

Oxford University Press Wins CRADA For Journal of the National Cancer Institute

Oxford University Press and NCI have signed a Cooperative Research and Development Agreement to privatize the Journal of the National Cancer Institute.

The agreement transfers over a five-year period responsibility for production of the semimonthly journal and its related information products. Oxford University Press will own the journal beginning with the first issue in January 1997.

(Continued to page 2)

<u>In Brief</u>

Pagano To Retire As Lineberger Director; Nursing Society Elects Yarbro As President

JOSEPH PAGANO, founding director of the UNC Lineberger Comprehensive Cancer Center, plans to retire as director in the summer of 1997. He will continue as director of the center's postdoctoral research training program and as a Lineberger Professor of Cancer Research and professor of medicine, microbiology and immunology. He will also have the title of director emeritus. A national search will be conducted for his successor. Pagano was appointed director of the center in 1975. . . **CONNIE HENKE YARBRO** was elected president of the International Society of Nurses in Cancer Care at the society's conference in Brighton, UK. Yarbro is clinical associate professor, University of Missouri, Columbia, and editor-in-chief of Seminars in Oncology Nursing. The society's other new officers are: vice-president, Gill Oliver, director of patient services, Clatterbridge Centre for Oncology, UK; second vicepresident, Carol Reed Ash, Kirbo Endowed Chair, Oncology Nursing, University of Florida, Gainsville.... PETER O'DWYER was appointed associate director of the division of neoplastic diseases at Jefferson Medical College and professor of medicine and pharmacology. He will serve as director of the Developmental Therapeutics Program at Jefferson's Kimmel Cancer Center. O'Dwyer has been a senior member in the division of medical science at Fox Chase Cancer Center. O'Dwyer is vice-chairman of the Eastern Cooperative Oncology Group. ... MAURICE BLACK, 78, director of the Institute for Breast Diseases at New York Medical College, died Sept. 14 in New York. He had liver cancer. Black, an early proponent of conservative breast cancer surgery, published 250 studies starting in 1953 supporting the view that radical surgical attempts to cure the disease were not consistent with its biology.

Vol. 22 No. 36 Sept. 20, 1996

© Copyright 1996 The Cancer Letter Inc. All rights reserved Price \$265 Per Year US \$285 Per Year Elsewhere

Congressional News Senate To NIH: Administrative Offices Should Consolidate Page 3

Senate Appropriations Report Language

On NCI, NIH Budgets ... Page 3

Cancer Meetings Listed For Next Three Months ... Page 6

Funding Opportunities Berlex Foundation Offers Fellowship Page 7

NCI Grants Criteria For Proposal Of New RFAs Written ... Page 8

This FAX edition of The Cancer Letter is provided as an upgrade to the regular annual subscription. For information, call 202-362-1809.

Reinventing NCI

Oxford University Press Signs CRADA To Privatize JNCI

(Continued from page 1)

JNCI costs the Institute more than \$1.7 million annually and 15 staff positions. The Institute earns about \$1 million from the journal's 10,000 subscribers, but cannot sell advertising or conduct extensive marketing.

Oxford, the largest university press in the world, was selected in a competition that drew about 20 applicants, sources said. It is the first time the CRADA mechanism, designed to commercialize technology developed by the government, has been used to transfer a government publication to the private sector.

NCI published the CRADA solicitation last December (**The Cancer Letter**, Dec. 1, 1995).

Electronic Journal Planned

Jaclyn Fox, senior editor and manager for US journals, said Oxford will develop an electronic version of JNCI as part of the agreement.

"We are very pleased," Fox said to **The Cancer Letter**. "Oxford is a nonprofit university press and we felt it was a good fit. We have a very strong journals program, particularly in this area."

Oxford publishes about 160 journals in a variety



Founded 1974 Member, Newsletter Publishers Assoc.

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 Subscriptions: subscrib@www.cancerletter.com World Wide Web URL: http://www.cancerletter.com

Subscription \$265 per year US, \$285 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages. of academic fields. Carcinogenesis is the organization's best known oncology journal, Fox said.

"One of the main changes will be the ability to market JNCI," Fox said. "As an international marketing group, we can expand to areas the journal has not reached, such as the Pacific Rim."

Julianne Chappell, managing editor of JNCI, said the Institute chose Oxford for its willingness to uphold the journal's peer review and oversight process.

"We have made a marriage of like minds," Chappell said. "Oxford is as interested as we are in maintaining the quality of the journal."

Under the agreement, NCI will continue to name the journal's editor-in-chief, currently Barnett Kramer, deputy director of the Division of Cancer Prevention and Control. Chappell will become executive editor when Oxford appoints a managing editor.

No NCI Support After Five Years

Under the agreement, NCI will provide the editorial facilities for five years. The Institute's staff would gradually go off the journal's payroll as they are replaced by Oxford staff. NCI officials have said they will try to place staff members in other positions in the Institute, Chappell said.

Also at the end of the transition period, NCI's Office of Cancer Communications will no longer produce the journal's news section. "At the end of the CRADA period, there will be no taxpayer money going into this journal," Chappell said.

JNCI monographs are included in the transfer, but Oxford will make the decisions about whether to fund publication of monographs, Chappell said.

JNCI: Highest "Impact Factor"

JNCI was founded in 1940. Last year, the Institute for Scientific Information listed the journal as having the highest "impact factor" among primary journals in cancer research. The impact factor is defined as the average number of times a paper is cited in scientific literature.

Oxford University Press traces its origins to the invention of printing from movable type in the 15th century, according to a history of the publisher.

The first printed book was made in Oxford in 1478. A century later, the Great Charter from King Charles I entitled the university to print "all manner of books."

The university's privilege to publish the King

James Authorized Version of the Bible in the 17th century spurred an expansion of the business over the next two centuries. A Bible warehouse established in London grew into a major publisher of educational books and began to use the name Oxford University Press in the late 19th century. Oxford opened a US office in 1896.

Oxford publishes 3,000 new books a year and currently has about 15,000 books in print. The organization employs about 3,000 people in more than 20 offices worldwide.

Oxford's US distribution center is based in Cary, NC.

Congressional News

Senate To NIH: Consolidate Administrative Functions

The Senate Appropriations Committee urged NIH to continue consolidation of administrative functions across the Institutes.

"Particular consideration should be given to the consolidation of functions across the Institutes, such as personnel, legislation, planning and evaluation, contracting, grant administration, and public affairs," the committee said in a report released late last week.

The committee recommended a \$2.326 billion budget for NCI, a \$78.1 million increase over the current year's budget of \$2.248 billion.

At this level, the NCI budget would be \$45.2 million above the President's proposal of \$2.281 billion, but \$59.6 million below the appropriation of \$2.386 billion proposed in the House bill.

Under the Senate bill, NIH would get \$12.415 billion, a \$487 million increase over the current year's budget of \$11.928 billion. The proposed appropriation is \$38 million above the President's proposal of \$12.377 billion, but \$333 million below the funding level of \$12.747 billion recommended by the House.

The Senate bill calls for spreading out the financing of the NIH Clinical Center over three years. The House bill contained a similar provision. The Administration proposed allocating \$275 million, the estimated cost of the project, during the upcoming year.

Capitol Hill sources said it was unlikely that the Labor, HHS and Education bill would be enacted as a single law before Oct. 1, the start of the new fiscal year.

Considering the controversial aspects of the bill, it appeared likely that the bill would not be enacted before Congress goes into recess for the elections. Thus, funding for NIH would likely be provided through continuing resolutions or an omnibus bill.

In another development, the conferees reconciling the House and Senate appropriations bills for the Department of Defense recommended that the DOD breast cancer research programs receive \$137 million and the prostate cancer program receive \$44 million.

Of the breast cancer money, \$100 million would fund peer reviewed programs, \$25 million would fund breast cancer outreach and information programs within the military, and \$12 million would fund specific research programs.

The National Breast Cancer Coalition sought \$150 for peer reviewed research in DOD.

In the DOD prostate cancer program, \$37 million would fund peer reviewed research, and another \$7 million would be allocated to specific programs. The DOD conference bill was not available.

The excerpted language of the Senate appropriations report on NIH and NCI follows:

Research agenda. The committee commends NCI on its efforts to support a balanced cancer research agenda—one which includes basic, clinical and translational research and which includes research in cancer prevention, control and survivorship. The committee also emphasizes that, within this balanced approach to cancer research, there should be flexibility in the use of funds to address high priority initiatives and to fund quality research programs and their applications.

The committee has reviewed the report of the NCI Director, "The Nation's Investment in Cancer Research" [the bypass budget], and is very pleased to provide additional funds to undertake some of the new and exciting approaches described in this document. The committee agrees that new technologies will be needed to allow researchers, physicians and patients to benefit from the vast amount of information that are certain to be available in the near future as a result of our expanding knowledge of cancer genetics and molecular biology. The committee encourages NCI to develop and implement the strategies necessary to achieve investment opportunities and looks forward to hearing about progress in these areas at next year's hearing. NCI is to be commended for efforts to direct special attention to novel proposals, particularly for patient-oriented research grants. The decision to provide a second review of novel and patient-oriented grants within 10 points of the payline sends a positive message to both the patient and the research community.

Infrastructure reforms. The committee supports NCI in its effort to respond to and implement the reforms recommended by the Bishop-Calabresi report of the National Cancer Advisory Board. The committee applauds the actions on the part of NCI, and NIH as a whole, to maximize the effective use of limited research dollars in our ongoing national effort to cure cancer.

Cancer centers program. The committee continues to strongly support the NCI-sponsored cancer centers program. This network is a national treasure, and needs to continue to be strengthened and expanded.

Breast cancer. The committee concurs with the NCI decision to place breast cancer research as a high priority and urges the Institute to continue to strengthen its budgetary commitment to breast cancer research.

The committee understands that the San Francisco Bay area has one of the highest rates of breast cancer incidence in the world, and mortality rates significantly higher than state and national levels. Regional variations in cancer rates can provide important information about environmental contributions to breast cancer. Epidemiologic investigations are needed to identify novel risk factors, including environmental exposures. The committee encourages the Institute, in conjunction with the National Institute of Environmental Health Sciences, to support research on the risk factors for the high breast cancer incidence and mortality rates in the San Francisco Bay area, and explore the feasibility of mapping disease rates along with environmental exposure information.

The committee is supportive of the NCI's initiative to gather more complete information regarding genetic damage, cell signal pathways and how these factors can lead to greater understanding of environmental factors and their relationship to breast cancer.

The committee requests that NCI be prepared to provide an update on progress on research risk factors for high breast cancer incidence and mortality rates in the San Francisco Bay area, as well as the Institute's cancer genome anatomy project during the fiscal year 1998 budget hearings. Over the past three years, breast cancer research has benefited from the increased involvement of lay breast cancer advocates. While maintaining the highest quality assurance through peer review, consumer involvement has helped to ensure that all breast cancer research reflects the experiences and wisdom of individuals from the scientific and lay communities. The committee encourages NCI to continue to give consideration to involvement of consumers in decision making related to breast cancer research, and to be prepared to report to the committee on progress that the Institute is making toward that goal at the 1998 hearings.

Sufficient funds have been included to support implementation of the National Action Plan on Breast Cancer at the fiscal year 1996 level.

Cancer prevention and control. The committee recognizes the important role of behavior in preventing cancer and reducing its effects. New scientific data indicate that psychosocial and complementary medicine interventions improve the quality of life and increase treatment compliance for cancer patients. The committee urges the NCI to conduct an inter-Institute initiative of basic and applied research on the psychosocial factors involved in treating cancer, AIDS, diabetes, heart disease, and other diseases with a behavioral component. The committee intends that grants for such behavior be made to cancer centers which have personnel and facilities to conduct complementary and psychosocial research projects on diverse ethnic and racial populations.

Behavioral research review. The committee is pleased that as part of a plan to refine its priorities, the NCI has undertaken a review of its behavioral research portfolio [and] looks forward to [the NCAB report] on this issue.

Clinical Research. The committee commends NCI for taking an important first step toward correcting the problem of appropriate reimbursement for the care provided to patients enrolled in peerreviewed clinical trials by negotiating an agreement with the Department of Defense. The agreement provides coverage for patient care to enrollees in DOD health care programs participating in phase II or phase III clinical trials that have been approved by NCI, an NCI-funded cancer center, or one of NCI's cooperative groups.

The committee understands that NCI is also in the process of negotiating similar arrangements with other federal agencies involved in the support of health care services. In negotiating these agreements, the committee urges NCI to be mindful of other quality mechanisms outside NCI. For example, a number of trials involving leukemia have been approved by the National Heart, Lung and Blood Institute. In addition, the review processes of the Food and Drug Administration, in granting investigational new drug exemptions, are second to none in their rigor. Finally, the committee encourages NCI to consider including phase I studies under the current, and future agreements with third-party payers.

Extramural construction. The committee recognizes that a key aspect of our national research capacity is our research infrastructure. Research facilities play an important role in supporting state-of-the-art research initiatives, which enable rapid translation of research progress from the bench to the bedside. The committee recommends that NCI reserve \$7 million for meritorious extramural construction needs in cancer research.

The committee urges that these funds be awarded to newly solicited grant applications with special priority given to applications devoted toward construction of new facilities to consolidate clinical research laboratory research activities in comprehensive cancer centers. Special priority should be given to comprehensive cancer centers with construction underway or facilities soon to be completed where awards from this appropriation will provide finished laboratory research space which could not otherwise be completed at this time within funds available. The committee further expects that the awards made with these funds will be at least equivalent in amount to the standard awards for construction projects provided through the National Center for Research Resources.

Ataxia-telangiectasia. The committee continues to view research on this rare genetic disorder as a high priority, not only because of the severe impact of the disease on children, but also because of the relevance of A-T research to many fields, including breast cancer. The committee encourages NCI to support additional studies on A-T heterozygotes with increased emphasis on the development of A-T therapies.

Gynecologic cancers. The committee encourages NCI to continue expand its efforts in basic and applied gynecologic cancer research, specifically the implementation of the recommendations from the NIH

consensus conferences on ovarian and cervical cancer. The committee also encourages NCI to give consideration to utilizing the SPORE mechanism to support research on gynecologic cancers.

Prostate cancer. The committee believes that prostate cancer research should be among NCI's highest priorities in order to decipher the mysteries of this complex disease.

Neurofibromatosis. The committee encourages NCI to continue to pursue an aggressive program in basic and clinical research in NF and urges NCI to employ novel approaches in the clinical development of NF research, including the use of: requests for applications, as appropriate; the National Cooperative Drug Discovery Group program; and Small Business Innovation Research grants. The committee requests that NCI be prepared to report on the status of its NF research program, including progress in implementing the recommendations of this and last year's committee reports, at its hearings on the fiscal 1998 budget.

Bionutrition. NCI continues to be a leader in the nutrition research area. Diet is second only to smoking in its association with cancer. The committee encourages NCI to continue its leadership in nutrition research, particularly with regard to women's health issues including breast cancer. The committee believes that clinical research units and general clinical research centers can provide an excellent focus for the intensive study of how nutrition can affect the tissues of human subjects to become less susceptible to cancer.

Cancer in minorities. There remains an unacceptably high incidence of cancer among the native Hawaiian population. The committee commends NCI for its recently released report which documents that native Hawaiians rank second in the nation in cancer mortality rates. Hawaiian males are second only to African-American males in overall cancer death rates, while cancer-related mortality rates of Hawaiian women are equal to those of African-American women, ranked only behind Alaskan women. The committee encourages continued research emphasis in these high-priority areas and expresses its gratitude for the work the Institute has done with the Hawaii Cancer Center.

Developing cancer centers. The committee urges the Institute with a portion of its increased funds to promote improved instrumentation and equipment at developing cancer centers in regions without existing comprehensive cancer centers, including giving consideration to issuing an RFP for equipment and instrumentation which is needed to measure levels of cancer causing chemicals in humans, and equipment needed to measure the activities of cancer genes in human breast tumors. It is critical that the physical as well as the grant resources be made available to compliment developing cancer centers. NCI, in coordination with the NCRR should do everything feasible to encourage the continued development of cancer centers that serve rural and minority populations with a high incidence of cancer. The committee expects that such programs will be discussed during the fiscal year 1998 hearings.

H.pylori infection. The committee urges the Institute to give consideration to joining in the trans-Institute research effort on H. pylori infection initiated by the NIDDK and the office of Research on Minority Health. Further research is needed on the connection between this bacteria and gastric cancer.

DES. The committee continues to strongly support increased efforts to study and educate the public about the impact of exposure to the synthetic hormone diethylstilbestrol. NCI and other institutes, along with the Office of Women's Health, have developed a plan for expanded activities in this area. The committee is pleased with the Institute's efforts in this area and expects NCI to continue its strong support for carrying out the recommendations of this plan.

Brain tumors. The committee continues its strong concern about the incidence of brain cancer. The committee reiterates its support for NCI, in concert with the NINDS, to fund up to five centers of excellence in brain tumor research. These centers will conduct basic, translational, and clinical research to determine the cause, mechanisms of development, diagnosis, and treatment of primary and secondary brain tumors. The committee believes there should be a maximum of information exchange and collaboration among the centers' investigators.

NIH Clinical Research Center. The committee supports the NIH request for authority to allow the Clinical Research Center to bill third-party insurers for nonresearch-related patient services. In a report issued last October, the HHS inspector general also encouraged NIH to modify its accounting system to collect the full costs of treating patients at NIH; separate research costs from nonresearch costs; collect insurance and financial information from patients; and develop a plan for implementing the new billing policies in consultation with insurance companies. *IOM to conduct study of cancer in minorities.* The committee has included sufficient funds for the Institute of Medicine to conduct a one-time review of the status of research into cancer among minorities and the medically underserved at NIH.

Genetic research. Genetics has become a critical component of all biomedical research and as such is central to the contemporary mission of NIH. Human genetic research and its applications have raised, and will continue to raise, significant ethical, social and legal issues. If left unaddressed, these issues could jeopardize progress in understanding human genetics and/or the use of newly developed diagnostic and therapeutic tools. The committee urges the Director to bring a coordinated effort at NIH to these critical legal, ethical, and social issues, which pertain to many diseases and disorders.

One issue in particular is the concern among the general public about the privacy of information, and especially, of genetic information, that may be obtained during the course of medical care, and recorded in the medical record. Some of these concerns are now focused on archival collections of human tissue samples that have been collected for clinical purposes and accrued for generations in academic medical centers, where they have provided a rich and irreplaceable resource for research on human diseases. The status, accessibility, and use of stored tissue samples raise important issues that require the careful balancing of considerations of patient autonomy and privacy with society's compelling interest in encouraging opportunities for biomedical discoveries, and the improvement of human health. The committee urges the Director to study these issues and recommend appropriate policies and procedures that will protect the rights of research subjects and assure the continuing availability and accessibility of the human tissue archive.

Cancer Meetings Listed For Next Three Months

October

Molecular Approaches to Cancer Therapeutics: 40th Anniversary Symposium of the Dept. of Experimental Therapeutics, Roswell Park Cancer Institute—Oct. 3-4, Buffalo, NY. Contact Dr. E. Mihich, tel: 716-845-5860, fax: 716-845-8857. National Coalition for Cancer Survivorship— Oct. 3-6, Albuquerque, NM. Contact Deborah Ash, tel: 301-650-9127.

Sixth Conference on Radioimmunodetection and Radioimmunotherapy of Cancer—Oct. 10-12, Princeton, NJ. Contact Lois Gillespie, Center for Molecular Medicine and Immunology, tel: 201-982-4600, fax: 201-982-7047.

Toward 2000 Symposium: New Ways to Cure Cancer—Oct. 11, Philadelphia, PA. Contact Fox Chase Cancer Center, Kathy Smith, tel: 215-728-5358.

Examining Errors in Health Care: Developing a Prevention, Education and Research Agenda— Oct. 13-15, Rancho Mirage, CA. Contact American Association for the Advancement of Science, Ellen Cooper, tel: 202-326-6431.

Society for Biological Therapy Annual Scientific Meeting—Oct. 23-27, Washington, DC. Contact Dr. Richard Smalley, tel: 608-276-6640, fax: 608-276-6644.

Advances in Sonography—Oct. 25-27, San Francisco, CA. Contact Society of Radiologists in Ultrasound, tel: 215-574-3183, fax: 215-923-1737, e-mail: sru@acr.org.

Piedmont Oncology Association 17th Annual Symposium—Oct. 25-26, Hilton Head Island, SC. Contact Comprehensive Cancer Center of Wake Forest University, tel: 910-716-4464, fax: 910-716-5687.

Lurie Cancer Center/Schweppe Colloquium in the Basic Sciences—Oct. 28-29, Chicago, IL. Contact Denise Barca, tel: 312-908-5258, fax: 312-908-1372.

Commission on Cancer First Annual Conference—Oct. 31-Nov. 1, Rosemont, IL. Contact American College of Surgeons, Connie Blankenship, tel: 312-664-4050.

November

New Developments in the Multidisciplinary Management of Thoracic Malignancies—Nov. 1, Cleveland, OH. Contact Ireland Cancer Center, tel: 216-844-5878.

Chemotherapy Foundation Symposium—Nov. 6-8, New York City. Contact Jaclyn Silverman, Mount Sinai School of Medicine, tel: 212-241-6772, fax: 212-996-5787.

Oncology Nursing Society Fall Institute—Nov. 8-10, Phoenix, AZ. Contact ONS, tel: 412-921-7373,

ext. 553.

Intersection of Pathology and Genetics on Hereditary Nonpolyposis Colon Cancer—Nov. 11-12, Bethesda, MD. Contact NCI Early Detection Branch, Dr. Sudhir Srivastava or Barbara Bonaparte, tel: 301-402-6480 or Dr. Miguel Rodriguez-Bigas, tel: 716-845-5815.

Recent Advances in Melanoma and Soft Tissue Sarcoma—Nov. 21-22, New York City. Contact Memorial Sloan-Kettering Cancer Center, Jean Campbell, tel: 212-639-3511, fax: 212-639-3535.

December

Pittsburgh Cancer Conference: Innovations in Cancer Care—Dec. 3-4, Pittsburgh, PA. Contact University of Pittsburgh Medical Center, Diane Applegate, tel: 412-647-8263, fax: 412-647-8222.

San Antonio Breast Cancer Symposium—Dec. 11-14, San Antonio, TX. Contact Lois Dunnington, tel: 210-567-4745, fax: 210-567-4822, e-mail: lois_dunnington@oncology.uthscsa.edu

Correction: The 8th World Conference on Lung Cancer is scheduled for Aug. 10-15, 1997, not 1996, as previously published in the May 31 issue of **The Cancer Letter**. Contact Secretariat, tel: 353-1-8306795, fax: 353-1-8309090.

Funding Opportunities

Berlex Oncology Foundation Offers Research Fellowship

The Berlex Oncology Foundation, a nonprofit organization established by Berlex Laboratories, is accepting applications for Clinical Oncology Research Fellowships.

Candidates must be fellows or junior faculty below the level of assistant professor at the start of the award. The fellowship provides the opportunity for an additional two years of clinical research training to academically-oriented physicians. The candidate must be within 10 years of acquiring an MD or DO degree and must be board eligible.

The award provides \$50,000 per year over a twoyear period. A 10% overhead allowance will be provided to the sponsoring institution.

Application deadline is Jan. 6, 1997.

Inquiries: Berlex Oncology Foundation, 80 West Madison Ave., Dumont, NJ 07628, tel: 201-385-0006, fax: 201-385-5650.

NCI Grants

Criteria Established For RFAs As NCI Reviews Funding Tools

NCI has established written criteria for its extramural staff to use to determine whether to propose a new Request for Applications for research grants.

Over the past year, the Institute has issued about a dozen fewer RFAs than in previous years, primarily due to internal review and "self-censorship" by division directors, said Marvin Kalt, director of the NCI Division of Extramural Activities, speaking at a recent meeting of the Board of Scientific Advisors.

Over the previous five years, NCI issued about 30 RFAs per year, Kalt said. "We have seen fewer concepts this year as division directors are rethinking their programs," Kalt said.

More RFAs could be proposed in the coming year as several advisory groups reviewing NCI programs begin to make recommendations for new initiatives, Kalt said.

RFAs involve intensive staff effort, Kalt said. It can take 13 months from the time of identification of a funding opportunity and actual award to an investigator, he said.

However, RFAs can help "seed" a field by synchronizing review of grant applications. Another potential advantage to RFAs is that applications are reviewed by special NCI review committees rather than NIH study sections, Kalt said.

Following is the text of the NCI Criteria for **Proposing Use of RFA Mechanism**:

Introduction: Requests for Applications are used to solicit applications for grants in specific research areas, with funds set aside for these institute-initiated research activities.

RFAs must be reviewed and approved by the NCI Executive Committee (EC) before formal concept review by the Board of Scientific Advisors. To provide maximum opportunity to support investigator-initiated research, the NCI will reserve the use of set-asides (RFAs) to stimulate research in new areas when warranted by scientific opportunity. In addition, consideration of decreased staffing levels requires that less work-intensive mechanisms be used whenever possible and appropriate.

To facilitate the RFA decision-making process, especially for EC concept review, an improved process

for justification of the use of the RFA mechanism is needed. The criteria presented below should be addressed in preparing justifications for RFA concepts.

RFA Concept Criteria:

1. What is the new scientific opportunity? How was it identified? In the context of the current state of knowledge in this area, what is the RFA intended to achieve?

2. Briefly describe current NCI grant/application portfolio in area, specifically addressing: a) funded (active) grants, b) pending (scored but unfunded) applications, and c) applications not scored, in the current and one previous fiscal year. Describe related research funded by other ICs [NIH institutes and centers].

3. Indicate why an RFA, and not another, less work-intensive mechanism (e.g., Program Announcement or announcement in NCI Home Page), is needed to take advantage of this opportunity.

Issues to be considered include:

a. need to <u>stimulate submission</u> of additional applications (discuss the quality of pending applications)

b. need for <u>increased funding</u> (set-aside or exceptions) to encourage submission of applications

c. need for <u>special review criteria</u> for peer review

d. need for <u>special review group</u> to review complex area

e. for Cooperative Agreements: need for <u>staff</u> <u>involvement</u> in funding mechanisms that can not be met by use of specific terms of award for R01s.

Discussion: In addressing the above issues, consider the actual need for set-asides and special reviews. There may be additional options for program initiatives, and the following questions are presented to stimulate thought:

—If exception funding were to be made available, would a PA be effective?

—If review criteria were presented to reviewers, would DRG review be appropriate?

—If review were conducted by a special review group, would a PA be effective (no set-aside)?

—Is there a need for a one-time submission date (to coordinate review and funding of a group of applications)?

—Would an on-going announcement with multiple receipt/submission dates indicate a continuing NCI interest and allow for better preparation of applications?