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'Interactive Research Project Grants' Proposed, Goal To Provide Step Between R01s And P01s

NCI's advisory boards took the first look at a proposal for a new use of the traditional R01 grant that the Institute's officials said they hope will provide an intermediate step between individual R01s and the more costly and complex program project grants (P01s). The proposed Interactive Research Project Grants program would allow three or more investigators to submit related R01 grant applications for collaborative

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In Brief

Allegra To Head NCI/Navy Branch; Sausville Promoted; Glatstein To Leave NCI For Dallas

APPOINTMENTS, DEPARTURE in NCI's Div. of Cancer Treatment: **CARMEN ALLEGRA** has been selected to succeed **John Minna** as branch chief at the NCI/Navy Medical Oncology Branch. Allegra has done "outstanding work" on 5-fluorouracil resistance and recently discovered a unique feedback inhibition of translation of thymidylate synthase, said DCT Director Bruce Chabner. He also organized a clinical colon cancer program at the NIH Clinical Center and will add that unit to the Navy's lung cancer efforts. Allegra "has the breadth of interest, the clinical skills, and the considerable administrative abilities that will be required to lead this complex group." **Bruce Johnson** was acting chief of the branch following Minna's departure last spring. . . . **EDWARD SAUSVILLE** will become chief of the Laboratory of Biological Chemistry, succeeding **Richard Cysyk,** who is moving to **John Driscoll's** Drug Synthesis & Chemistry Laboratory. Sausville came to NCI as a clinical associate. . . . **ELI GLATSTEIN,** chief of NCI's Radiation Oncology Branch, plans to leave NCI in February to become head of radiation therapy at Univ. of Texas, Southwestern Medical School in Dallas, where he will join Minna, a friend and collaborator. Glatstein came to NCI 15 years ago. "It is difficult to put in words Eli's importance to NCI," Chabner said. "He has given us clinical credibility, integrity, a commitment to getting the best for his people, and demanding the best from them. He has established a first rate radiobiology group here, a group we intend to hold on to as firmly as we can." He also has been advisor to "countless numbers of young trainees who have gone on to illustrious jobs at the nation's foremost research institutions. It will be difficult to find his replacement." Glatstein told **The Cancer Letter:** "I wouldn't have stayed as long as I did if I didn't like working for Vince DeVita [former NCI director], Bruce Chabner, and [NCI Director] Sam Broder. "Bruce Chabner has the greatest integrity of anyone I know. He's a real mensch."

BSCs Look At 'Interactive RPG' Proposal, Are Somewhat Skeptical

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research on a common theme. The goal of the initiative is to encourage more clinical research funding through research project grants, the most stable NIH funding mechanism. Another reason for the program is the increasing budgetary pressures on P01s.

Members of NCI's four Boards of Scientific Counselors, all of which met this week and last week, varied in their opinions of the proposed new mechanism, but were nearly unanimous in asking for further clarification. Their questions concerned study section review of the collaborative proposals, for whom and what kinds of research the mechanism would be most useful, whether two should be the minimum number of investigators rather than three, and some skepticism about whether it would have the intended effect of encouraging clinical collaborations. There was also outright opposition to the initiative.

The idea to create interactive R01 grants was born last spring, soon after the House Appropriations Committee asked NIH to fund 6,000 new grants each year, with no "downward negotiations." NCI was directed to fund 840 competing grants, out of a total of 3,076 research project grants.

P01s cost five to six times more than R01s but still count as only one award toward the RPG total. NCI Director Samuel Broder began telling advisors that "it doesn't take a rocket scientist" to figure out that fewer P01s could be funded under the new rules. He also said Congress would not like it if NCI began playing a "numbers game" of counting P01s by the number of projects they contain.

NCI officials defended the P01 mechanism as a way of encouraging integrated laboratory and clinical research, but also began considering a new mechanism that might be similar to the P01, but enable each project to count as a separate grant. (**The Cancer Letter,** June 21).

Under the IRPG concept presented this week, NCI would issue a program announcement to encourage investigators to submit concurrent, collaborative applications. Applications would be reviewed by standing study sections whenever possible. In addition, NCI would consider funding applications beyond the payline that contribute to the group effort, through the NCI Executive Committee's exception funding authority.

Applications could be from one or a consortium of institutions, and would be accepted beginning next Feb. 1. It would be a way for investigators who do not need extensive shared resources or facilities to collaborate on research questions that are more complex or require efforts beyond what is feasible in a single R01, said Marvin Kalt, deputy director of the Div. of Extramural Activities. Kalt presented the initiative to each of the BSCs.

"We believe that many fields of cancer research could benefit from formalizing an intermediate level of collaboration among independent equals, where common interests, ideas, data, and materials, not physical facilities, are shared by the participants," Kalt said.

"Typically, the IRPG approach will be suited to many basic research questions, to applications proposing to develop and apply innovative technologies, or to develop and evaluate potential new therapeutic approaches," Kalt continued. "For example, basic researchers may with to pursue sequentially related steps in a process such as drug metabolism. It also would be possible to propose a well focused phase 1 or phase 2 drug trial where the trials were linked to correlated basic studies or evaluation of samples gathered as a result of the trial. Research projects that relate to multiple facets of a single class of drugs might be explored, such as was done under the taxol RFA.

"In contrast, this mechanism is not meant as a substitute for straightforward clinical trials where the protocol is already standardized and no correlative basic investigations are planned. As an R01, an innovative original research theme must be discernible if the applications are to be competitive."

The Div. of Cancer Prevention & Control board voted to approve the concept, though several board members expressed reservations, and three abstained from the vote.

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"It seems to me the critical question is whether multicenter trials could go in as R01s," DCPC board member Ross Prentice said.

"I think the answer is yes," Kalt said. "They could do the same protocol, but there needs to be some individuality at each site."

"I would be surprised if this would allow for a clinical trial," DCPC board member Maryann Roper said. If three centers each with 50 patients in a protocol were to apply and one center was turned down, the other R01s would not be able to stand on their own, she said. "I would hope the language is either loose or tight enough so the review committee doesn't toss it out."

"Certainly for phase 3 clinical trials this is not the mechanism," Kalt responded.

"If the intent is to decrease the number of P01s in favor of R01s, without knowing how multicenter trials could be funded, the end result would be to make funding easier for basic science and not encourage clinical research," Prentice said.

DCPC Director Peter Greenwald said he thought that, "the intent of the Executive Committee was to allow clinical research to be done" through R01s. "After hearing this, now I'm a little less clear."

Ronald Levy, new chairman of the Div. of Cancer Treatment board, said he opposed the new mechanism. "I'm all for collaboration, but there's nothing to prevent that now." Investigators can submit linked R01s at present. "It's the wrong response to the problem. The problem is that this is a response to the numbers game," he said, referring to the budget constraints on P01s. "It works to the detriment of program projects."

"We are trying to expand opportunities," Kalt said. "It is not meant to replace the P01 mechanism. We are trying to say for that group of investigators that see something intermediate, we want to give them every possible opportunity."

Other board members questioned how the scientific review would be managed for clinical and basic collaborations, and whether a package of R01s would have to go to two or three different study sections. Kalt said NCI program staff would be assigned to a package of R01s to shepherd them through the process and help bring them back together at the end.

"Few of our P01s would fit into this mold," DCT Director Bruce Chabner said.

"We view this as an experiment," Kalt responded.

DCT board member Ralph Weichselbaum noted that the potential for exception funding made the IRPG attractive. Lester Peters, whose nomination for the DCT board is pending, said exception funding "is an anathema to those submitting regular R01s."

The DCT board had not completed its meeting by **The Cancer Letter's** presstime this week, but it did not appear that the board would vote on the initiative. The Div. of Cancer Biology, Diagnosis & Centers board members had similar concerns, and also did not take a formal vote. The Div. of Cancer Etiology board was scheduled to discuss the proposal at its meeting later this week.

Advisors Ok 'Five-A-Day' Program To Urge Americans To Eat Produce

NCI will work with the produce industry and community based coalitions to encourage Americans to eat more fruits and vegetables under a new grant program approved in concept last week by advisors to the Div. of Cancer Prevention & Control.

The $20 million project would provide grants to 10 coalitions to conduct a national media campaign to encourage fruit and vegetable consumption and to work with grocers and the produce industry in communities to develop educational efforts.

The concept, based on a California program that had NCI and produce industry support, was approved on a 10-3 vote by the DCPC Board of Scientific Counselors at its meeting last week. The most contentious issue in the board's discussion was the question of efficacy. The data from the California study on whether a media campaign did cause an increase in produce consumption will not be available for two years, project director Jerianne Heimendinger, Cancer Control Science Program, said.

Following is the concept statement:

Five-a-Day for Better Health. Concept for a new RFA, total funding $20 million, up to 10 grants, $400,000 per grantee per year, five years. Goal: To increase the per capita consumption of fruits and vegetables from 2.5 to 5 servings daily by the year 2000. Objectives: 1) To increase public awareness of the importance of eating at least five servings of fruits and vegetables every day for better health. 2) To provide consumers specific information about how to incorporate more servings of fruits and vegetables into daily eating patterns.

As a part of the capacity-building grants for state health departments, NCI has supported a 5-A-Day statewide initiative in California to increase vegetable and fruit consumption among consumers there. Since the media campaign began in 1988, the message has been promoted by 15 supermarket chains, representing more than 1,600 stores, at their own expense. Over 225 media interviews have occurred, resulting in over 43 million media exposures. The dollar value of industry and mass media contributions is estimated at over $1.5 million. Both California and numerous national industry organizations have asked NCI to take the lead in expanding the 5-A-Day concept to the national level.

Persons in the lower quartile of fruit and vegetable intake (1

or fewer daily servings) experience about twice the risk of cancer compared with those in the highest quartile (4 or more servings). Thus, increasing the per capita consumption to 4 or more servings a day should result in a reduction in incidence of the diet-related cancers of 25%, preventing approximately 146,000 new cancers per year. Ten percent of U.S. adults had no fruits, fruit juice or vegetables on any given day, according to the NHANES II study.

Approximately 60 companies or commodity groups have contributed $415,000 to create the nonprofit Produce for Better Health Foundation.

The proposed 5-A-Day national program will be a 5-year collaborative effort between NCI and the PBHF, with the intent to extend the program for a second five-year period. The program will build on the experience and materials developed by the California program. The PBHF will work with NCI to develop retail interventions and the national media campaign. NCI will fund community coalitions or health departments to develop, implement, and evaluate community health education interventions, expanding the project into restaurants, food assistance programs, and community organizations.

The major components of this program are the media campaign, the retail point of purchase program, and the community level interventions.

The purpose of the media campaign is to create consumer awareness, increase knowledge, and provide motiviation and specific suggestions for including more fruits and vegetable in the daily diet. The retail grocery program will provide consumers with information at the point of purchase to help increase their purchase and consumption of fruits and vegetables.

The community coalition/health department component of this program will provide a means of activating communities to create innovative ways of reaching their consumers, including minorities and underserved populations. The coalitions will need to indicate how they will determine the most appropriate channels for their populations and how they will develop, implement, and evaluate their programs. The community level interventions will allow an opportunity to answer important research questions about a program of this nature, and will bring the program more personally to the consumer's attention.

Funds for the Office of Cancer Communications in this concept will be used to develop the national media campaigns, including camera-ready materials that will be used by the media and in the national supermarket intervention. Funds for support contracts will be utilized to evaluate the program, provide technical assistance, and support meetings, etc. Each grantee will be responsible for evaluation of their programs using grant funds provided.

Phase I: Planning (Year 1). The first year of the project will be spent creating a strategic plan for the national program, revising the California materials for national audiences, creating new materials, collecting and analyzing baseline data, planning the national media campaign and point of purchase programs, and developing an RFA for community coalitions. Two NCI staff members will be hired to direct the project. The point of purchase program will be introduced in Year 1.

Phase II: Implementation (Years 2-5). During the second year, the national media campaign will be introduced. NCI will continue to develop materials, especially culturally-sensitive materials for specific market segments, monitor industry participation, and coordinate the national mass media campaign.

During the second year, an RFA will be advertised for community coalitions or health departments who wish to participate in the 5-A-Day program. The purpose of the RFA will be for coalitions/health departments to serve as channels for creating state and local level interventions that will complement the media campaign, working with their local industry partners and community groups.

The third and fourth years will be a continuation of the activities created in years one and two, as well as continued "media waves" to maintain interest in the campaign. The community level projects will develop a national network in order to maintain consistent scientific quality and to compare data across studies.

The activities in the fifth year will be a continuation of project activities and an assessment of the program's effectiveness. If a decision is made to continue the program, strategic planning for the next 5 years will begin. If a decision is made to terminate the program, transfer of the interventions to the community for continuation will be accomplished and a final evaluation will be produced.

Should the program terminate in Year 5, money is requested for Year 6 to complete all evaluation efforts, produce materials that may be useful for other intervention, and disseminate results.

Examples of the types of research questions which might be addressed by the community coalitions through the grant mechanism are:

(1) Which of two intervention channels is the more effective for reaching a specific ethnic or target population? Within one state, three comparison communities might be chosen: one would receive only the national media exposure + national supermarket intervention; one might receive media + supermarket + church intervention; and one might receive media + supermarket + worksite intervention.

(2) Which combination of components in an intervention channel is more effective? Within one state, two comparison communities might be chosen: in the one community, supermarket interventions would consist of signs and brochures in the produce section, logos on plastic and paper bags, newspaper ads with 5-A-Day messages, and periodic newsletters for customers; in the second community, interactive events would be added, such as tastes testing of produce, supermarket tours, a nutritionist who is periodically available to answer customer questions, etc.

(3) Using the Prochaska/DiClemente stages of change model (1983) which as been applied to smoking and only recently to diet, it might be possible to test in one state two strategies for moving contemplators to the decision stage. For example, in one state three comparison communities might be chosen: in one community, no special messages for contemplators would be used; in one community, additional focused messages would be used addressing the barrier of convenience; in a second community, messages and incentives would be used to address the barrier of access, etc.

"Of all the things I think we could do besides smoking cessation to really impact cancer, this is it," DCPC Director Peter Greenwald said. "I'm really impressed with the enthusiasm of the industry."

Board member Ross Prentice questioned whether this concept should be a higher priority than scientific research, and said the data on produce consumption and cancer is not clear. "It seems strange to be acting on a $20 million project without knowing the effectiveness," Prentice said.

Greenwald agreed that there is not as much data on this relationship as there is with smoking and cancer, but said there is enough information for NCI and other agencies to have issued dietary

recommendations. "To me, a decision not to act in the face of this amount of data is as much a statement as a decision to act," he said. He also noted that Americans are eating more cereal grains to enhance fiber intake, but have not gotten the message about produce.

Board member Carol D'Onofrio said the message "could do no harm," but questioned the concept's method of forming coalitions to get the message out. "We're putting all our eggs in a coalition basket as a way to get things done. We're doing cholesterol through a coalition, diet through churches, smoking through churches. We have coalition on top of coalition, and now we'll have 10 more," she said. "I would like to se us do more basic research on how to change diets and who changes and for how long."

Board member Robert Greenberg said he agreed with Prentice and was concerned about conducting this project without knowing the data from the California program. On the other hand, if the program is effective, "it might interfere with diet trials that are going on," and put NCI in an ethical dilemma of studying the question of fruit/vegetable consumption on cancer incidence while simultaneously telling people to eat more fruits and vegetables.

New board Chairman Alfred Haynes spoke in favor of the concept. "Unless we do something positive about diet we will miss an important opportunity to do something about cancer."

The board approved the concept on a 10-3 vote, with Greenberg, Prentice, and board member Maryann Roper opposed.

SPORE Eligibility, Costs Clarified In Addendum To RFA, Q & A Session

As a result of a meeting with potential applicants for the new Specialized Programs of Research Excellence in breast, lung, and prostate cancer, NCI has issued an "addendum" to the RFAs to clarify eligibility and cost issues and has extended the deadline for the letter of intent to Nov. 22.

The SPORE grants are NCI's new $22.5 million effort to establish special research centers focusing on the three major types of cancer. Staff from NCI's Div. of Biology, Diagnosis & Centers met with applicants on Oct. 8 in St. Louis to discuss the program. (The RFAs were published in the Oct. 4 issue of **The Cancer Letter.**) More than 100 scientists attended; as of early this week 34 letters of intent had been received for the breast SPORE, 31 for prostate, and 20 for lung.

Following are the three modifications to the RFAs announced in the addendum:

1. Under eligibility requirements, an alternative to a minimum of three independent investigators who are successful in obtaining peer reviewed research directly related to the relevant cancer, is a minimum of three independent investigators, each having published articles which significantly address the relevant cancer in peer reviewed research journals, and who when combined represent experience in both laboratory and clinical research. Because of the scarcity of peer reviewed research support for prostate cancer, NCI will be as flexible as possible in its interpretation of this eligibility requirement for SPOREs addressing prostate cancer.

2. In complying with the direct cost cap of $1.5 million, the indirect costs related to subcontracts to other institutions or organizations will not apply toward the cap, but the total dollar request may not exceed $2.5 million.

3. The deadline for the letter of intent is extended from Oct. 25 to Nov. 22. While this document is not required, it provides an opportunity for all potential applicants to establish a dialogue with NCI staff and to have all questions and problems related to the SPORE RFAs resolved. The letter of intent may be especially useful for resolving issues related to eligibility requirements.

Where will the money for the SPOREs come from? That was a frequently asked question in Bldg. 31 conference rooms this week. NCI Director Samuel Broder told the Div. of Cancer Treatment Board of Scientific Counselors that "we will not cannibalize existing P30s [cancer center support grants]" to fund SPOREs, and the money will not be taken out of the research project grant pool (R01s, P01s). "It will come out of some other area."

"Most likely it will come out of contracts," DCT Director Bruce Chabner told the board later. He also mentioned cancer education and research management and support.

Questions & Answers On SPOREs

Also as a result of the St. Louis meeting, DCBDC staff put together a list of questions commonly asked by potential applicants and NCI's answers, in order to clarify the RFA further:

Q. On the requirement for a minimum of three independent investigators with successful peer reviewed research support, is it limited to only NIH grant support? A. No. All research support that has been peer reviewed by mechanisms equivalent to NIH peer review process will be acceptable (inclusive of both federal and non-federal support institutions and NCI funded cooperative groups).

Q. According to the RFA, to be eligible to submit a SPORE application, there must be at least three investigators who have or have had peer reviewed research directly related to the cancer in question. Is this a hard and fast rule? What about the area of prostate cancer, which has little peer reviewed funded research? A. The idea is to have a critical mass of investigators within the SPORE application who are knowledgeable, active researchers in a given cancer site. Three investigators seems like a reasonable minimum if a SPORE is to be effective in conducting translational research and is to have the most immediate impact possible on reducing incidence and mortality. It is difficult to envision a

SPORE being effective without this critical mass of experienced investigators.

However, there may be investigators whose experience with one form of cancer is directly applicable to another form of cancer. Also, there may be investigators who have published their research on a particular form of cancer in peer reviewed journals but do hot have any traditional peer reviewed support. Both of these types of investigators would meet the eligibility requirement.

The field of prostate cancer research is one where strict interpretation of the eligibility requirement might discourage innovative applications, and one which clearly does not enjoy significant peer reviewed funding. NCI will interpret the requirement for three investigators for the prostate cancer SPORE in the most reasonable and flexible way possible, as long as potential SPORE applicants can defend their ability to conduct the kind of research that is being requested in the RFA. Applicants who are doubtful about their eligibility should address the issue in a letter of intent and receive approval from NCI before submitting an application. (See addendum above.)

Q. Is there a geographical preference/restriction to funding SPORES? A. No.

Q. Do NCI designated cancer centers have an advantage in competing for SPOREs? A. Not necessarily. The SPORE initiative will result in funding applications that contain the most innovative ideas. However, there is a provision in the RFA for a SPORE to be part of an NCI designated cancer center when such a situation arises at an institution.

Q. Do the SPORE initiatives favor groups of scientists who already have significant research programs in breast, lung, and prostate cancer? A. Clearly, existing large groups have the resident expertise to form a critical mass of scientists familiar with cancer; however, these groups, as well as all other new groups, must submit applications that propose new, innovative approaches to achieve translational research objectives. Thus, it is likely that existing groups will be more successful if they expand their expertise and perspective to generate new approaches that are not being pursued with existing support.

Budget Issues

Q. Within the $1.5 million direct cost cap for a SPORE application, are there caps on particular budget categories such as the career development program or developmental funds? A. No. Applicants should use good judgement in deciding what to request for each budget category in order to have a maximum impact on the conduct of research.

Q. In the case of a multi-institutional SPORE, will indirect costs on subcontracts count toward the direct cost ceiling? A. Normally this is the case. However, NCI will allow an applicant not to count indirect costs on subcontracts toward the direct cost cap as long as the total award does not exceed $2.5 million. The award must go to a single institution. (See addendum, above).

Q. In a SPORE involving a multi-institutional consortium can there be a principal investigator and a co-principal investigator from two different institutions? A. Yes, but NIH officially recognizes only one principal investigator in its data base. Thus, the principal investigator should be affiliated with the institution that receives the award. However, the co-principal investigator is recognized by peer reviewers in their scientific evaluation of the application and by NCI program staff who administer the active grant.

Q. Will there be constraints on the use of funds for clinical trial research? A. No, assuming that the proposed research is appropriate to the purpose and objectives of the SPORE (e.g. conceived with basic researchers to understand the reasons for the success or failure of the trial).

Q. Are purchases of large equipment permissible among budget items? A. Yes.

Q. Is it possible to carry over funds from year to year to provide support for anticipated pilot studies? A. Yes, but it requires approval from NCI. Most well justified requests carry over, especially in the case of developmental funds for pilot studies, will be approved.

Q. What is the reason for funding SPOREs initially for only three years? A. NCI realizes that a three year period is too short for any SPORE to produce research results that will impact on cancer incidence and mortality. However, it is a sufficient time to reevaluate through peer review whether the scientific approaches and directions required of a SPORE are being developed successfully, and whether the career development programs, specialized resources, and use of developmental funds are functioning effectively. If the SPOREs are not performing satisfactorily, then it is likely that there will be a completely new competition for SPORE support. However, if after peer review evaluation it is determined that SPOREs are functioning effectively, then they will be renewed for another five years. We hope that after eight full years of support, the unique, innovative research approaches developed by SPOREs will have a major practical impact on improving cancer prevention, detection, diagnosis and treatment.

Scope of SPOREs

Q. To what extent is NCI concerned about research objectives being pursued with existing support or proposed pending applications that might overlap with research proposed as part of SPORE applications? A. SPORE applications are intended to stimulate the exploration of new ideas and the development of new, innovative research approaches that will help to reduce incidence and mortality of breast, prostate, and lung cancer. Achievement of this goal will require the involvement of new people and/or the establishment of new research interactions and collaborations within an institution. While it is likely that some research objectives, which are currently funded or proposed as part of new applications, will be contained within SPORE applications, it is also likely that these research objectives will be reoriented and restructured to meet the translational research emphasis required of SPOREs. If an institution is competitive for a SPORE award, research overlap issues will be dealt with when the award is negotiated.

Q. In conjunction with the clinical trials, are projects that include culturing human cells, or animal models, appropriate for SPORE applications? A. Yes, particularly with respect to the prostate SPORE RFA, which calls for development of models. However, the main objective of all SPOREs is to address human cancer.

Q. What flexibility will there be in developing specialized resources? A. There is considerable flexibility as long as the resources are specialized to the research needs of the SPORE. The only requirement is that each SPORE develops a dedicated activity for collecting and distribution human cancer tissue. However, it is expected that this resources will take time to develop properly, and initially will serve the research needs of the SPORE before it can provide cancer tissue effectively to scientists outside the SPORE. If a SPORE exists within the umbrella of an NCI designated cancer center, then it should benefit from resources existing within the cancer center rather than duplicating these resources.

Q. Is it desirable to have external advisory committees as well as internal groups involved with the SPORE to evaluate the research? A. Yes, especially if it enhances the capability of the SPORE to generate innovative ideas.

Q. Must SPOREs be able to address all areas of research ranging from prevention and detection to diagnosis and therapy? A. NCI is interested in new research ideas in all of these areas,

but does not expect every SPORE initially to have equal capabilities in all of these areas. It is hoped that the capability of each SPORE to conduct innovative research in all of these areas will increase with time.

Q. Can SPOREs utilize the resources existing within NCI clinical cooperative groups? A. Yes, as long as access tot he resources in the cooperative groups is clearly stated and that there is a need for such studies in terms of the innovative research projects to be reviewed as part of the SPORE application.

Senior Leadership/Training/Developmental Funds

Q. Can the same biostatistician expert serve as senior leader in both breast and prostate SPOREs submitted by the same institution? A. Yes.

Q. Does the principal investigator have to be an R01 funded investigator? A. No.

Q. How flexible will NCI be with time commitments of investigators who wish to participate in a SPORE but who are fully committed in terms of percent time to other funded research? A. The percent time commitment for each investigator who participates in a SPORE should be commensurate with his/her research effort. NIH does not allow any individual to be committed in excess of 100 percent. Investigators who find themselves in this situation should anticipate identified funded activities that they will have to give up in order to conduct research within the SPORE.

Q. Do clinicians have to spend 100 percent of their time on research if they participate in the SPORE? A. If a clinician is a senior individual, he would devote a percent time that is commensurate with his research effort on the SPORE. If the clinician is at a junior level and supported through the career development fund, he/she should spend 100 percent of his/her time in research. However, this 100 percent could be divided 75-80 percent to hand on research and 20-25 percent to clinical activities related to the cancer thrust of the SPORE. But the career development fund should not pay for the 20-25 percent of effort in the clinic.

Q. Can graduate students be supported to do research on prostate cancer within a SPORE? A. Yes, for their percent effort in SPORE research.

Q. Is it permissible to use career development funds to pay medical fellows planning to enter into academic research? A. Yes, as long as the career development funds are being used to support individuals whose careers in research are to be focused on the cancer site that is supported through the SPORE. Career development funds are not intended solely to provide individuals with research experiences, but are intended to expand the number of investigators doing research in the field.

Q. What are the constraints on the use of career development funds? A. Career development funds can be used for anyone who has an advanced doctoral degree (e.g., a junior person wishing to develop a research career in the cancer site or a senior individual reorienting current research objectives). There are no time constraints on the length of support someone should receive, but these funds should be used in a way that is clearly for career development purposes and not for research staffing purposes.

Q. Can developmental funds from the SPORE support established investigators who wish to expand or develop their expertise in the SPORE? A. Yes.

Q. How specific must the application be in the use of developmental funds? A. Some specificity as to ideas that are suitable for immediate feasibility testing may provide peer reviewers with concrete examples of how the SPORE can use these funds effectively. However, some funds should remain unspecified to take advantage of new opportunities as they arise.

Q. To what extent can SPOREs be involved with foreign scientists, institutions and resources? A. There can be collaborative relationships between SPOREs and foreign investigators, but the SPORE cannot pay for research activities outside the U.S.

Review of SPOREs

Q. Describe the clinical protocol review process as it relates to SPOREs. A. Clinical trials research proposed as part of the application must have institutional IRB approval and pass peer review evaluation. Clinical studies initiated in noncompeting years of SPORE support must also have appropriate IRB approvals, and must be contained within annual progress reports for NCI review.

Q. How do NCI staff envision the peer review process for SPOREs? A. It is likely that there will be separate peer review groups for each SPORE, but it is impossible to predict the exact process until the applications have been received.

Q. Does NCI anticipate site visits? A. Not necessarily. Responses to RFAs usually are not reviewed by a site review process.

Q. Since the scoring system will weight four areas differently, how are you going to arrive at a single priority score? A. Each member of a special review committee for SPORE applications will be given clear instruction regarding the four areas requiring weighted consideration. However, only one single priority score will be voted by each reviewer and only one average score for all reviewers will appear on the summary statement.

Further information and copies of the complete RFAs may be obtained from the Centers, Training & Resources Program, phone 301/496-8537, or the Organ Systems Coordinating Branch, phone 301/496-8528.

NCI Advisory Group, Other Cancer Meetings For Nov., Dec., Future

National Coalition for Cancer Survivorship Annual Assembly--Oct. 31-Nov. 3, Denver, CO. Contact Betty Barbour, phone 303/239-3424.

Leukemia Society of America Medical Symposium--Nov. 1-2, St. Louis, MO. Contact the society, phone 212/573-8484.

Therapy of Acute Leukemias--Nov. 1-6, Rome, Italy. Contact Haematology, Univ. La Sapienza, Via Benevento 6, 0016 Rome, Italy.

European Assn. for Cancer Research 11th Meeting--Nov. 3-6, Genova, Italy. Contact Ist. Naz. per la Ricerca sul Cancero, V. le Benedetto XV, 10, 16132 Genova, Italy.

Hormone Replacement Therapy & Endometrial Hyperplasia--Nov. 4, Holiday Inn Crowne Plaza, Rockville, MD. Contact Technical Resources Inc., 301/770-3153.

American Society for Therapeutic Radiology & Oncology Annual Meeting--Nov. 4-8, Washington, D.C. Contact Michael Bernstein, ASTRO, 703/648-8910.

Bristol-Myers Squibb Symposium on Cancer Research: Application of Basic Science to Hematopoiesis & Treatment--Nov. 4-5, Seattle, WA. Contact Stephanie Curran, Convention Services Northwest, 1809 7th Ave. Suite 1200, Seattle, WA 98101, phone 206/292-9198.

American Society of Cytology Annual Meeting--Nov. 5-10, Los Angeles, CA. Contact Dr. Yener Erozan, 1015 Chestnut St., Ste. 1518, Philadelphia, PA 19107, phone 215/922-3880.

Colon Cancer: Diagnosis in an Era of Cost Containment--Nov. 7, Chicago, IL. Contact Michael Bernstein, American College of Radiology, 703/648-8910.

Cancer Research Manpower Review Committee--Nov. 7-8, Holiday Inn, Chevy Chase, MD. Open 8-9 a.m. on 7th, closed 8th.

Cancer Education Review Committee--Nov. 8, Holiday Inn, Chevy Chase. Open 8:30-9 a.m.

Photodynamic Therapy in Cancer Treatment--Nov. 7-8, Knoxville, TN. Contact Thompson Cancer Survival Center, phone

615/541-1433.

Advances in Innovative Oncology: Biomodulation & Chemotherapy--Nov. 7-9, New York City, Holiday Inn Crowne Plaza. Contact Jaclyn Silverman, Div. of Medical Oncology, Box 1178, Mount Sinai School of Medicine, One Gustave Levy Place, New York, NY 10029, phone 212/241-6772.

Cancer Education Review Committee--Nov. 8, Holiday Inn, Chevy Chase, MD. Open 8:30-9 a.m.

Legal Issues in Nursing--Nov. 8, Washington, D.C. Contact Helen Bowles, Washington Hospital Center, 202/877-6215

Cancer Management Course--Nov. 8-9, Knoxville, TN. Contact Dr. John Bell, American College of Surgeons, Cancer Dept., 55 E. Erie St., Chicago, IL 60611, phone 312/664-4050.

World Conference on Lung Cancer--Nov. 10-14, Melbourne, Australia. Contact Dr. D. Ball, Peter MacCallum Cancer Inst., 481 Little Lonsdale St., Melbourne 3000, Victoria, Australia.

Women & Cancer: Early Detection & Follow Up Care--Nov. 13, Berkeley, CA. Contact Mary Grim, Alta-Bates Herrick Hospital, phone 415/540-1420.

Prostate Cancer: Screening and Treatment Controversies--Nov. 15, Chapel Hill, NC. Contact Office of CME, CB #7000, 231 MacNider Bldg., UNC School of Medicine, Chapel Hill, NC 27599, phone 919/962-2118 or 919/962-1664.

American Assn. of Pharmaceutical Scientists Annual Meeting--Nov. 18-21, Washington, D.C. Contact AAPS, 703/548-3000.

Advances in Biology and Clinical Management of Melanoma--Nov. 19-22, Houston, TX. Contact M.D. Anderson Cancer Center, 713/792-3030.

Current Issues in Pediatric Hematology/Oncology--Nov. 21-23, Orlando, FL. Contact Nancy Pollock, FAPTP, PO Box 13372, Gainesville, FL 32604, phone 904/375-6848.

National Cancer Advisory Board--Nov. 25-26, NIH Bldg. 31 Conf. Rm 10, open 8 a.m. on Nov. 25. Open Nov. 26 at 8 a.m. in NIH Masur Auditorium.

NCAB Committee on Planning & Budget--Nov. 25, NIH Bldg. 31 Rm 7, 5 p.m.

NCAB Committee on Women's Health & Cancer--Nov. 25, NIH Bldg. 31 Rm 8, open 5:45 p.m.

International Symposium on Cervical Cancer--Nov. 27-29, 1991, Saint Lucia, Windward Islands. Sponsored by Saint Lucia Cancer Society and Minstry of Health. Contact Dr. Jean Paul Ryst, Ministry of Health, Chaussee Rd., Castries, Saint Lucia, W.I., phone 80945-32668.

Cellular Responses to Environmental DNA Damage--Dec. 1-6, Banff, Alberta, Canada. Contact American Assn. for Cancer Research, Public Ledger Bldg. Suite 816, 6th & Chestnut Sts., Philadelphia, PA 19106, phone 215/440-9300.

American Endocurietherapy Society Midwinter Meeting--Dec. 3-6, Las Vegas, NV. Contact AES, 1101 Market St., Philadelphia, PA 19107, phone 215/574-3158.

San Antonio Breast Cancer Symposium--Dec. 6-7, San Antonio, TX. Contact Lois Dunnington, 512/567-4745.

Cancer Management Course--Dec. 6-7, Chicago. Contact Dr. Penfield Faber, American College of Surgeons, Cancer Dept., 55 E. Erie St., Chicago, IL 60611, phone 312/664-4050.

Data Monitoring in Cancer Clinical Trials--Dec. 8-12, Leuven, Belgium. Contact European School of Oncology, Via Venezian 18, 20133 Milan, Italy.

NIH Consensus Development Conference on Acoustic Neuroma--Dec. 11-13, NIH Masur Auditorium, Bethesda, MD. Contact Prospect Associates, 1801 Rockville Pike, Suite 500, Rockville, MD 20852, phone 301/468-MEET.

European Conference on Pain Research--Dec. 12-13, Brussles, Belgium. Contact M. Staquet, Rue Heger-Bordet, 1, B-1000 Brussles, Belgium, phone 322/539-2805.

Future Meetings

ACS National Conference on Prostate Cancer--Feb. 13-15, San Francisco. Contact Andy Cannon, American Cancer Society, 1599 Clifton Rd. NE, Atlanta, GA 30329, phone 404/329-7604.

Current Perspectives & Future Directions in Clinical Flow Cytometry--April 25-28, Baltimore, MD. Contact New York Academy of Sciences, 2 East 63rd St., New York, NY 10021, phone 212/838-0230.

World Conference on Tobacco & Health--May 3-7, Buenos Aires, Argentina. Contact Conference Secretariat, Union Antitabaquica Argentina, Riobamba 1124 4 piso, 1116 Buenos Aires, Argentina, phone 814-0342, fax (54-1)814-0342.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Executive Plaza South room number shown, National Cancer Institute, Bethesda MD 20892. Proposals may be hand delivered to the Executive Plaza South Building, 6130 Executive Blvd., Rockville MD.

RFP NCI-CM-27732-49

Title: Clinical trials of biological response modifiers (master agreements)

Deadline: Approximately Dec. 20

NCI's Div. of Cancer Treatment, Biological Resources Branch, Biological Response Modifiers Program is soliciting proposals for highly innovative approaches to evaluate new agents or concepts in cancer therapy with biological response modifiers. Proposals are sought from investigators who have extensive preclinical experience in the area of the proposal and the unique technical capabilities to address the issues of mechanisms of action essential for the early clinical development of new BRM regimens. Proposals may be from single institutions, consortia, nonprofit, and commercial entities.

The BRMP specificially entend to establish master agreements under which MA holders will compete for subsequent master agreement orders for novel strategies for cancer treatment with BRMs. A clinical study of BRMs consisting of at least one clinical protocol shall be conducted by the MA holder for each MAO award. Depending on the availability of funds, a limited number of MAOs may be awarded at the time of award of MAs.

Offerors competing for this MA will be required to include as part of the proposal a specific proposal for a clinical trial. The MA holder shall conduct a phase 1a, 1b, or phase 2 trial of BRMs in accordance with NCI approved protocols that are submitted in response to individual specific MAOs issued under the MA.

The objectives of a phase 1a trial are to provide the parameters and characteristics of side effects and toxicity, and to establish the dose limiting toxicity and the maximum tolerated dose. The objectives of a phase 1b trial are to establish the optimal biological dose, i.e., the dose that produces the optimal desired response by route and schedule of administration, for the parameters deemed important with respect to a particular biological agent. The major objective of a phase 2 trial is the determination of therapeutic efficacy in defined patient populations.

Master agreements will be awarded beginning approximately June 30, 1992.

Contract Specialist: Sandra Lehner
RCB Executive Plaza South Rm 603
301/496-8620