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# Educational Strategies On Mammography, Not Guidelines, To Come From NCAB

The National Cancer Advisory Board said it would not issue guidelines or take a position on the value of screening mammography for women in their 40s.

Instead, the NCAB plans to recommend strategies for educating women about the benefits and drawbacks of the test.

"We will not be able to say the exact age at which a woman should start mammography," NCAB Chairman Barbara Rimer said after the board's meeting Feb. 25. "We will not be able to say how often a woman

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*In Brief*

## Voters Support Increase In Research Funds, Poll Finds; Baynes Heads BMT Unit In Detroit

**NATIONAL SPENDING** on medical research should be doubled by the year 2002, according to public opinion polls conducted in three states by Research!America, a nonprofit alliance of universities, private industry, and voluntary health organizations. The results of the poll, conducted in Louisianna, Ohio and Wisconsin "strongly support" legislation introduced by **Sen. Connie Mack** (R-FL), which calls for doubling the budget of NIH, as well as legislation introduced by **Sen. Phil Gramm** (R-TX), which seeks to double federal spending in basic science and medical research. Research!America, based in Alexandria, VA, said the results were based on telephone survey of 1,000 adults in each of the three states. . . . **ROY BAYNES** was named director of a new bone marrow transplantation program at the Barbara Ann Karmanos Cancer Institute in Detroit. Baynes, formerly of the University of Kansas Medical Center, also will lead the institute's stem cell and transplantation biology program and hematologic malignancies multispecialty practice. He was appointed professor at the Wayne State University School of Medicine. The new BMT unit, located in the Detroit Medical Center's Harper Hospital, is scheduled to open March 5. The $4 million, 13,000 square feet facility contains 19 inpatient beds, a data processing center, and eight apheresis and stem cell collection stations. . . . **JOHN BENNETT**, professor of oncology at the University of Rochester Cancer Center, Rochester, NY, was elected chairman of the Myelodysplastic Syndromes Foundation for a five-year term. The new foundation was formed to promote prevention, treatment and study of MDS, a group fo hematologic bone marrow diseases that can progress to acute myeloid

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## Working Group To Advise NCI On Educational Materials

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should get mammograms." Research studies have not answered those questions, she said.

The board formed an eight-member working group to advise NCI on the development of educational materials on screening mammography for women in their 40s.

Also, the working group will consider whether a data monitoring committee should be put in place to review results from international trials of screening mammography and alert NCI when findings have changed.

The board asked the working group to make its recommendations in time for the board's next meeting, scheduled for June 16-18.

**Rimer To NCAB: "Think About The Data"**

The board acted following a two-hour discussion of data from eight randomized trials of screening mammography that had been presented last month to an NIH Consensus Development Conference.

The consensus report from that conference, issued by an independent panel of advisors to NIH, was heavily criticized by oncology and radiology organizations—as well as several members of Congress—for not recommending routine screening mammography for all women in their 40s (**The Cancer Letter**, Jan. 31).

The final report of the consensus conference was expected to be released next week, sources said.

It was not the board's role to "vote for, vote against, repudiate or throw out the draft panel report," Rimer said. "The panel report stands on its own. Our focus needs to be on the next steps."

Rimer asked the board to "think about the data" and consider the message NCI should send to health care providers and women about mammography.

"Today is not going to be the end of this discussion," Rimer said. "In some ways it is just the beginning."

Women tend to overestimate both the risk of developing breast cancer and the capabilities of mammography, said Rimer, director of cancer prevention, detection and control research at Duke University Medical Center.

Since 1993, when NCI retracted its recommendation for screening mammography for women aged 40-49, Rimer said she and her colleagues at Duke have been studying women's information needs on breast cancer.

Some of the research involves providing each woman a with an individualized estimate of breast cancer risk using a which weighs such risk factors as age at menarche, age at first live birth, and family history of the disease, Rimer said. The model was developed by NCI scientist Mitchell Gail.

Women and their health care providers need a "tool kit" of information products to help them in making an informed decision, Rimer said.

An educational approach might be more accepted by health care providers and women than a guideline, Rimer said.

"I believe very strongly from what I've heard in the last few weeks that there is a great deal more agreement than we had previously recognized in this field," Rimer said.

**Role of NCAB Questioned**

Some NCAB members as well as members of the President's Cancer Panel questioned whether the board has a legitimate role in the latest controversy over screening mammography.

NCAB member Zora Brown, president of Cancer Awareness Program Services, in Washington, DC, said some women do not seek treatment even after a positive finding on a mammogram. The board should

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place greater attention on access to treatment, she said.

"I think the focus on mammography has been blown beyond what it would accomplish for us," Brown said. "I am troubled that we are focused so much on whether mammography is going to reduce mortality and not going beyond what we do as a result of finding a cancer."

Fran Visco, president of the National Breast Cancer Coalition and a member of the President's Cancer Panel, agreed. "I think we have blown this debate all out of proportion," Visco said. "We should focus on the women over 50 who don't get mammograms and, primarily, on getting treatment for those who are diagnosed with breast cancer.

"If we are really concerned with saving women's lives, the debate should be around making certain that all women and their families have access to health care," Visco said.

Harold Freeman, chairman of the President's Cancer Panel, asked why the board was involved in the mammography issue. "Usually in the past, consensus panel decisions were accepted," Freeman said. "Why is this one different?"

"A consensus panel report is a statement about the scientific evidence," Rimer said. "It does not say how to communicate that evidence. It doesn't say what the next steps are in research. We need now to say what NCI can do."

Rimer said the board has the responsibility to provide advice when asked. "Treatment of breast cancer is obviously a very important part of what NCI does, but we were asked to provide advice both to the director of NCI and the secretary of HHS on this particular issue of what are the next steps in communicating the message of mammography to women in their 40s," she said.

NCI Director Richard Klausner said the NCAB had agreed last summer to discuss mammography following the consensus conference.

"It's not that I asked for this discussion," Klausner said. "This was not set up in order to reanalyze the consensus conference.

"We had agreed that this board wanted to discuss mammography and the time to begin that was after the consensus conference," Klausner said.

Consensus conference provide a "stage" for public discussion, but are not a final step, NIH Director Harold Varmus said to the board. "Rick's responsibility here is to ask the board for advice about what the NCI should do next," he said.

**Evidence Of Benefit Is "Weak"**

Data on the benefit of screening mammography for women in their 40s are uncertain, said Donald Berry, professor of statistics at Duke University and a member of the consensus panel.

Combined data from eight randomized trials demonstrate a 17 percent reduction in mortality for women who begin screening in their 40s, Berry said to the board.

The confidence interval for this benefit is about zero percent to 30 percent, using an analysis that adjusts for the wide variations in the studies, Berry said. This figure is statistically significant, Berry said.

"This is a figure you can hang your hat on; however, it is a wide hat," Berry said, in reference to the wide confidence interval.

Using his analysis, Berry said there is an 80 percent probability that women in their 40s would experience a 17 percent reduction in breast cancer mortality from regular screening mammography.

In other words, if 10,000 women were screened, four could possibly have a longer life.

"We don't know whether that means 'lives saved,'" Berry said.

Berry calculated that between 2,000 to 5,000 days of life would be added for every 1,000 women in their 40s screened.

Risks of mammography for women in their 40s include finding cancers earlier than may be necessary, and false positive findings in about 30 percent of those screened.

The risk of radiation-induced cancers, false negative findings, and false reassurance to women, were "non-issues," Berry said. In this, he differed from the view of the consensus report, he said.

"If these are negatives, they are reflected in the data," Berry said.

Similarly, the question of whether mammographic detection of ductal carcinoma in situ (DCIS) is a benefit or a risk also is reflected in the mortality reduction, Berry said.

Because the evidence of benefit is "weak" and the reduction is small, "mammography is not an imperative health measure for women in their 40s," Berry said.

Most of the new data from randomized trials that had been presented to the consensus panel had not

been peer reviewed, Berry said. Only the new data from the screening trial by the Health Insurance Plan of New York was peer reviewed, he said.

Berry said he asked principal investigators of the trials for the raw data tapes, but never received any. He said some data came to him through e-mail messages.

"To establish national policy by way of e-mail is not ideal," Berry said. "[The panel] should get the actual raw data."

**Minorities And Screening: Little Data**

Otis Brawley, director of the NCI Office of Special Populations, said little data exist on screening mammography in minorities. Only 2 percent of the participants in the European and Canadian studies were non-white.

In the HIP study, 18 percent of the participants were black. However, there seemed to be no difference in outcome between black and white women, Brawley said to the board.

Though there is no data, some screening experts "suspect" that screening is less effective in younger black women because of the greater incidence of high-grade disease in that population, Brawley said.

Brawley said his office will host a meeting next month on screening in minority populations to seek expert recommendations on future research directions.

While the breast cancer mortality rate has fallen in whites, the rate continues to increase in blacks, driven primarily by deaths of black women over age 50, Brawley said.

"As we have this discussion, we should not let it overshadow the fact that 50 percent of women aged 50 to 70 do not get mammograms," Brawley said to the board. If all women in that age group got mammograms, "we could save 10 times the number of lives" that would be saved by screening women in their 40s, he said.

**Members of NCAB Working Group**

Frederick Li, chief of cancer epidemiology and control at Dana-Farber Cancer Institute, and Robert Day, president and director of Fred Hutchinson Cancer Research Center, were named co-chairmen of the NCAB working group.

Other members include Rimer; J. Michael Bishop, director, The George Williams Hooper Research Foundation, University of California, San Francisco; Kay Dickersin, associate professor, University of Maryland School of Medicine; Barbara Gimbel, member of the Society of Memorial Sloan-Kettering Cancer Center; Sandra Millon-Underwood, associate professor, University of Wisconsin-Milwaukee; Ellen Stovall, executive director, National Coalition for Cancer Survivorship.

*Patient Advocacy*

## Committee To Advise NCI On Consumer Liaison Group

NCI has formed a planning group of cancer patient advocates and Institute staff to advise the Institute on the formation of a consumer liaison group.

The purpose of the planning group, which is temporary, is to help NCI define the role of the Director's Consumer Liaison Group, define the membership process of the group, and define the criteria, categories and rating system to identify and rank potential members of the new group, the Institute said (**The Cancer Letter**, Feb. 7).

The planning group is scheduled to meet March 13-14, in Bethesda. The first meeting of the DCLG is scheduled for June 23-24, at NCI.

Members of the planning group are:

Consumer-advocates: Kathryn Adams, Cure for Lymphoma Foundation; Diane Blum, executive director, Cancer Care Inc.; Elizabeth Clark, president, National Coalition for Cancer Survivorship; Jane Reese-Coulbourne, executive director, National Breast Cancer Coalition; Sharon Green, executive director, Y-Me National Breast Cancer Organization; Elmer Huerta, member, Intercultural Cancer Council; Karen Jackson, national president, Sisters Network; Peggy McCarthy, project manager, Alliance for Lung Cancer Advocacy, Support and Education; Susan Weiner, advocacy vice-chair, North American Brain Tumor Coalition; and James Williams Jr., board member, US-TOO International Inc.

NCI staff: Leslie Ford, associate director, Div. of Cancer Prevention and Control, Early Detection Clinical Oncology Program; Ruthann Giusti, special assistant, Div. of Cancer Epidemiology and Genetics; Brian Kimes, associate director, Centers, Training and Resources Program; Mary McCabe, special assistant, Div. of Cancer Treatment,

Diagnosis and Centers; Eleanor Nealon, director, Office of Liaison Activities; Susan Sieber, deputy director, Div. of Cancer Epidemiology and Genetics; Chris Thomsen, acting chief, Cancer Information Service Branch, Office of Cancer Communications.

## NCI Publishes New Edition Of Cancer Statistics Reference

NCI has released the latest edition of "Cancer Rates and Risks," a 205-page reference book with cancer statistics and brief chapters by NCI experts on known cancer risk factors.

The first section of the book, Rates, uses tables to show cancer incidence, mortality, and survival rates. It uses charts to show how these rates have changed over time. Also included are internationals cancer statistics so readers can compare U.S. rates to those of other countries.

The second section, Risks, is a collection of chapters by NCI experts on environmental and genetic risk factors. Some chapters discuss which cancers are associated with a specific risk factor. Other chapters discuss which known risk factors are associated with a specific cancer site. Every chapter includes a comprehensive bibliography that readers can use as a starting point to learn more about each of the topics covered.

"Cancer Rates and Risks" is written in lay language for science writers, public health officials, and the interested public. The latest edition is about twice the size of the previous edition and synthesizes much of what scientists have learned during the past 10 years about cancer risks, the Institute said.

The book also could be useful to scientists who want to communicate information about cancer risk factors to the general public.

Single free copies of this publication are available through NCI's Cancer Information Service, tel: 1-800-4-CANCER.

## Komen Foundation Seeks Nominations For Reviewers

The Susan G. Komen Foundation is seeking nominations for reviewers to read grant applications submitted for various funding programs.

Nominations will be considered based on qualification and area of expertise and chosen according to the need in each funding program. Invitation to become a member of a review board will be issued by the foundation. Review members serve for a one-year term.

Komen Foundation reviews for national grants are facilitated through the national foundation headquarters; no meetings or travel are required. Review committee lists are not publicly available until the review is complete. Reviews are conducted with strict conflict of interest and confidentiality. Basic, clinical and translational research will be a blind review. Applications are held to a strict page count, specific to each program, not exceeding a five-page summary in any program. Reviewer comments are not required.

Nominations should be sent via fax or mail by March 15 to the foundation: 5005 LBJ Suite 370, Dallas, TX 75244, fax: 972-385-5005; tel: 972-385-5000.

*Funding Opportunities*

## RFPs Available

**N02-CB-77032-08**

Title: **Technical And Scientific Support And Management**

Deadline: Approximately April 14

One five-year incrementally funded contract is expected to be awarded in order to assist the Radiation Effects Branch, Division of Cancer Biology, NCI. The Radiation Effects Branch is seeking scientific, medical and technical support services for its international collaborative program on evaluation of the radiation-induced effects resulting from the accident at the Chernobyl Nuclear Power Plant on thyroid diseases, especially thyroid cancer, among children exposed to radioactive fallout in Belarus and Ukraine and on leukemia and other hematologic diseases among Ukrainian liquidators (also known as the clean-up workers) who worked at the plant at the time of the accident or performed cleanup work within five years thereafter. NCI is seeking scientific, medical, technical and logistical services in support of NCI staff in their project management tasks, and in their interaction and collaboration with Belorussian and Ukrainian colleagues in implementing three bilateral research protocols covering epidemiological, clinical and radiation dose reconstruction studies in Belarus and Ukraine on radiation-induced thyroid cancer and leukemia, including assessment of the risk for these diseases as a function of radiation dose, sex and age at the time of the accident.

This effort will include the estimation of a large

number of individual thyroid and bone marrow doses by means of physical and biodosimetric techniques. The primary effort will focus on the identification of American scientists and physicians who will constitute working teams in collaboration with the NCI to work with Belorussian and Ukrainian investigators. It is expected that with few exceptions the professional personnel constituting these teams will have had previous experience in working together on similar projects. Areas of demonstrated expertise must include the following: radiation epidemiology of cancer, ultrasonography as applied to detection of radiation-induced thyroid tumors, diagnosis of (and changes in morphology and function due to) radiation-induced thyroid disease, diagnosis and etiology of radiation-induced leukemia/lymphoma and other hematologic diseases, radiation pathology, statistical analysis and quality control of data, specific clinical assays, radiation dosimetry and dose reconstruction, risk analysis, etc. Special attention will be given to quality control measures for all procedures and findings. An additional secondary effort is expected to provide logistical support for various scientific meetings, for the coordination of travel arrangements related to or resulting from the above activities, and for possible limited training of foreign personnel within the U.S. It is anticipated that this project will require approximately 7 to 8 FTEs per year during the proposed 5-year contract period. Special skills will require 1) familiarity with radioecological, radiobiological and relevant biomedical terminology, 2) prior involvement in large international multi-center, multi-disciplinary epidemiological studies, and 3) sensitivity to foreign cultural, socio-economic and political factors, and working environments.

Inquiries: Todd Cole, Contract Specialist, NCI, Research Contracts Branch, TCS, 6120 Executive Blvd Rm 603-MSC 7220, Bethesda, MD 20892-7220, tel: 301/435-3822, fax: 301/402-6699.

**RFP NCI-CM-87011-75**
Title: **Assistance to the Developmental Therapeutics Program**
Deadline: May 30

The Developmental Therapeutics Program of the NCI Division of Cancer Treatment, Diagnosis and Centers is seeking an organization to provide assistance in specific areas of its extramural program, with particular emphasis on the functions of the network of action/decision point committees which guide the progression of potentially useful anticancer and anti-AIDS agents through the entire preclinical drug discovery and development process. These activities extend from the acquisition and input of new natural and synthetic materials into the system through the initial and secondary evaluations and subsequent preclinical development phases leading to approval for Phase I clinical trials. The scientific disciplines involved included chemistry, biology, pharmacology, toxicology and the pharmaceutical sciences, and technical expertise in the management of computerized databases. The contractor will have access to proprietary information on compounds acquired by the NCI and the contractor shall be required to treat all information obtained under this contract as strictly confidential.

The Government will provide the contractor with guidelines governing this requirement. Office space for staff and files provided by the contractor shall be within one hour travel time by private automobile from the DTP offices in order to be readily accessible on demand within a working day. It is anticipated that a single level of effort award will be made for a five-year period of performance with incremental funding each year. Offerors will be invited to submit proposals for 6,420 direct labor hours per year. The Standard Industrial Classification Code is 8731. This is a recompetition of a contract performed by NOVA Research Co.

Inquiries: Bernice Evans Belt, NCI, RCB, TCS, 6120 Executive Blvd Rm 603-MSC 7220, Bethesda, MD 20892-7220, tel: 301-496-8620, email: beltb@rcb.nci.nih.gov.

*In Brief*

## Hynes, Ruoslahti, Knudson Receive Gairdner Awards

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leukemia. The foundation is based in Crosswicks, NJ, with a statistical office at University of Rochester, headed by statistician **Christopher Cox**. . . . **THREE CANCER RESEARCHERS** were regonized by the Gairdner Foundation, of Willowdale, Ontario, Canada. They are **Richard Hynes**, professor of biology at the Massachusetts Institute of Technology; **Erkki Ruoslahti**, presdient and CEO of the Burnham Institute, in La Jolla, CA; and **Alfred Knudson**, distinguished scientist at Fox Chase Cancer Center, in Philadelphia. Hynes and Ruoslahti were honored for their discovery and characterization of the molecular basis of the interaction of cells and the surrounding extracellular matrix. Knudson was recognized for his statistical analysis of retinoblastoma. . . . **NIH CONSENSUS PANEL** report on cervical cancer from a conference last year, has been printed and is available from the NIH Office of Medical Applications of Research. For free single copies, contact NIH Consensus Program Information Service, PO Box 2577, Kensington, MD 20891, tel: 888/644-2667. . . .

**GRANT CHECKS** totalling $1.2 million were donated to more than a dozen Washington, DC, hospitals and research centers by the National Race for the Cure at a ceremony Feb. 26 in Washington. The 1996 race drew 31,400 runners and walkers, making it the largest 5K race in the US. This year's race is scheduled for June 7 and is expected to raise more than $1 million. The race was established by the Susan G. Komen Breast Cancer Foundation.

## NAS To Honor Outstanding Scientists At Annual Meeting

The National Academy of Sciences has selected several individuals to receive awards honoring their outstanding contributions to science.

The awards will be presented on April 28 at a ceremony in Washington, DC, during the Academy's 134th annual meeting.

Following are awards in biomedical research and recipients:

The NAS Award in Chemical Sciences—**M. Frederick Hawthorne**, professor of chemistry, department of chemistry and biochemistry, University of California, Los Angeles.

The NAS Award for Chemistry in Service to Society—**Ernest Eliel**, professor of chemistry emeritus, department of chemistry, University of North Carolina at Chapel Hill.

The Richard Lounsbery Award—**James Rothman**, chair, program in cellular biochemistry and biophysics, Memorial Sloan-Kettering Cancer Center.

The NAS Award in Molecular Biology—**Richard Scheller**, investigator, Howard Hughes Medical Institute, and professor, department of molecular and cellular physiology, Stanford University School of Medicine, and **Thomas Sudhof**, investigator, Howard Hughes Medical Institute, and Gil Distinguished Chair in Neurosciences Research, department of molecular genetics, University of Texas Southwestern Medical Center.

The Troland Research Awards—**Richard Ivry**, associate professor, department of psychology, University of California, Berkeley, and **Keith Kluender**, associate professor, department of psychology, University of Wisconsin, Madison.

The Selman A. Waksman Award in Microbiology—**Carl Woese**, professor of microbiology, department of microbiology, University of Illinois at Urbana-Champaign.

George Thorn also will be honored at the April 28 ceremony. Thorn is Samuel A. Levine Professor of Medicine, Emeritus, and Hersey Professor of the Theory and Practice of Physic, Emeritus, Harvard Medical School, Howard Hughes Medical Institute, Boston, and was chosen to receive the 1997 Public Welfare Medal, the Academy's highest honor.

The Academy recognized Thorn "for his establishment, guidance, and administration of the Howard Hughes Medical Institute, a major force for the welfare both of scientists and students." This award was established in 1914 to honor "distinguished contributions in the application of science to the public welfare."

## NCI Seeks Applications For Small Business Research

Title: **Development Of Novel Technologies To Support Cancer Research**

Annual Receipt Dates: April 1, Aug. 1 and Dec. 1 for STTR; April 15, Aug. 15, and Dec. 15 for SBIR

The purpose of this notice is to emphasize the importance of this research topic, development of novel technologies to support cancer research, to the Technology Development Branch of the Cancer Diagnosis Program, Division of Cancer Treatment, Diagnosis and Centers, NCI. This notice is intended to encourage projects that propose development of technologies in two areas: the generation of representational full length cDNA libraries and the development of high throughput technologies for analysis of the spectrum of molecular alterations in primary tumor tissues. Investigators may propose projects to develop and/or to implement one of these technologies. Ultimately the technologies or resources developed with the technologies must be commercially viable and preferably useful within a clinical setting.

Through the Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) mechanisms, small businesses can receive funding for early phase development of innovative technologies and proof of principle studies leading toward commercialization of these technologies.

The solicitations are available electronically through the NIH, Office of Extramural Research "Small Business Funding Opportunities" home page located at http://www.nih.gov/grants/funding/sbir.htm. In addition, a limited number of hard copies of the solicitations have been produced. Subject to availability, they may be

obtained from the PHS STTR/SBIR Solicitation Office, phone (301) 206-9385; fax (301) 206-9722; email: a2y@cu.nih.gov.

Research objectives: The rapid increase in our understanding of tumor biology coupled with the technology and data emerging from the human genome project, offer the opportunity for a change in the way cancer research is done. It is becoming clear that cancer is not a single disease but many, and that cancers arise from the gradual accumulation of genetic changes in single cells. It is not clear which changes and how many changes are required to cause a cancerous state. Technologies that make possible the evaluation of multiple alterations in tumor tissue at the level of DNA, RNA or protein will facilitate the identification of genes involved in cancer and will provide diagnostic and prognostic information useful for cancer patient management. This notice is intended to encourage technology development projects in the following two categories: representational, full length cDNA libraries and high throughput technologies for analysis of the spectrum of molecular alterations in primary tumor tissues.

Representational, Full-Length cDNA Libraries: Current technology for generating cDNA libraries allows the production of representative libraries of partial genes or production of more limited libraries of full length clones, which are generally enriched for shorter genes. In addition, technology exists to create normalized (reduced redundancy) cDNA libraries. However, it is not currently possible to efficiently generate representational libraries of full length cDNAs. In order to derive the maximum benefit from existing libraries and to find expressed genes not present in existing libraries, new technologies for generating full length representational cDNA libraries are necessary.

Investigators may propose to develop the novel technologies for generating these libraries or, if they have existing, proven technologies for this purpose, they may propose to generate appropriate libraries using their existing technology. Approaches for demonstrating that the clones in the libraries encode the entire sequence of the mRNA from which they were derived and contain a representative sample of the original mRNA population of the selected tissue must be described. Investigators may also propose to develop technologies for generating libraries which are enriched for genes differentially expressed from appropriate tissues. Appropriate tissues are those which will provide information about gene expression during cancer initiation and/or progression. In all cases, the end result must be a technique or a resource which can be made into a commercially viable product. For example, applicants applying through the STTR mechanism may propose to move technology previously developed at an academic institution to a small business for the purpose of producing specific libraries. Applicants applying through the SBIR mechanism may propose, for example, to develop novel technologies for the construction of the cDNA libraries and to commercialize either the methodology or the resulting libraries. The most desirable technologies will be those which are adaptable to high-throughput systems.

High-Throughput Analysis of Tissue Samples: Previous studies designed to correlate molecular alterations in tumors with clinical parameters have suggested the potential importance of measuring these changes as a part of clinical decision-making. The sequencing of the human genome and ongoing development of technologies to analyze genetic alterations on a genome-wide scale may soon make it feasible to simultaneously evaluate all or a subset of the nucleic acid alterations in tumor tissue. Similar technologies to detect patterns of protein expression or to detect changes in proteins functioning in pathways of cellular regulation are also needed. The continuing development of both nucleic acid and protein based technologies will facilitate the discovery of new alterations in tumor cells and, ultimately, the rapid collection of diagnostic and prognostic information that may be useful in cancer patient management.

Investigators should propose development of nucleic acid or protein based technologies and studies to assess their use in analysis of primary tumor specimens. They may propose to develop a high-throughput technology to characterize cancers at the molecular level, to modify existing technologies for use in a clinical setting, or to commercialize technologies that currently exist only in a laboratory setting. For example, applicants applying through he SBIR mechanism might develop a high-throughput technology then collaborate with an academic institution to procure appropriate tissue samples for validation of their technology on clinical specimens. Applicants applying through the STTR mechanism might propose to move technologies developed in an academic setting for the high-throughput screening of tissue samples into the development of commercial kits or devices. Technologies may be designed to analyze a variety of alterations including genome-wide cytogenetic changes; mutations in constellations of genes known to be important in tumor initiation and progression, including genes that are members of pathways of cellular regulation; analysis of all possible mutations in a single gene; changes in patterns of gene expression at the level of both RNA and protein; or changes in protein function. Development of sample preparation technologies and/or informatics systems to support collection and evaluation of research data may also be proposed.

Inquiries: Jennifer Couch, DCTDC, NCI, 6130 Executive Blvd Rm 513-MSC 7388, Bethesda, MD 20892-7388, tel: 301/496-1591, fax: 301/402-1037, email: couchj@dcbdcep.nci.nih.gov