into a similar agreement between HCFA and NCI, to use their demontration authority, and perhaps move it in the same direction," Lee said.

"I have to confess, we have not thought about this until Rick [Klausner] and Steve [Joseph] sat down and came up with what I consider a creative idea," Lee said. "So we have not pursued it with HCFA up to now, but we certainly intend to do so."

About 30,000 cancer patients enroll in NCI clinical trials each year. The DOD agreement "will move us in the direction of ensuring that trials will enroll enough patients to answer vital research questions about cancer," said NCI Director Richard Klausner.

Under the demonstration project, if a DOD patient is considering participation in a clinical trial, his or her physician would determine which NCI clinical trials might be appropriate and what institutions are enrolling patients in that trial. The physician would obtain DOD approval and arrange for evaluation of the patient at the institution selected. Physicians at the institution selected would determine whether the patient is eligible for the study.

TRICARE/CHAMPUS providers seeking information or authorization for treatment in an NCI-sponsored trial may call 800/779-3060. Clinical trials information is available through the NCI Cancer Information Service, 800/4-CANCER. Health professionals may call the PDQ Search Service, 800/345-3300.

Cancer Prevention Fellowship Program Accepting Applicants

The NCI Division of Cancer Prevention and Control is accepting applications for the Cancer Prevention Fellowship Program.

The purpose of the program is to train individuals from a multiplicity of health science disciplines in the field of cancer prevention and control.

The program provides for Master of Public Health training, participation in the DCPC Cancer Prevention and Control Academic Summer Course, working at DCPD directly with individual preceptors on cancer prevention and control projects, and brief field assignments in cancer prevention and control programs at other institutions.

Eligible applicants would have an MD, DDS, or DO degree from a US, territorial, or Canadian medical school. Foreign medical graduates must have current USMLE or ECFMG certification and appropriate experience, or PhD or other doctoral degree in a related discipline. The foreign education must be comparabe to US institutions.

The applicant must be a US citizen or resident alien eligible for citizenship within four years.

Fellows will be accepted for up to three years of training beginning July 1, 1997.

For a fellowship application, contact Douglas Weed, Cancer Prevention Fellowship Program, NCI Division of Cancer Prevention and Control, Executive Plaza South, Suite T-41, 6130 Executive Blvd., MSC 7105, Bethesda, MD 20892-7105, or call Barbara Redding, tel: 301/496-8640, fax: 301/402-4863, e-mail: reddingb@dcpceps.nci.nih.gov

RFA Available

RFA CA-96-008

Title: **Studies of the Viral Etiology of AIDS-Associated Malignancies**

Letter of Intent Receipt Date: April 15

Application Receipt Date: May 24

NCI invites investigator- initiated research grant applications for support of basic studies on the role of viruses and other biological agents in the etiology and biology of malignancies associated with AIDS, including, but not limited to, Kaposi's sarcoma and AIDS-related non-Hodgkin's lymphomas.

Support will be through the research project grant (R01) and the FIRST Award (R29). Total direct cost award for the five-year R29 grant period may not exceed

$350,000 and the direct cost award in any R29 budget period may not exceed $100,000. Total project period for each application may not exceed five years. Approximately $1 million in total costs per year for up to five years will be committed to fund five to six awards.

The goal of this RFA is to stimulate research on the role of viruses and other biological agents in the etiology and biology of malignancies associated with AIDS, including but not limited to Kaposi's sarcoma and AIDS-related non-Hodgkin's lymphomas. Possible oncogenic or etiologic agents that might interact with HIV include the Epstein-Barr virus, cytomegalovirus and other human herpesviruses, human papillomaviruses, human T-lymphotropic viruses or unknown but suspected retroviruses or other microbes. Research might also focus on etiologic agents functioning as a co-factor(s) in the context of HIV infection or on HIV serving as a co-factor in the context of other viral or microbial infections. Proposed areas of investigation might include but are not limited to: (1) the role of viruses and/or biological factors and/or co-factors in the etiology of AIDS-associated malignancies; (2) interactions between viral nucleic acid sequences, viral and cellular genes and/or proteins which might be involved in the initiation and progression of AIDS-associated malignancies, e.g., interactions with cellular oncogenes; (3) the role of direct and indirect processes, such as autocrine and paracrine mechanisms and effects, by which single or multiple viral or microbial infections play a role in the initiation and progression of AIDS-associated neoplasms; (4) the use of currently available, appropriate and well-justified animal models to investigate the molecular basis of AIDS-associated malignancies; and (5) investigations of the alteration of pathogenesis and oncogenesis as a consequence of the immune status of the patient.

Inquiries: Kenneth Cremer, Division of Cancer Biology, NCI, Executive Plaza North, Suite 540, MSC 7398, Bethesda, MD 20892-7398, tel: 301/496-6085, fax: 301/496-2025, e-mail: cremerk@epndce.nci.nih.gov

RFA CA-96-005

Title: **Program Projects In Nutrition And Basic Biology Research For Cancer Prevention**

Letter of Intent Receipt Date: April 12

Application Receipt Date: July 19

The NCI Division of Cancer Prevention and Control and the NCI Division of Cancer Biology are reissuing an invitation for Program Project Grant applications for multidisciplinary nutrition and basic biology research relevant to the prevention of cancer, with a special emphasis on breast cancer, prostate cancer, and cancer in women and minorities. This RFA seeks to improve understanding of the roles of dietary patterns, individual dietary constituents, and nutritional status in the development and prevention of cancer. The objectives of this RFA are to increase the pool of quality applications addressing nutrition and human cancer prevention using multidisciplinary approaches; to stimulate the use of modern biological approaches and techniques in order to elucidate the effects of nutrition on cancer initiation, promotion, progression, and prevention; and to promote the translation of knowledge of the impact of nutrition on the basic biology of cancer into dietary interventions for its prevention.

Application of the tools and techniques of the basic biological sciences in research designed to increase understanding of the complex role of nutrition in cancer prevention will be enhanced significantly by a mechanism that promotes collaborations across disciplines and across institutions. Investigators are encouraged to submit P01 applications for a multidisciplinary research program in nutrition and basic biology for cancer prevention with a focused theme and a minimum of three interrelated and synergistic individual component projects that comprise basic research efforts and at least one component project involving human subjects or human tissues.

Up to $2 million in total costs per year for up to four years will be committed to fund two to three awards.

Inquiries: Susan Pilch, NCI Division of Cancer Prevention and Control, 6130 Executive Blvd, Room 212 MSC 7328, Bethesda, MD 20892-7328, tel: 301/496-8573, fax: 301/402-0553, e-mail: PilchS@dcpcepn.nci.nih.gov

Victor Fung, NCI Division of Cancer Biology, Executive Plaza North, Suite 700, 6130 Executive Blvd MSC 7420, Bethesda, MD 20892-7420, tel: 301/496-5471, fax: 301/496-1040, e-mail: FungV@epndce.nci.nih.gov

Program Announcement

PAR-96-028

Title: **AHCPR Small Project Grant Program**

The Agency for Health Care Policy and Research was established to improve the quality, appropriateness, and effectiveness of health care services and access to these services. These purposes are achieved by supporting research and by promoting improvements in clinical practice and in the organization, financing, and delivery of health care services.

The AHCPR announces a program of small grants (R03), designed to take advantage of time-dependent opportunities; reduce the costs of developing applications for small research projects, including demonstrations and evaluations; and shorten the time and burden of the review process.

Inquiries: Jill Bernstein, Deputy Director, Office of Planning and Evaluation, Agency for Health Care Policy and Research, 2101 East Jefferson St., Suite 603, Rockville, MD 20852-4908, tel: 301/594-1455, fax: 301/594-2157.

RFPs Available

RFP N01-CP-71007-21
Title: **Interdisciplinary Studies In Occupational Cancer**
Deadline: Approximately May 13

The Occupational Studies Section of the Environmental Epidemiology Branch, Epidemiology & Biostatistics Program, NCI Division of Cancer Epidemiology and Genetics, is soliciting proposals from qualified organizations for the recompetition of an existing contract currently being performed by Westat Inc. which provides support for the OSS. The proposed contract will support data collection activities for 20 to 25 projects. The studies to be supported by this contract are designed by NCI investigators who also analyze and interpret study results. The contractor must be capable of providing support for a number of studies conducted simultaneously in widespread geographic regions of the US and other countries. A critical capability is to be able to respond quickly to changes in priority and to supply support to urgent new efforts. Types of support needed in the conduct of studies will vary, but may include: (1) study initiation and liaison, (2) preparation of study materials and procedures, (3) data collection, (4) data preparation, (5) computer programming and data processing (6) study monitoring, quality control and reporting. Use of PCs. wherever possible, is encouraged for data collection, processing and manipulation. However, the NIH/DCRT computer facility (which has IBM mainframe computers) can also be accessed as needed by remote terminals to be provided by the contractor on their own premises. The contractor must demonstrate how it will accomplish the task of attendance at face-to-face discussions on a nearly daily basis with the NCI Project Officer(s)—(mandatory requirement). A Senior Industrial Hygienist must be provided who has been certified by the American Board of Industrial Hygiene, and must have access to a laboratory accredited by the American Industrial Hygiene Association (mandatory requirement).

Inquiries: Barbara Shadrick, Contracting Officer, tel: 301/496-8611, NCI Research Contracts Branch, CECS, 6120 Executive Blvd, EPS/Room 620, Bethesda, MD 20892-7224.

RFP-NO1-CP-61019-21
Title: **Prospective Immunoepidemiologic Study Of Low-Grade Squamous Intraepithelial Lesions Of The Cervix**
Deadline: Approximately April 18

Environmental Epidemiology Branch, NCI Division of Cancer Epidemiology and Genetics, is seeking offerors for a new contract to process, store, test, and ship blood samples collected as part of a large prospective study of immunological markers involved in the pathogenesis of cervical neoplasia. As a mandatory requirement, offerors are required to be located within one hour driving distance of the main campus of the NIH. The study, in which 7,200 women with low-grade cervical lesions will be enrolled over an 18-month period and followed at six-month intervals for an average of four years, is designed to assess cell-mediated immune parameters among study participants and to determine whether these immune markers are predictive or correlate with disease progression and regression. The offeror must have demonstrable experience in conducting immunological assays on a large number of specimens. Experience in data management and sample tracking of large number of specimens and assay results is also essential. The assays to be performed under this contract are highly technical, research-based assays which require well-trained, experienced, and dedicated personnel. Services to be provided by the contractor shall include: 1) Receipt and logging of fresh peripheral blood samples, 2) timely separation and cryopreservation of PBMCs from fresh whole blood, 3) separation and storage of plasma and red blood cells from fresh whole blood, 4) establishment of EBV-transformed PBMC lines, 5) performance of immunologic assays using PBMCs isolated from whole blood, including lymphocyte proliferation in response to virus-specific antigens, measurement of cytokine levels produced by PBMCs in culture in response to stimulation with virus-specific antigens, and measurement of cytotoxic response of PBMCs stimulated by virus-specific antigens against virus antigen expressing target cells in vitro, 6) computerization of individual assay results, 7) storage of cryopreserved materials in small aliquots in mechanical and liquid nitrogen freezers, 8) preparation of frozen samples for shipment to the NCI repository, and 9) maintenance of strict and well documented quality control procedures. At initiation of the contract, the offeror shall work closely with the NCI Project Officers to standardize and finalize the protocols to be used at the offeror's laboratory during the period of the contract. The offeror shall receive fresh whole blood samples from four clinical centers on a daily basis. The offeror shall be capable of developing mechanisms to communicate with the four clinical centers and the coordinating unit regarding the type, volume and timing of specimen shipments. All biospecimens stored in the repository must be entered into the Biospecimen Inventory System. The BSI is an information system designed to track and control the acquisition, storage, requisition and distribution of biological specimens. Training and documentation on the use of the BSI will be provided by the NCI at no cost to the contractor. It is anticipated that the proposed contract will be a cost-reimbursement, completion type contract for a four-year period of performance.

Inquiries: Barbara Shadrick, Contracting Officer, tel: 301/496-8611, NCI RCB, 6120 Executive Blvd, EPS/ Room 620, Bethesda, MD 20892-7224.