THE CANCER LETTER

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Utah, NIEHS Report Finding BRCA1 Gene For Familial Breast, Ovarian Cancer

Scientists at the Univ. of Utah, Myriad Genetics Inc. of Salt Lake City, and the National Institute of Environmental Health Sciences last week reported the isolation of the BRCA1 gene, which is believed to be responsible for almost half of the cases of inherited breast and ovarian cancer.

In two articles to be published in the journal Science on Oct. 7, the researchers report the gene's location on chromosome 17q21 and the detection of mutations of the gene in breast cancer cases. A dozen laboratories around the world have been searching for the gene in the past four years.

Threatening to overshadow the finding itself were the circumstances

(Continued to page 2)

In Brief

Calabresi: Rimer "Outstanding" For NCAB Chair; Board Should Maintain Strong Leadership Role

PAUL CALABRESI, who was replaced by Barbara Rimer, of Duke Univ., last week as chairman of the National Cancer Advisory Board, congratulated Rimer on her appointment in a statement to **The Cancer Letter**: "I am very pleased that Barbara Rimer's appointment has been confirmed. She is highly qualified and I know that she will provide outstanding leadership and effective direction for the NCAB in the future. Barbara and I have talked on the telephone and I am delighted that she and I will have the opportunity to work together to ensure a smooth transition for the important activities of the board. It is essential particularly during these extremely challenging times for health care and research that the NCAB continue to exert strong leadership for the National Cancer Program. The board has never been stronger, and I am deeply grateful to all of its outstanding members for their profound dedication and invaluable contributions to this crucial endeavor." (See page 6 for Rimer's Letter to the Editor) . . . . **SURGICAL ONCOLOGY** department status has been granted to the surgical oncology program at the Univ. of Illinois at Chicago College of Medicine by the Illinois Board of Higher Education. The program had been an independent academic unit in the dean's office. The new department is one of the first surgical oncology departments in the country and the first in Illinois. . . . **OVARIAN CANCER** consensus report from the NIH consensus conference held earlier this year has been published. Contact William Hall, NIH Federal Bldg. Rm 618, Bethesda, MD 20892, Tel: 301/496-1143.

Breast Cancer Activists Protest For Early Release Of Sequence

(Continued from page 1)

surrounding its announcement. The articles were still in peer review when the news was reported by NBC News Sept. 13. Responding to the NBC story, on the following day NIH organized a news conference and, with permission from Science, released copies of the draft articles.

As breast cancer activists scrutinized the released information, they saw what they described as a glaring omission: the DNA sequence was left out of the materials.

In a Sept. 18 statement, the National Breast Cancer Coalition issued an ultimatum calling for the sequence to be deposited in GenBank, a federally-funded human genome database, by 6 p.m. of the following day.

After the scientists countered that the sequence had been placed in GenBank, but would not be available to the public until Oct. 7, NBCC President Fran Visco urged the researchers to make the gene sequence public immediately.

"This delay in making the sequence public is unacceptable," Visco wrote in a Sept. 19 letter to principal investigator Mark Skolnick of Univ. of Utah and Myriad Genetics. "We call upon you to personally release the gene sequence today by any and all methods available."

Myriad declined, saying that it would follow "standard procedure" for release of the gene sequence at the time of publication.

"All of the information is being made available to the public," Alexander Kamb, director of research at Myriad, said to **The Cancer Letter**. "We can't unilaterally make the decision to release the GenBank information prior to publication. If there were a groundswell of public opinion to change the system, we would go along with it."

Myriad, formed in 1991, has filed for a patent on the gene and hopes eventually to develop a diagnostic test for familial breast cancer. Earlier this year, Myriad pinpointed p16 as a melanoma susceptibility gene.

"Large And Complex Gene"

Reaction to the finding was congratulatory but cautious among the scientists who participated in the BRCA1 race.

"It will be critical to see if the same gene has mutations in the families with breast and ovarian cancer with whom we have worked," said Mary-Claire King, American Cancer Society professor of genetics at the Univ. of California at Berkeley, who first postulated the existence of the gene in 1990.

"If we can find mutations in DNA from members of these families, we will be convinced that this is BRCA1," King said. "We have every expectation that we will be able to confirm the NIH-Utah findings, and congratulate our friends on a very lovely piece of work."

Skolnick led a team of 44 researchers at five other institutions and NIH in the search for the BRCA1 gene. Roger Wiseman of NIEHS led the federal effort. Contributing to the report were scientists at McGill Univ., Eli Lilly and Co., Memorial Sloan-Kettering Cancer Center, Duke Univ., and the Faculty of Health Sciences in Tab Linkoping, Sweden.

BRCA1 may be involved in 45 percent of the inherited form of breast cancers. These make up about 5% of all breast cancer.

Skolnick and his colleagues studied eight very large families in which many individuals appeared to have the inherited form of breast cancer. They narrowed the possible location of BRCA1 to chromosome 17q21, which contains 2 million base pairs. They looked for differences in that section between family members and in people who had no family history of breast cancer. The researchers found abnormal sections of DNA in four of the eight families. The abnormalities were different among the families, but within each family, every woman with breast or ovarian cancer had the same abnormality.

Eventually the research team narrowed BRCA1 to 80,000 base pairs.

King said the gene described in the Science papers

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will be difficult to work with. "This BRCA1 candidate is a very large and complex gene," she said. "It is not a gene previously studied in any species. It is going to be difficult, to say the least, to understand how this gene predisposes some women to breast and ovarian cancer.

"There is a great deal more work to be done by geneticists before women have results from this gene that will matter to our lives," King said.

Complicating the process is the number of mutations that BRCA1 may take. Already, the Skolnick team has found 10 mutations.

In a third paper to be published in Science, the researchers said they believe a second breast cancer gene, which they named BRCA2, is located on chromosome 13. Mutations of that gene may be as important as BRCA1 in breast cancer risk.

Access To DNA Sequence

A leaked story followed by a rushed announcement proved to be a suboptimal way to present an important news development to the public, several observers said.

"This didn't follow scientific protocol," an NIEHS official said to **The Cancer Letter**. "Had it been published first and then released, you would have seen the gene sequence, and it all would have made more sense."

"We had nothing to do with that leak—in fact, we were really disturbed by it," agreed Myriad's Kamb. "We refused to talk to the press until we had talked to Science. That really should not happen."

When NIH decided to hold a press conference, the editors of Science took the extraordinary step of releasing the draft papers three weeks prior to the publication date, before the papers had completed peer review and editing.

"We were concerned about getting the proper and correct information out," said Carolyn Martin, a spokesman for Science. "We were concerned about the people who would be affected by this news."

Kamb said the company left out the DNA sequence from the draft papers in order to protect its interests. "There are some people who won't respect your priority," he said to **The Cancer Letter**. "Obviously, we have some financial interest in this."

Myriad has deposited the DNA sequence in GenBank, a genome database accessible through the InterNet communications network.

GenBank will make the sequence public on Oct. 7, in conjunction with the Science publication. The Science articles will include the sequencing information and the GenBank access number.

Kamb said Myriad would provide the sequence prior to Oct. 7 to any scientist who agreed to collaborate with the research group. Post-publication, scientists can download the sequence and use it for any non-commercial use.

That's not soon enough, insists NBCC's Visco, who is also a member of the President's Cancer Panel.

"Until the gene sequence is disclosed, scientists around the world who have been searching for this gene cannot move to the next step," said Visco. "Every day lost in research on BRCA1 will ultimately result in the loss of women's lives. Why are they keeping it from the scientific community and the public? We are concerned that they are motivated by financial gain, at the expense of women's lives."

NIH policy requires grantees to release the sequence at the time of publication. The National Center for Human Genome Research requires its grantees to place the sequence in databases within six months of discovery, a spokesman for the center said to **The Cancer Letter**. Myriad and the Skolnick group will meet both of these guidelines when the sequence is released Oct. 7.

"The Profit Motive"

By moving to protect its research for potential commercialization, Myriad is not doing anything new, Kamb said to **The Cancer Letter**.

"All of the biotech companies have patented gene sequences and gene products, and that allows them to bring these to the market," Kamb said. "Amgen patented erythropoietin, for instance. The motives for people who do research are seldom completely altruistic. There is the motive to be the first, and there is the profit motive.

"In order to attract investment from the private sector, you have to have some kind of incentive, and that is patent protection," he said.

"Private sector investment speeds up the progress that can be made."

NCI Extends PRI Contract For Frederick By Six Months

NCI has given a six-month extension to Program Resources Inc. for the operations and technical support contract at the Frederick Cancer Research and Development Center in Frederick, MD, **The Cancer Letter** has learned.

The seven-year, $1 billion contract, one of five large contracts that support the center, was under recompetition this year and was scheduled to be awarded this month. At least one other group besides PRI was in competition for the contract when NCI officials decided earlier this month to delay the award.

NCI officials confirmed that the PRI contract was extended.

"The NCI intends to extend the contract in order to allow sufficient time to complete the recomepetition," Philip Amoruso, director of NCI's Office of Administrative Management, said to **The Cancer Letter**. "It is a very large contract and extremely complex. An additional time is necessary to complete the recompetition."

Amoruso declined further comment.

Sources said the extension was needed to give NCI time to review its intramural research program, including the FCRDC. The review is part of a streamlining and overhaul of the NIH intramural program initiated last fall by NIH Director Harold Varmus.

A panel co-chaired by Paul Calabresi, former chairman of the National Cancer Advisory Board, and Michael Bishop, Univ. of California, San Francisco, is leading the NCI intramural program review.

The Frederick operations and technical support contract is likely to be reduced from seven years to three years, sources said. Competitors were asked to resubmit proposals.

The Request for Proposals for the contract was issued in June 1993.

ODAC Recommends Approval Of Esophageal Cancer Therapy

The FDA Oncologic Drugs Advisory Committee last week recommended approval for a light-activated treatment for esophageal cancer, designed to destroy cancerous tissue and reduce swelling so that some patients with complete obstruction can eat normally.

No timetable for marketing approval was set, but officials of Quadra Logic Technologies Inc., the maker of the drug Photofrin (sterile porfimer sodium), said they would meet with FDA to discuss the proposed approval.

The committee voted 11-1 to recommend approval of Photofrin for patients with partially or completely obstructive esophageal cancer who, in the judgment of their physicians, would not be suitable candidates for laser therapy.

Approval was also recommended for the laser and fiber optic system used to activate the drug.

Treatment of Symptoms

"This may be the first time in FDA history we've seen an oncological drug worked up entirely for the treatment of patient symptoms," said Robert Temple, director of the FDA Office of Drug Evaluation I.

There are an estimated 11,000 new cases of esophageal cancer and about 10,000 deaths annually in the US. The five-year survival rate is less than 10 percent.

Treatment consists of surgery, chemotherapy and radiation. The most important aspect of patient care is tumor control in order to allow the patient to eat.

The esophagus can be mechanically dilated and a tube inserted; cancerous tissue can be burned away using electrocautery or the laser; or the tissue can be chemically destroyed by injection.

All of these techniques have drawbacks, the drug sponsor pointed out. Mechanical dilation can result in perforation of the esophagus, for instance; injections can be difficult to control.

The laser treatment is uncomfortable and can result in esophageal perforation; in addition, it is particularly difficult to use in the case of complete obstruction.

Results Similar To Laser

When injected intravenously, Photofrin is preferentially retained in the tumor. When red laser light is applied to the abnormal tissue, the drug causes destruction of malignant cells, which can then be scraped away.

Data presented by the company showed that treatment with Photofrin offered results similar to those achieved by laser, without the laser's drawbacks. However, patients treated with Photofrin had a slightly higher rate of life-threatening respiratory insufficiency.

Despite this effect, "in patients with complete obstruction, [Photofrin] is the only feasible palliative approach," said Charles Lightdale, director of clinical gastroenterology at Columbia-Presbyterian Hospital and an investigator in two studies of Photofrin.

ODAC member Richard Gelber, of Dana-Farber Cancer Institute, said he voted against the motion to approve Photofrin because he would have preferred establishing more specific indications for use of the treatment.

—Jan Ziegler

BSC Chairmen Not Advisory, Closed Meetings Ok, NIH Says

Responding to a protest by **The Cancer Letter**, NIH officials reiterated their claim that the chairmen of the NIH Boards of Scientific Counselors who met to discuss the revamping of the intramural program Aug. 1 did not act as an advisory committee.

The Cancer Letter challenged the NIH decision to close the meeting by showing up to cover it (**The Cancer Letter**, Aug. 5), and subsequently filed a protest with HHS Secretary Donna Shalala (**The Cancer Letter**, Aug. 12).

"In the opinion of the [NIH] Office of General Counsel, that meeting did not fall under the requirements of the Federal Advisory Committee Act because the purpose of the meeting was to obtain advice of *individual* attendees and not for the purpose of utilizing the group to obtain consensus advice or recommendations," Anne Thomas, NIH associate director for communications, wrote to **The Cancer Letter**.

Thomas wrote that her letter, dated Sept. 12, constituted a response to a protest by **The Cancer Letter** to Shalala.

Thomas cited the General Services Administration Management Regulations that exempt groups "convened for the purpose of utilizing the advice of individual attendees and not for the purpose of utilizing the group to obtain consensus advice or recommendations."

In an interview last month, Thomas cited the same regulation, 41 CFR, Ch. 101, subpart 101-6.1004.

In a statement, the editors of **The Cancer Letter** said the explanation reiterated by Thomas was unacceptable:

"We view this as an inadequate response to our protest to Secretary Shalala. As a practical matter, it is impossible to distinguish between a meeting in which an agency seeks the opinion of individual attendees and a meeting where an agency seeks the opinion of a group as a whole.

"This rationale, if accepted, would allow NIH to open or close virtually any meeting in an arbitrary and capricious manner. With so much at stake, we have no choice but to continue to pursue this matter vigorously."

NIH officials said the BSC chairmen were expected to meet again in mid-January.

Rebecca Daugherty, an attorney with Reporters Committee for Freedom of the Press, said the Aug. 1 meeting appears to be subject to FACA requirements.

"NIH has brought together people who are major policy makers on advisory boards, and asked them to sit down together in order to get their views," Daugherty said. "They wanted to know how these people as a group felt about these issues.

"The idea that they were not looking for a consensus view is absurd," Daugherty said.

The Federal Advisory Committee Act of 1972 requires that all meetings of advisory committees be held in the open and announced in the Federal Register.

Meetings may be closed for reasons that include national security, personal privacy in matters involving individuals, and confidential business information. Notice must be published even for closed meetings.

The Aug. 1 meeting was not announced in the Federal Register.

Univ. of Pittsburgh Seeks Biostatistician For NSABP

The Pittsburgh Cancer Institute and the Univ. of Pittsburgh Department of Biostatistics have initiated a search for a new director of the biostatistical center of the NSABP.

Until last month, that position was held by Carol Redmond, who, along with the former NSABP leader Bernard Fisher, is facing an inquiry by the HHS Office of Research Integrity.

On Aug. 12, Redmond signed a memorandum of understanding, accepting a job of a faculty statistician at the biostatistical center. Redmond retains her position as chairman of the Department of Biostatistics.

The individual who will be recruited to the top biostatistics post at NSABP is also expected to be appointed as an associate or full professor at the department of biostatistics.

"I view this as a very important and attractive position to assume responsibility for the biostatistics and information systems for the PCI research programs as well as for all of our activities related to multicenter trials," Ronald Herberman, NSABP interim chairman and director of PCI, said to **The Cancer Letter**.

Herberman said that the new biostatistics director is likely to be a part of the PCI bid to conduct multicenter trials through the NCI Community Clinical Oncology Program (**The Cancer Letter**,

Sept. 9). "The person recruited will have the responsibility for that as well as our multicenter trials," Herberman said.

Last month, PCI applied for a research base CCOP grant from NCI. If the application is approved, the CCOP will allow PCI to conduct the same trial activities that can be conducted by cooperative groups.

The NSABP biostatistical center, which has a staff of over 50, is responsible for statistical design, randomization, registration, data collection, processing, quality control and analysis of all NSABP studies.

According to an announcement by Pitt, job requirements include a PhD in biostatistics as well as extensive experience in management and coordination of large multicenter clinical trials.

"Distinguished record of original and collaborative peer reviewed publications and grant support are essential," the announcement said.

According to the university, about 90 percent of support for the NSABP chief biostatistician's position will come from research funding from NCI. The salary will be commensurate with qualifications and rank, the university said.

The curriculum vitae and names of three references should be sent by Nov. 15 to Chair, Search Committee, 318 Parran Hall, Dept. of Biostatistics, Univ. of Pittsburgh, Pittsburgh, PA 15261.

In a related development, a hearing on a motion seeking immediate reinstatement of Fisher as chairman of the cooperative group was delayed by a week to Sept. 26. The parties are reported to be exploring the possibility of a settlement.

Letter to the Editor

New NCAB Chair Seeks Ideas From Scientists And Patients

To the Editors:

Thanks for your coverage of the National Cancer Advisory Board and President's Cancer Panel chair appointments (**The Cancer Letter**, Sept. 16). I also want to emphasize that although the mammography debate is of great relevance and importance to the public health, there are many other urgent issues facing the NCI.

Government personnel, scientists, cancer advocates, patients and others should know that the NCAB is their board. I welcome ideas and opinions about cancer priorities, future directions and concerns, and will share them with the NCAB in summary form.

My E-mail address is: Rimer001@mc.duke.edu. My mailing address is: Barbara K. Rimer, Dr. PH, DUMC, 2200 W. Main St., Ste B150, Durham, NC 27705.

Barbara Rimer
Director, Cancer Prevention and Control Research, Duke Comprehensive Cancer Center

RFPs Available

RFP NIH-ES-94-46
Title: **Studies To Evaluate The Toxic And Carcinogenic Potential Of Selected Chemicals In Laboratory Animals Via Inhalation**
Deadline: Approximately Nov. 3

The purpose of this contract is to evaluate the toxic and carcinogenic potential of selected chemicals of interest. Exposure to these test chemicals is via inhalation. This project includes two year studies of vanadium pentoxide and napthalene, prechronic and two year studies of propylene glycol mono-t-butyl ether, decalin and tetralin. The base contract award shall include work activities associated with the development of generation and monitoring methods, as well as health and safety concerns along with 14-day studies of decalin, propylene glycol mono-t-butyl ether, and tetralin. The Government may, pending the availability of funds, exercise options for: a 14-day study of vanadium pentoxide; a 54-day study of naphthalene; 90-day studies of decalin, propylene glycol mono-t-butyl ether, and tetralin; two year studies of vanadium pentoxide, napthalene, decalin, propylene glycol mono-t-butyl ether, and tetralin; and a special 90-day study of vanadium pentoxide. Award of one cost-reimbursement, completion type contract with an estimated period of performance for the base contract of approximately eight months is contemplated. Exercise of all options under this solicitation could result in a multi-year cost reimbursement type contract with a total term of four years five months.

Inquiries: Marilyn Whaley, Contracts & Procurement Management Branch, OM, NIEHS, 79 T.W. Alexander Dr., 4401 Bldg, PO Box 12874, Research Triangle Park, NC 27709.

RFP NIH-NIAID-DAIDS-95-17
Title: **Small Animal Models Of Lentivirus Infection For Evaluating HIV Therapeutics**
Deadline: Approximately Nov. 30

The Developmental Therapeutics Branch, Basic Research and Development Program, Division of AIDS, NIAID, NIH, has a requirement for the evaluation of antiviral therapies/strategies for HIV-1/AIDS in

established small animal models of lentivirus infection. These capabilities will be used by the Division of AIDS, NIAID, it its effort to develop antiviral therapies/ strategies for human subjects infected with HIV-1. Evaluation encompasses in vitro and in vivo determinations of efficacy and toxicity, and when needed, limited pharmacokinetics for in vivo studies. Further characterization and modification of the proposed animal model, or development of other models may be required. Therapies to be tested, alone and in combination, include antiviral agents (drugs and biologics), gene-based and other novel strategies. Examples of lentivirus models considered at this time to be appropriate for this RFP include HIV-1 in immunocompromised mice constituted with human cells or tissues and feline immunodeficiency virus in cats; nonhuman primate models are excluded from the competition.

This announcement is for the recompetition of several current animal model contracts. It is anticipated that two level-of-effort, cost-reimbursement type contracts will be awarded and that the period of performance for each contract will be four years (estimated start date August 1, 1995).

Inquiries: Bruce E. Anderson, Contract Management Branch, NIAID, Solar Bldg, Room 3C07, 6003 Executive Blvd., Bethesda, MD 20892-7610, Tel: 301/496-8371, FAX: 301/402-0972.

RFP NIH-NIAID-DAIDS-95-19
Title: **In Vitro Test Systems For Evaluating Chemotherapies Against HIV**
Deadline: Approximately Dec. 9

The Developmental Therapeutics Branch, Basic Research and Development Program, Div. of AIDS of the National Institute of Allergy and Infectious Diseases (NIAID), has a requirement for in vitro test systems to evaluate chemotherapies against HIV. The Contractor will be required to do the following with compounds provided by the Government: evaluate potential therapeutic agents in cell-based in vitro assays for anti-HIV efficacy and cytotoxicity; analyze the data generated in antiviral and cytotoxicity assays; and provide an assessment of the experimental data. The RFP contains mandatory qualification criteria that excludes pharmaceutical companies from participating as an offeror or subcontractor.

This announcement is a recompetition for two current contracts (Emory University and IIT Research Institute). It is anticipated that two level-of-effort type cost-reimbursement contracts will be awarded and that the period of performance will be 5 years. The start date of the contract will be on or about July 9, 1995.

Inquiries: Ross Kelley, Contract Management Branch, NIAID, Solar Bldg, Room 3C07, 6003 Executive Blvd, MSC 7610, Bethesda, MD 20892-7610, Tel: 301/402-2234, FAX: 301/402-0972.

RFAs Available

RFA CA-94-030
Title: **Small Grants For Historically Black Colleges And Universities**
Letter of Intent Receipt Date: Oct. 28
Application Receipt Date: Jan. 20

The NCI Cancer Biology Branch, Division of Cancer Biology, Diagnosis, and Centers invites new faculty at Historically Black Colleges and Universities (HBCUs) to apply for small research grants to pursue basic science projects that are relevant to the goals of the NCI. The aim of this RFA is to provide new HBCU faculty with an opportunity to establish a research program to which they will commit time both during the academic year and the summer.

Applications may be submitted by Historically Black Colleges and Universities. The faculty member who serves as Principal Investigator for the project must have had no more than seven years of experience beyond his or her post-doctoral training. Applications from minority and women investigators are especially encouraged. This RFA will use the NIH small grant (R03) mechanism. The total proposed project period for each application submitted may not exceed three years. The total proposed direct costs for each year may not exceed $85,000, up to $35,000 of which may be used for equipment purchases in the first year. The anticipated award date is August 1, 1995. Approximately $1,000,000 in total costs per year will be committed to fund applications. It is anticipated that 8 to 10 awards will be made.

This RFA is designed to provide new faculty at HBCUs with an opportunity to initiate cancer-related research projects, sustain their continued professional growth, and build a research base in institutions that often have less than a critical mass of researchers. These specialized small research grants can support pilot projects that have less preliminary data and a narrower scientific focus than is required for an investigator-initiated research project (R01). In addition to the opportunity to implement a research program, this RFA will enable HBCU faculty to involve students in an on-going research project. The ability to observe and participate in on-going cancer research projects at the undergraduate or graduate level would broaden the educational experience for the students, provide mentoring opportunities for the faculty and possibly attract more minority students into scientific and clinical careers in cancer research.

The areas of basic in vitro and in vivo research supported by the NCI, including biology, chemistry, and other disciplines, are appropriate for this RFA. Collaborations within, or external to, the applicant institution are encouraged whenever they are appropriate to provide resources and expertise that is germane to the research proposed in the application.

Inquiries: Dr. Cheryl L. Marks or Dr. Gladys M. Glenn, Division of Cancer Biology, Diagnosis, and Centers, NCI, 6130 Executive Blvd, Room 505, Bethesda, MD 20892-7385, Tel: 301/496-7028, FAX: 301/402-1037.

RFA CA-94-031

Title: **Specialized Programs Of Research Excellence In Prostate Cancer**

Letter of Intent Receipt Date: Nov. 18

Application Receipt Date: Feb. 21

The NCI Organ Systems Coordinating Branch of the Division of Cancer Biology, Diagnosis and Centers invites grant applications for Specialized Programs of Research Excellence (SPORE) in Prostate Cancer. The intent of this initiative is to expand the Prostate Cancer SPOREs from the current two SPOREs to a minimum of three SPOREs through open recompetition by making awards to those institutions that are judged to be able to conduct the highest quality balanced translational research approaches on the prevention, etiology, screening, diagnosis, and treatment of prostate cancer.

Because basic research in prostate cancer has lagged that of the other major solid tumors, greater leeway is given for basic research studies on prostate cancer. However, such studies must have translational potential or significance. SPOREs are at institutions that have made or will make a strong institutional commitment to the organization and conduct of these programs. SPORE applicants will be judged on their current and potential ability to translate basic research findings into innovative research settings involving patients and populations. Each SPORE is encouraged to conduct rehabilitation and quality-of-life research. Each SPORE must provide career development opportunities for new and established investigators who wish to pursue active research careers in translational prostate cancer research; develop and maintain human prostate cancer tissue resources that will benefit translational research; develop extended collaborations in critical areas of research need with laboratory scientists and clinical scientists within the institution and in other institutions; and participate with other SPORES on a regular basis to share positive and negative information, assess scientific progress in the field, identify new research opportunities, and promote inter-SPORE collaborations to resolve areas of scientific controversy.

Each SPORE and the "network" of SPOREs is expected to conduct research that will have the most immediate impact possible on reducing the incidence of and the mortality due to human prostate cancer.

To be eligible, applicant organizations must have 1) a minimum of three independent investigators who are successful in obtaining peer-reviewed research support directly related to prostate cancer, and who together represent experience in both laboratory and clinical research, or alternatively, a minimum of three independent investigators, each having published articles in peer-reviewed research journals that significantly address prostate cancer, and who as a group represent experience in both laboratory and clinical research; 2) access to a patient care and service facility that serves prostate cancer patients and, if the facility is not part of the parent institution, a statement that assures access to prostate cancer patients for clinical research; the statement must be signed by the responsible officials of the applicant institution and the consortial care facility; 3) while applications must be submitted from a single institution, they may include subcontracted collaborative scientific arrangements with scientists from other institutions as long as these arrangements are clearly delineated, and formally and officially confirmed by signed statements from the responsible officials of each institution. However, a full institutional commitment must come from the parent institution receiving the award.

Support of this program will be through the P50 Specialized Center Grant mechanism. The total project period for a competing P50 renewal SPORE application may not exceed five years; new applicants or applicants that have received P20 SPORE feasibility awards in the past may request up to three years of support. Each new or competing renewal P50 SPORE application may request a maximum annual direct cost of $1.5 million and maximum annual total cost of $2.5 million. The earliest anticipated award date is Dec. 1, 1995.

NCI anticipates making at least three awards and anticipates setting aside $2.5 million per award or $7.5 million total for the initial year's funding.

The goal of this RFA is to expand the current Prostate Cancer SPORE program with the addition of at least one new SPORE. Each SPORE assembles critical masses of laboratory and clinical scientists to work together on human prostate cancer and to focus on innovative translation of basic findings into research settings involving patients and populations. The ultimate objective is to reduce incidence and mortality, and to increase and improve survival to the disease. The essential characteristics of a SPORE include (1) a strong scientific program which will have a clear impact on the human disease, (2) a strong innovative developmental or pilot research program which can respond quickly to new research opportunities, (3) a strong career development program to develop and expand the scientific cadre of investigators dedicated to translational research on human prostate cancer, (4) a human prostate cancer tissue procurement resource, an animal model resource, and other resources specifically dedicated to translational research objectives, and (5) a willingness and commitment to work with other SPOREs.

Inquiries: Andrew Chiarodo, DCBDC, NCI, Executive Plaza North Suite 512, 6130 Executive Blvd MSC 7386, Bethesda, MD 20852-7386, Tel: 301/496-8528.