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Cancer Centers Program To Implement Most Changes Sought By Review Group

The NCI Cancer Centers Program will implement most of the revisions to the review and requirements for the Cancer Center Support Grant proposed by an advisory committee, an Institute official said.

The proposed changes include the more rigorous review of the CCSG, more flexibility in the use of grant funds, decreased paperwork for centers reapplying for the grants, and no unfunded mandates, Robert Wittes, director of the Division of Cancer Treatment, Diagnosis and Centers, said to the NCI Board of Scientific Advisors recently.

The Cancer Centers Program Review Group, after studying the

(Continued to page 2)

In Brief

Smyth Moves From AOR To Bristol-Myers; Lurie Center Wins Grants From Army, NCI

A. COLLIER SMYTH was named vice president for medical affairs at the Oncology and Immunology Division of Bristol-Myers Squibb Co. of Princeton, NJ, the company said. Smyth is the former vice president for medical affairs at American Oncology Resources Inc., a Houston-based physician practice management firm. . . . **LURIE CANCER CENTER** of Northwestern University received a four-year, $4.27 million grant from the U.S. Army Medical Research and Materiel Command for a project titled "Increasing Access to Modern Multidisciplinary Breast Cancer Care." Principal investigator is **Monica Morrow**, director of the center's Clinical Breast Cancer Research Program. The award provides for eight research projects on access to breast cancer care by minority women, education, dietary intervention, minority participation in clinical trials, and cost-effectiveness of new technologies. Center Director **Steven Rosen** also announced that NCI awarded the center four-year competitive renewal of its Cancer Center Support Grant, for $1.47 million per year... **UNION INTERNATIONALE** Contre le Cancer (UICC) has elected officers for 1998-2002. The new officers and their countries are: President-elect, **M. Robinson** (Israel); secretary general-elect, **G.P. Murphy** (USA); treasurer-elect, **L. Denis** (Belgium); chairman of finance committee-elect, **J. Baity** (USA). **Max Burger** (Switzerland) will chair the Governing Board of the International Cancer Foundation. For information on UICC, visit the Web site at http://www.uicc.ch, or send

(Continued to page 8)

NCI Proposes A Ratio Cap On Cancer Centers Grant

(Continued from page 1)
program for nine months, sent its report to NCI officials and advisory groups in October (**The Cancer Letter**, Oct. 18).

"Philosophically, we agree with the content of this report," Wittes said to the BSA at its Nov. 21 meeting. "I am convinced personally that what these institutions need at this particular time above all is flexibility. I was convinced of this before the review.

"This review basically confirms this, and points the way toward particular areas in which flexibility is needed," Wittes said.

The Cancer Centers Program has an annual budget of $147 million and funds 55 Cancer Center Support Grants. The program also administers the Specialized Programs of Research Excellence grants, which has an annual budget of $20 million.

Joseph Simone, executive director of the Huntsman Cancer Care Program at the University of Utah, was chairman of the review group.

NCI Proposes 20% Cap

After receiving a storm of protest from smaller cancer centers, NCI will not implement the report's recommendation for a $500,000 cap on the amount the CCSG can increase upon renewal, Wittes said to the BSA.

"What they didn't like was that if you do the numbers, it would take you a pretty long time to go from a small program to a large program," Wittes said. "They didn't like the idea of waiting from 15 to 30 years to go from small to large."

Instead, Wittes proposed a cap on the size of the total award request of 20 percent of the sum of the NCI research funding base to the institution as a whole and NIH (non-NCI) research funding to investigators that are integral members of the cancer center.

"We are not wedded to this," Wittes said. "Someone will have to make the determination of what is cancer-related and who are integral members of the center."

In the early 1990s, the centers program studied and eventually recommended placing a cap on renewal increases of an amount equal to 20 percent of a center's NCI research funding. The recommendation was endorsed in 1992 by the National Cancer Advisory Board, but never formally adopted by NCI.

However, NCI's instructions to the CCSG peer review committee suggest the use of a 20 percent ratio as a "trigger point" for examining a center's budget (**The Cancer Letter**, March 22).

Phase-Out Funding

Other funding issues in which NCI proposes different solutions than the review group's report:

●Report recommendations: For centers ranked lowest in each review cycle, funding should be phased out over three years, with a center receiving 80 percent of the grant the first year, 60 percent the second, and 40 percent the third year. For centers that receive priority scores above the payline, use a sliding scale for funding.

NCI proposal: Establish a payline for center grants each year. For competing applications falling below the payline, phase out would take place over one to two years. New grant applications falling below the payline would not be funded. Institutions being phased out could reapply as soon as deficiencies noted in peer review have been corrected.

For competing applications falling above the payline, use a sliding scale based on priority score to determine the level of funding as a percent of peer review recommended levels.

No cap on the increase that can be requested in

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Editors: **Kirsten Boyd Goldberg, Paul Goldberg**
Founder: **Jerry D. Boyd**

P.O. Box 9905, Washington, D.C. 20016
Tel. (202) 362-1809 Fax: (202) 362-1681
Editorial e-mail: kirsten@www.cancerletter.com
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recompeting applications, so long as the total request does not exceed the cap on the size of the total award (the 20 percent ratio).

Review Issues, Funds for Training

Other issues on which NCI and the report differ, according to Wittes:

● Report recommendation: All grants of a particular type (comprehensive versus non-comprehensive) should be reviewed at a single meeting. There would be two committee meetings per year.

NCI proposal: Stay with three review cycles per year due to difficult review logistics and loss of flexibility for providing short grant extensions.

● Report recommendation: Center should be able to use developmental funds for interim support for training in special situations.

NCI proposal: It is not clear whether P30 grants permit support for training, there are conflicts with other grant mechanisms, and this would be difficult to review. NCI proposes the use of developmental funds from the "pilot project" category for support of junior researchers working in special situations involving new research initiatives.

● Report recommendation: Centers should be designated as "cancer research centers" or "comprehensive cancer research centers" to more accurately describe the activities supported by NCI.

NCI proposal: Leave out "research" because it may be a "red flag" in the present health care environment.

At its recent meeting, the NCAB supported the recommendation for putting the word "research" in the designation.

Recommendations To Implement

Wittes said NCI will implement the following recommendations of the committee:

—Two types of cancer centers.

—No separate review of comprehensiveness.

—Inclusion of significant clinical and population-based efforts, where they exist.

—More precise definition of criteria for cancer control research.

—No unfunded mandates.

—Concentration in review on quality of science and value added.

—Increased flexibility for the center director in allocating funds among categories.

—Elimination of excessive record-keeping for the CCSG application.

—Firm separation of program and review at NCI.

—Selection of excellent investigators as peer reviewers.

—Up to 25 percent of budget for developmental funds.

—Retention of the staff investigator category.

—Funding for SPOREs should not compete directly with funding for CCSG.

—Phase out present use of planning grants; if continue, use more rigorous criteria and review.

—Development of robust informatics program.

—Development of separate funding mechanisms outside the CCSG for support of non-research service functions.

"Best People" Needed For Peer Review

The increased flexibility sought by the report will require that peer review be conducted by the "best people in the country," Wittes said to the BSA.

"If we are going to construct this program in a manner that increases flexibility, then the fineness and sophistication in judgment that reviewers are going to be called upon to exercise is correspondingly greater," Wittes said. "We are going to need the help of everybody connected with our advisory groups, with the review committee itself, with the cancer center directors and senior leaders of the centers to make sure that this happens.

"If we can get selections of the best people in the country to come and look at these [grants], then I'm convinced that this will work," Wittes said.

"If we can't, I'm equally convinced it won't work, and the peer review system will break down."

Last Cancer Letter For 1996; Best Wishes For New Year

This issue of **The Cancer Letter**, Vol. 22, No. 48, is the final issue for 1996.

The Cancer Letter editors and staff wish all subscribers a happy and healthy holiday season and New Year.

Stay with us in 1997 for **The Cancer Letter's** 23rd consecutive year.

The next issue, Vol. 23, No. 1, will be dated Jan. 10, 1997.

Reinventing NCI

Natural Product Screen Closes; NCI To Target HIV Resistance

The NCI Developmental Therapeutics Program will no longer screen natural product cell extracts for activity against HIV, Institute officials said.

The screening program is being closed in response to an evaluation of NIH AIDS research submitted to NIH Director Harold Varmus last March. The report criticized the nonselective screen for producing mostly non-nucleoside reverse transcriptase inhibitors, of which there are already several in clinical use.

"No truly novel agent has reached the clinic" for treatment of HIV as a result of NCI's $100 million drug screening program, said the report of the NIH AIDS Research Program Evaluation Working Group. The evaluation was led by Arnold Levine, of Princeton University.

The whole-cell assay will be maintained for screening synthetic compounds submitted by extramural researchers, Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers, said to **The Cancer Letter**.

"The Levine committee had no enthusiasm for the whole-cell assay," Wittes said. "It is in part because of those recommendations that we are shutting it down. We think that experiment has been done and it is time to move on to others."

To replace the screening program, NCI is planning to form a group of investigators to study the structural basis of drug resistance, Wittes said. The group could include intramural and extramural researchers, and would be organized from the Frederick Cancer Research and Development Center in Frederick, MD.

Meanwhile, NCI is planning a review of the Developmental Therapeutics Program, to be conducted by a panel of extramural advisors. The committee will be led by Susan Horwitz, professor of pharmacology at Albert Einstein College of Medicine, and Stuart Schreiber, professor of chemistry at Harvard University.

Screen "No Longer Warranted"

The antiviral drug screen is no longer necessary in the era of rational drug design, the Levine committee said in its report to Varmus. "Although this program identified active agents in the mid-1980s when its cell-based antiviral screen was the only assay available, DTP's continued dependence on this nonselective screen is no longer warranted," the report said.

"Since the screen is not aimed at specific molecular targets, compounds identified as active may have the same target as agents already well studied in the clinic, as has been the case for the non-nucleoside reverse transcriptase inhibitors identified by DTP," the report said. "The few agents that have advanced to further study represent a restricted number of antiviral mechanisms, and no truly novel agent has reached the clinic."

The Levine committee report said that as a result of the dependence on the nonselective screen, the productivity of the DTP has been limited. The report called for further review and restructuring of the program, as well as oversight by a scientific advisory board.

"A substantial decrease in the size and funding of the DTP's current AIDS-related drug discovery effort is appropriate," the report said.

However, the committee praised DTP's library of defined compounds, its acquisition contracts, and its capabilities in medicinal chemistry, the characterization of drug mechanisms, and the assessment of toxicology and pharmacology that support Investigational New Drug filings with FDA.

"Because the pharmaceutical industry's continued active interest in drug discovery for HIV and its associated [opportunistic infections] and malignancies cannot be assured, maintenance of a drug discovery infrastructure supported by NIH may be justifiable," the report said. "However, resources would be better utilized if the DTP's efforts were refocused on the development of novel mechanism-based screens with high through-put capacity that are derived from basic research advances."

The committee suggested that, "DTP should use its core resources to support NIH-wide antiretroviral discovery efforts by providing compounds and natural products for various screening endeavors as well as medicinal chemistry, pharmacologic, and toxicologic support as needed."

New Role For DTP

Ending the HIV drug screening, NCI sought a new role for DTP's AIDS drug development capabilities, NCI Director Richard Klausner said to the National Cancer Advisory Board recently.

"The decision we have made is to create a structure and biology based AIDS drug discovery program based upon the important biologic, pharmacologic, biochemical and genetic issues of resistance," Klausner said. "We believe there is a real gap in infrastructure for understanding resistance, understanding the biochemistry, the genetics of resistance, to develop databases about restrictions on resistance in the virus, whether it is due to RNA sequence restriction or protein sequence restriction.

"We will be involved in doing structure-function analysis and specific structural analysis of resistance proteins, of trying to figure out how we can learn about the nature of resistance from looking at evolutionary reverse enzymes or targets, and to attempt in a systematic way to help develop the science of the approach to resistance biology," Klausner said.

The change to the DTP drug screening program is one of several changes that have taken place in AIDS research at NCI. Over the past year and a half, NCI has shifted about 30 percent of its AIDS research funds from intramural research to extramural grants, Klausner said.

In August 1995, about 12 percent of the NCI's $225 million budget for AIDS was spent on grants. This year, nearly 50 percent of the AIDS research budget will fund grants, Klausner said.

NCI increased funding to the AIDS Malignancy Consortium and the AIDS Malignancy Bank, provided over $6 million to cancer centers for translational research on AIDS malignancies, increased funding for AIDS malignancy research in the cooperative groups, and funded five AIDS oncology training programs to be developed at cancer centers, Klausner said.

NCI To Expand Diagnostic Imaging Program

In another development in the Division of Cancer Treatment, Diagnosis and Centers, David Bragg, chairman of diagnostic radiology at University of Utah, will spend seven months at NCI to form a new diagnostic imaging program.

The new program will be "larger and more ambitious" than the current imaging program, Wittes said to **The Cancer Letter**.

Bragg is a member of the NCI Board of Scientific Advisors and a former member of the National Cancer Advisory Board.

"We are actively considering creation of a national clinical trials capability for imaging that would take off from the excellent work of the Radiation Diagnostic Oncology Group (RDOG) studies over last several years and would provide the country with the capability of ongoing evaluation of emerging technologies that look particularly interesting for cancer imaging," Wittes said. "It would be a multicenter activity, but exactly how it will be organized is what we are trying to think through."

NCI also is organizing an Imaging Technology Working Group to advise the Institute on directions in imaging research. The group is expected to begin meeting early next year, Wittes said.

NCI Initiatives

Advisors OK Grants For AIDS, Minority Training Programs

Advisors to NCI have approved the Institute's plans to set aside $12.5 million over the next five years from the investigator-initiated grants budget to support two new grants programs to train young investigators.

The NCI Board of Scientific Advisors approved in concept two new Requests for Applications at its meeting Nov. 22.

One RFA concept proposes to fund five grants, at a cost of $9 million over four years, to train clinical scientists in conducting patient-oriented research in conjunction with appropriate management of patients with AIDS malignancies.

The second RFA concept would fund five grants at a cost of $3.5 million over five years to provide minority scientists with an extended period of sponsored research to help in the transition from a mentored research environment to an independent research career.

The excerpted text of the concept statements follow:

AIDS-Oncology Clinical Scientist Development Program. RFA concept, Cancer Training Branch, DCTDC. Five awards, first-year set-aside $1.5 million; total $9 million over four years. Program Directors: Vincent Cairoli, Ellen Feigal.

Background: The AIDS Malignancy Working

Group, which includes NCI staff and extramural scientists, identified the need for interdisciplinary training programs to provide the spectrum of clinical and research skills necessary for conducting patient-oriented research in conjunction with appropriate management of patients with HIV/AIDS malignancies. At present, there is no specific subspecialty of medicine in the area of HIV/AIDS, nor are there any formal, nationally recognized training programs integrating the specialized skills in Hematology, Oncology, and Infectious Diseases needed to address AIDS-related malignancies. The expanding population of patients with HIV/AIDS and malignancies have complex multi-system illnesses, requiring the expertise of physicians with considerable multidisciplinary knowledge.

Purpose of RFA: NCI proposes to solicit applications for Clinical Scientist Development Program awards to support institutional, multidisciplinary, training programs focused on the HIV/AIDS Oncology field.

The goal of the program is to train a cadre of clinicians with the highly specialized skills necessary to address the clinical and research problems associated with AIDS-related malignancies. There is an important need for trained AIDS-Oncology specialists to exploit research opportunities, conduct patient-oriented research, and provide the clinical management skills necessary for advancement in this field.

These training programs should also produce individuals with skills for promoting translational research in other areas of Oncology, as the relationships between the underlying immune deficits and cancer development are elucidated.

Funding: The average cost per trainee is approximately $95,000/yr. which includes salary of up to $50,000, plus fringe benefits, $20,000 other expenses, and indirect costs. This will be a 2 year training program for each trainee; therefore, the cost for producing 45 new investigators over a 4 grant period would be about $1.5M for year 1, rising to $3.0M for years 2 and 3 due to overlap, and falling back to $1.5M for year 04.

Career Development And Mentored Peer Review Award. RFA concept, Comprehensive Minority Biomedical Program, NCI Division of Extramural Activities. Five awards, first-year set-aside $500,000, total $3.5 million over five years.

NCI invites underrepresented minority research scientists who have been the recipient of an NIH Research Supplements for Underrepresented Minorities award who need an extended period of sponsored research as a way to gain scientific expertise while bridging the transition from a mentored research environment to an independent research/academic career scientist to submit applications.

This award offers opportunities for a mentored peer review experience which will enhance the candidates knowledge and understanding of the peer review process with the intended purpose of developing skills with the expectation that the candidate will submit a grant application for nontargeted mechanisms (R29; R01; F32).

This award is aimed at fostering the research careers of outstanding, junior minority scientists who: 1) have been the recipient of an NIH Research Supplements for Underrepresented Minorities award; 2) are located at a majority institution; and 3) are committed to developing and sustaining academic research programs.

In The Cooperative Groups

Enrollment Complete In PCPT, Three Years After Beginning

Enrollment in the Prostate Cancer Prevention Trial has been concluded, trial organizers said.

The trial conducted by cooperative groups has enrolled 18,000 men three years to the day after it began, precisely meeting the projected date for completing enrollment, said Charles Coltman, chairman of the Southwest Oncology Group and a member of the trial's steering committee.

"We hit the target on the button," Coltman said to **The Cancer Letter**. "Accruing this many people three years to the day after the trial opened is a monumental accomplishment."

The trial stopped accepting new patients last Friday.

PCPT, which tests the ability of the hormonal agent finasteride (Proscar) to delay the onset of prostate cancer, is the first cancer prevention trial to proceed at a relatively even pace.

Enrollment in the Breast Cancer Prevention Trial, which tests the ability of the drug tamoxifen

to prevent breast cancer in asymptomatic women, suffered a setback in the midst of the controversy over the National Surgical Adjuvant Breast & Bowel Project, the cooperative group that conducts the trial. BCPT is expected to meet its enrollment targets next spring, NCI officials said.

Value of Genetic Studies

The progress of the two trials demonstrates that clinical trials cooperative groups are capable of conducting prevention trials in asymptomatic populations, several observers said.

At the outset of the two prevention trials, critics said the cooperative groups, which include physicians who typically see cancer patients, would be ill-equipped to accrue healthy participants.

Otis Brawley, director of the NCI Office of Special Populations and a member of the PCPT steering committee, said the trial's principal accomplishment will be the creation of repositories of genetic material from annual biopsies undergone by the trial's participants.

"If we prevent prostate cancer with this trial, it's going to be wonderful," Brawley said. "But, just as importantly, we are going to learn about genetics and biological behavior of prostate cancer and other prostatic diseases. The most significant value of the trial lies in the genetic studies it is going to support."

The trial will follow 18,000 men for the rest of their lives and collect eight annual prostate biopsies for every man enrolled.

Beyond supporting genetics studies, that information could lead to insight into the value of screening for prostate cancer as well as to a refinement of screening methods, Brawley said.

The trial is scheduled to be completed in the year 20003.

Unharmed By Erroneous Reports

PCPT enrollment appears to have been unharmed by recent news stories that stated erroneously that the hormonal agent finasteride was "useless" in the treatment of benign prostatic hyperplasia (**The Cancer Letter**, Sept. 6).

Though erroneous and irrelevant to prostate cancer, the news stories triggered hundreds of inquiries at PCPT sites.

However, after receiving information from PCPT staff, only a small number of men dropped out of the trial, Coltman said.

NSABP Operations Office Moves To Allegheny Hospital

The operations center of the National Surgical Breast & Bowel Project has begun a cross-town move from the University of Pittsburgh to Allegheny General Hospital.

The hospital's research unit, Allegheny-Singer Research Institute, received a $70 million five-year grant from NCI to conduct operations of the cooperative group. The grant's first year funding is $13 million.

"I am delighted we have been able to stabilize NSABP and continue our mandate," said NSABP chairman Norman Wolmark, director of the Allegheny Cancer Center and chairman of the Department of Human Oncology at Allegheny University of the Health Sciences.

Wolmark said that for the first time since NSABP became embroiled in a controversy three years ago, the group has been able to offer a full complement of clinical trials in breast and colon cancers. The controversy stemmed from submission of falsified data by a researcher in Montreal.

The cooperative group's biostatistics operation remains at the University of Pittsburgh, where it is funded through two separate NCI grants.

Patient Advocacy

Four Survivorship Programs Receive NCCS Awards

Four innovative cancer survivorship programs for minority populations received special awards from the National Coalition for Cancer Survivorship, the NCI Cancer Information Service, and Bristol-Myers Squibb Oncology at the 10th anniversary meeting of the NCCS in Albuquerque, NM, recently.

The programs, People Living Through Cancer in Albuquerque, Women Achieving Victory and Esteem in Detroit, Celebration of Living in Tuscaloosa, AL, and Sisters Network based in Houston, TX, each receive $5,000 to develop a program model that can be adapted for use by other minority cancer survivor groups.

The four programs will work with the CIS to develop effective methods to increase awareness of the CIS toll-free number in minority communities. The awards were funded by Bristol-Myers Squibb Oncology.

In Brief

Oleson Moves To Arizona; Meisenberg To Maryland

(Continued from page 1)

email to: info@uicc.ch. . . . **JAMES OLESON** was named professor and head of the Department of Radiation Oncology at the Arizona Cancer Center and the University of Arizona College of Medicine. He also will serve as the cancer center's director for clinical research. Oleson was chairman of the Department of Radiation Oncology at Health Care International, Glasgow, Scotland. . . . **BARRY MEISENBERG** was appointed deputy director of clinical affairs at the University of Maryland's Marlene and Stewart Greenebaum Cancer Center in Baltimore, MD. Meisenberg, an associate professor of medicine and oncology, was the director of bone marrow transplantation at the Scripps Clinic and Research Foundation, La Jolla, CA. . . . **KAREN MATTSON SMITH** will join Capitol Associates Inc., of Washington, DC, in January as a legislative assistant. She was a legislative assistant to Sen. Mark Hatfield (R-OR), chairman of the Senate Appropriations Committee. Capitol Associates specializes in health, education and human resources policy. . . . **ONCOLOGY NURSING** Certification Corp. said 4,309 registered nurses took the Oncology Certified Nurse test administered Sept. 28 at 116 sites around the US, and 86 percent or 3,710 passed. There are now 17,942 oncology certified nurses. For information on the exam, contact ONCC, tel: 412/921-8597. . . . **JON KERNER**, associate director for prevention and control, Georgetown University's Lombardi Cancer Center, received the Community Service Award from the Breast Cancer Resource Committee, a nonprofit organization based in Washington, DC. The award recognized Kerner's work for better breast health for African American women. . . . **UNIVERSITY OF CALIFORNIA, BERKELEY** named a cancer activist and a tobacco researcher as Public Health Heroes, a new award bestowed by the university's School of Public Health. **Andrea Martin**, executive director of The Breast Cancer Fund, received the award for the organization's efforts to raise funds for breast cancer programs. **Stanton Glantz**, professor of medicine at the University of California, San Francisco, Institute for Health Policy Studies, received the award for his tobacco research and anti-smoking advocacy.

Program Announcement

PAR-97-014

Title: **Innovative Approaches To Developing New Technologies**

Application Receipt Date: Feb. 13

The mission of the Biomedical Technology area of the National Center for Research Resources is to support research to identify, create and develop innovative technologies and to provide these technologies for biomedical research. Areas of emphasis are biomedical engineering, biomedical computing, and technologies for the study of structure and function at all levels of living systems. Purpose of this PA is to encourage submission of new R21 applications to explore new research paradigms in engineering, instrumentation, physics, mathematics or computer science as applied to biomedical research. The projects should provide the opportunity to develop new technologies, methods, devices, and materials that provide greater understanding of fundamental elements of biological phenomena. These efforts should lead to new approaches to the solution of basic research questions in order to prevent, diagnose, and treat disease and disability.

Support will be through the NIH exploratory grants (R21) mechanism, with direct costs limited to $75,000 per year for up to two years. Indirect costs will be provided. Although these grants are not renewable, they are expected to provide the opportunity to collect sufficient preliminary data to apply for future support from either the NCRR or other NIH Institutes and Centers. These funds may not be used to supplement projects currently supported by Federal or non-Federal funds, nor to provide interim support for projects under review by PHS, nor to support thesis or dissertation research.

Purpose of this PA is to provide the opportunity to:

—explore new approaches, test imaginative new ideas or to challenge existing paradigms in technologies related to biomedical research;

—develop significant changes in an existing high technology important to biomedical research; or

—translate a scientific concept into the basis for a future technology that leads to the solution of important biomedical research problems.

The research must be unusually imaginative or drastically different from past paradigms with the potential to lead to a significant expansion of biomedical research horizons. The proposal should contain an element of risk as it must encompass work at the frontiers or the limits of understanding of a problem.

Inquiries: Dr. Dov Jaron, Biomedical Technology, National Center for Research Resources, 6705 Rockledge Dr. Rm 6160-MSC 7965, Bethesda, MD 20892-7965, tel: 301/435-0755, fax: 301/480-3659, email: dov.jaron @nih.gov