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Organ Systems Program Reorganization Complete; Annual Conferences To Replace Working Groups

The Organ Systems Program, as an extramural oriented activity built around permanent, multidisciplinary working groups each focusing on one solid tumor, will cease to exist

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In Brief

NIH Conference To Explore Conflict Of Interest Issues; Five NCI Executives Win PHS Awards

POTENTIAL CONFLICTS of interest which are cropping up with greater frequency as academic and nonprofit institutions develop for profit subsidiaries while receiving government research funds will be the subject of a conference at NIH June 27-28. Issues for discussion include whether research results are unduly influenced by ownership of company assets or stock; how honoraria and consultantships should be treated when an investigator has federal support for similar work; disposition of intellectual and biological property obtained from government financed work; whether students or research plans are being directed to areas of lesser scientific merit to enhance the potential for monetary gains; possible remedies or sanctions. Preregistration and a fee of $10 for coffee breaks and miscellaneous expenses are required. Contact Mark Brown, Social & Scientific Systems, 7101 Wisconsin Ave., Suite 610, Bethesda, MD 20814, phone 301/986-4870. . . . **PHS AWARDS**: **John Hartinger**, chief of NCI's Financial Management Branch, received the Superior Service Award for "excellent leadership in the management of NCI's budget, innovative use of computer technology and superb direction of the Financial Management Branch;" **Maryann Roper**, NCI deputy director, received the Special Recognition Award for "her exemplary leadership" of NCI and "exceptional contributions" to planning of AIDS programs; **Marianne Wagner**, chief of the Personnel Management Branch, received Special Recognition for Productivity, for "providing substantive leadership" in developing and improving the organization of the personnel management program; **Alan Rabson**, director of the Div. of Cancer Biology & Diagnostics, and **Stuart Aaronson**, chief of the Laboratory of Cellular & Molecular Biology in the Div. of Cancer Etiology, received Distinguished Service Medals. Rabson was honored for exceptional contributions to American science as a scientist and administrator. Aaronson was honored for outstanding contributions in the fields of retrovirology, oncogenes and growth factors.

New OSP: No Permanent Working Groups, Two Big Annual Conferences

(Continued from page 1)
at the end of July. The seven existing working groups will be disbanded; in their place will be a system controlled by NCI, in which conferences will be convened to do what the working groups have done in the past.

The new plan, called the Organ Systems Coordinating Program, was presented last week to the National Cancer Advisory Board, where it evoked only the mildest of dissent.

The Organ Systems Program started life as the Organ Site Program and was primarily a creature of the NCAB, growing out of a modest NCI generated, solid tumor oriented effort of the 1960s. NCAB members initiated the addition of new groups and resisted fiercely any efforts to cut back the program or to kill it.

The current board includes no supporters of the former program who were willing to go to the mat with NCI over the drastic changes, as other NCAB members did with former Director Vincent DeVita on numerous occasions in the early 1980s. Enrico Mihich and Walter Lawrence expressed concerns, but they had no support from anyone else.

The board, in fact, was not even asked to vote on the matter. "We felt this should be a staff decision," Brian Kimes told **The Cancer Letter** after the meeting. Kimes is associate director for extramural research of the Div. of Cancer Biology & Diagnosis, where the new program is housed.

Part of the realignment is transfer of the Organ Systems Section, formerly located in the Cancer Centers Branch of the Div. of Cancer Prevention & Control, to DCBD. It is being elevated to branch status and will be known as the Organ Systems Coordinating Branch. Andrew Chiarodo, long time chief of the section (it was a branch at one time, before the previous reorganization), will stay on as branch chief. The position probably will have to be competed due to federal regulations, but Kimes, DCBD Director Alan Rabson and NCI Director Samuel Broder want Chiarodo in that job.

Also staying with the program are Elizabeth Anderson and William Straile, scientist administrators.

Here's how Kimes described the Organ Systems Coordinating Program:

The purpose would be to promote multidisciplinary research in solid tumors; emphasize research in etiology, biology, diagnosis, prognosis, and treatment based on novel concepts; serve as a responsive vehicle for addressing high priority areas in the National Cancer Program; serve as one focus for tracking, reporting, and evaluating information related to solid tumor research within NCI; and promote dialogue and interactions across NCI divisions.

Major operational elements would include two "major, comprehensive workshops per year," three focused workshops per year, program announcements, conference grants, reporting, tracking, information, and evaluation activities, and the Organ Systems Committee.

The Organ Systems Committee consists of representatives of each NCI division and is chaired by Kimes, with David Longfellow of the Div. of Cancer Etiology as vice chairman.

There will be no outside advisory committee, Kimes told **The Cancer Letter**. The new program was devised without any input from non-NCI people and apparently will continue without any, except perhaps from the NCAB if its Organ Systems Committee remains in force.

The Organ Systems Coordinating Program will report directly to Broder, who said, "I plan to actively participate in the management of the program. It will remain a principal link and vehicle for communication and interaction between the institute staff and scientists in the biomedical research community. We fully recognize that it is the past contributions of working grooup members and participant scientists that have formed the creative foundation of the Organ Systems Program."

The new program, Broder said, "will preserve the most effective elements of the past and will efficiently continue to identify

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and explore future scientific opportunities in solid tumor research."

"NCI believes this plan is a realistic one for promoting multidisciplinary solid tumor research," Kimes said. "It is also a plan which can be modified and expanded as successes accrue and additional resources become available. There is increasing evidence that the etiology of solid tumors is different from leukemias and lymphomas, and thus if NCI is to implement an effective plan for reducing cancer incidence and mortality, there must be an increased and progressive emphasis on solid tumor research now and in the future."

Broder said that he hoped participants in the Organ Systems Program "will form a partnership with NCI in addressing national priorities related to disproportionate mortality rates among minorities, underserved populations and people over the age of 65."

In addition to program announcements and requests for applications (both aimed at stimulating R01 grant applications, with RFAs involving funds set aside specifically for a particular area of research) which come out of OSP initiatives, Kimes told **The Cancer Letter** that he hoped it would generate some program project applications.

Mihich pointed out that "the original attempt to keep the working groups with representation of NCI staff has been abandoned in favor of ad hoc working groups created around workshops. That is a major change. . . You are relying on occasional ad hoc input for NCI promoted workshops. You won't have the same broad based input. That's fine, that's the choice you made. But that's the reality."

"I'm disappointed," Lawrence said. "The working groups as they were formulated worked fine."

The Organ Systems Coordinating Center at Roswell Park Memorial Institute will go out of business at the end of July when the cooperative agrement with NCI expires. NCI has approved a no cost extension to permit some loose ends to be wrapped up.

James Karr, director of the coordinating center who fought a losing battle to keep the program intact, is optimistic that the new arrangement can succeed. "I hope that people in the working groups as well as other scientists will participate in the program when called upon, and help make it work. The fact that Dr. Broder and Dr. Rabson have indicated they will be actively involved is a real plus, and is absolutely necessary to its success."

The first two major conferences will be on breast and prostatic cancer. "Major emphasis will be placed on approximately two solid tumor sites each year," Kimes said. "This will be accomplished through two major comprehensive workshops involving key extramural scientists and NCI staff. Each workshop will be evaluated and summarized by an ad hoc working group selected from the workshop participants. Potential inititives from these workshops will be pursued by the NCI divisions and will involve working group members, NCI staff, and members of the NCI boards of scientific counselors. The working groups and their members will help NCI implement these recommendations as the process moves forward for developing research initiatives in the program of program announcements and requests for applications. Summaries of the workshops along with working group evaluations and recommendations will be prepared for publication in major cancer journals."

Approximately three smaller, focused workshops will be held annually to address issues of immediate concern to NCI. Ad hoc working groups will be used to address those issues.

Kimes indicated that NCI's budget restrictions made it necessary to cut back on the scope of the program. "While NCI continues to expend substantial resources in support of research related to the current seven organ systems, realistically, resources are not available to pursue seven or more OSP workshops and resulting initiatives in a major way each year. Competition among the seven sites can be avoided if sufficient resources are committed to reviewing and evaluating two organ systems adequately each year. Over time, all of the major solid tumors will be emphasized by NCI in a substantive way. In order to reaffirm interest and commitment in funding investigator initiated basic and clinical research, NCI plans to issue seven program announcements addressing the areas of bladder, breast, central nervous system, large bowel, pancreas, prostate, and upper aerodigestic cancers."

"I hope the current working groups will continue to help us develop these anannouncements," Broder added. "New ideas on major solid tumors that are stimulated by these announcements will be given priority consideration in the institute's funding plans."

Conference grant applications to establish traditional biannual or triannual investigator

initiated conferences in the major solid tumors will be encouraged, Kimes said. These are envisioned as Gordon Conference type meetings which would become established, traditional meetings within solid tumor fields, such as the currently established Prout's Neck Conferences for prostate cancer. NCI would provide substantial support for these conferences, Kimes promised.

1991 Bypass Budget Would Fund 50% Of Competing Grants, Add 5 Centers

The National Cancer Advisory Board last week approved a 1991 fiscal year bypass budget for NCI of $2.405 billion, which would restore cuts taken in the President's 1990 fiscal year budget and enable 50 percent of competing grants to be funded.

President Reagan's farewell budget requested $1.6 billion for NCI, only a 4.7 percent increase over FY 1989. The fiscal year 1991 bypass budget would provide a 46 percent increase over the President's 1990 budget.

The bypass budget would provide $212.5 million for AIDS research, a 40 percent increase over the President's 1990 budget request of $151.3 million.

NCI is the only NIH institute with authority to develop, make public and submit directly to the President its own budget. That authority was granted by the National Cancer Act. The bypass budget, drawn up by staff with the advice of the NCAB, is intended by law to tell the President the amount required, based on scientific needs and opportunities, to carry out the National Cancer Program to the optimal degree.

Here's what the bypass budget, if approved by the President and Congress, would mean in the 1991 fiscal year, which starts Oct. 1, 1990:

<>Research project grants (ROIs, POIs)--The bypass budget would provide $1.03 billion, a 34.5 percent increase from the President's 1990 budget of $768 million. This amount would restore reductions taken in fiscal year 1990 for continuing and competing grants; fund competing grants at full recommended levels; award 50 percent of approved competing grants (approximately 1,500 competing projects). By comparison, NCI estimates it will fund only 29 percent of approved grants in 1990.

<>Cancer centers--The bypass budget allocates $144.8 million to centers, a 43 percent increase over the President's 1990 budget. This would enable NCI to pay continuing centers at committed levels and competing centers at full recommended levels; fund five new centers in 1991; continue funding of one or more minority demonstration centers.

By contrast, in the President's 1990 budget, funding for the centers dropped to $97 million, a $1.2 million decrease, for cancer activities.

<>Cancer prevention and control--The bypass budget provides $156.6 million, a 111 percent increase over the President's 1990 budget of $74 million.

This amount would enable NCI to increase smoking cessation efforts including COMMIT and ASSIST Programs; expand nutrition laboratory; augment the Community Clinical Oncology Program to include minority CCOPs and increase the prevention clinical trials network through collaborative efforts with the existing Clinical Cooperative Groups; expand prevention education program.

<>Clinical cooperative groups--The bypass budget provides $94.3 million, a 58 percent increase over the 1990 request of $59.7 million.

If this amount were allocated, NCI would expand accrual to high priority trials; increase patient accrual efforts including increased initiatives for minorities and other segments of the population, including people over age 65.

<>Training--The bypass budget would provide $45.2 million for the National Research Service Awards, a 36.7 percent increase over the President's 1990 budget of $33 million. This would enable the program to support 1,600 full time equivalent trainees and provide a stipend increase.

In addition, the bypass budget would provide funding for 50 percent of approved applications and implement new training and education initiatives for college and precollegiate students.

<>Construction--The bypass budget would request $55 million for construction, as opposed to zero construction funds in the President's 1990 budget. This would enable the modernization and upgrading of facilities in the extramural community and at the Frederick Cancer Research Facility.

<>Supercomputer--Provide $40 million for the upgrade and expansion of biomedical research computing capabilities.

<>Minority initiatives--Increase efforts to determine differences in cancer etiology and survival for minority populations, including blacks, Hispanics, Hawaiians and Native Americans; expand the number of historically

black colleges and universities involved in prevention awareness efforts; increase support for NIH MARC program to attract students from minority institutions to pursue careers in the biomedical sciences.

<>Over 65--Expand efforts to determine survival and mortality differentials in persons over age 65 compared with those under 65; provide supplements alone or through cofunding arrangements with the National Institute on Aging in areas of expertise and opportunities relative to the prevention, early diagnosis and treatment for persons over 65.

<>Diagnosis program--Increase efforts to expedited the transfer of new diagnostic approaches into clinical application.

<>Drug development--Expand natural products chemistry research and screening efforts in preclinical drug development.

<>Vaccine research--New emphasis on cancer related vaccine research, viral research, specific antigens and markers for tumors, for example, tumor infiltrating lymphocytes and the special cell surface epitopes that elicit such host defense cells.

<>Women's cancer detection program--Expand and enhance efficacy of outreach activities relative to mammography and Pap tests.

<>Information dissemination--Expand the Cancer Information Service to fully support 26 contracts and to provide each with health educators; augment patient education activities to emphasize projects for the elderly; increase distribution of publications and handling of telephone inquiries.

The expansion also would increase the number of public service announcements, especially outreach programs aimed at minorities; increase methods to address information dissemination in the areas of cancer prevention, diagnosis and treatment where illiteracy is a factor.

<>Perhaps the most crucial problem facing NCI is the reduction in number of positions (full time equivalents, or FTEs). Since 1982, NCI has experienced about a 20 percent reduction in the number of FTEs.

The bypass budget includes funding for 2,600 FTEs. NCI now has 2,150 FTEs, and needs at least an 8 percent budget increase to maintain current the current level of full time positions.

Under the President's 1990 budget, NCI would lose 28 FTEs for cancer, but would receive 32 additional FTEs for AIDS, resulting in an overall increase of four FTEs.

Settlement In Lawsuit Clears The Way For Human Gene Transplant Study

A court agreement reached this week finally clears the way for the first human gene transplant experiment and requires NIH to open future decision making on human gene experiments to the public.

The settlement came in a lawsuit filed Jan. 30 challenging the use of a foreign gene in experiments to be conducted on 10 patients with melanoma by NCI Surgery Branch Chief Steven Rosenberg.

The suit was filed by the Foundation on Economic Trends and its president Jeremy Rifkin. The suit had claimed that the NIH Recombinant DNA Advisory Committee approved the experiment on melanoma patients without conducting proper public hearings.

Federal District Judge John Penn signed the agreement to dismiss the suit. Under the terms of the settlement, the committee must hold all deliberations and votes in open public sessions.

HHS Secretary Louis Sullivan approved the ammendments to the advisory committee's charter, which contains the new requirement.

In January, the advisory committee and NIH Director James Wyngaarden gave final approval for Rosenberg and investigator French Anderson of the National Heart, Lung & Blood Institute to treat malignant melanoma patients with tumor infiltrating lymphocytes, a technique Rosenberg pioneered.

The TIL cells generated from each patient's tumor will be genetically marked by inserting a gene that codes for resistance to neomycin and reinfused into the patients. The gene coding will enable TILs to be tracked for longer periods than in the past, the researchers have hypothesized.

In addition, the researchers hope to insert into the TILs cytokines that will increase their therapeutic effectiveness. Cytokines such as tumor necrosis factor, alpha interferon and interleukin-2 are being considered for this therapy, Rosenberg told the National Cancer Advisory Board in February.

Two Concepts For Cancer Screening Approved By DCPC; Total $12.6M

Two major new grant concepts that would commit a total of $12.6 million to improve cancer screening and early detection for low income minority women and Hispanics have been approved.

The Div. of Cancer Prevention & Control

Board of Scientific Counselors gave concept approval to the two programs, which are scheduled to start in the 1990 fiscal year.

The Board also approved a concept statement for the reissue of an RFA for cooperative agreements with an unspecified number of state health departments to develop cancer control demonstration projects.

Summaries of the concept descriptions and board discussion follow:

Public health approaches to increasing the use of mammography and cervical cytology among unscreened women aged 40 years and over. Three or more awards in different geographic areas, five years, total cost $5.1 million. Allocation as follows: $900,000 a year for the first, fourth and fifth years and $1.2 million a year for the second and third years.

The goal of this project is to develop, implement and evaluate programs designed to increase breast and cervical cancer screening of older, low income, low education level and minority women.

The primary objectives of this research are to demonstrate how a consortium of community agencies can:

1. Characterize utilization patterns for mammography and cervical cytology screening in the target population through baseline surveys. These data will establish frequency of screening, as well as assess barriers to utilization.
2. Design and pilot test interventions to recruit women in need of mammography and a Pap smear that can be integrated with other health services used by these women, and affect the behavior of women who are not health agency clients.
3. Evaluate the effectiveness of specific interventions to reach the target population for breast and cervical cancer screening.
4. Assure compliance with follow up recommendations for women with anything but completely normal mammograms and smears.
5. Describe prospectively the screening behavior of the targeted women in view of current NCI recommendations, i.e., establish that women are coming back at recommended intervals for screening.

Each year 41,000 women die of breast cancer and 4,500 die from cancer of the cervix. Women most likely to die are the least likely to have been screened. Among women age 40 and over, those of lower income, lower education level and members of minority groups are less likely to have been screened for cancer.

Public agencies or institutions, such as health departments, community health centers, outpatient clinics or public hospitals frequently are health care providers for lower socioeconomic status populations, or have the responsibility for assuring that health services are available. However, these agencies have not been developing strategies to increase the availability and utilization of mammography and Pap smears by women over age 40. Although not identical, the overlap in risk status for breast and cervical cancer based on age provides strong justification for linking efforts in these two areas.

A consortium approach, involving multiple organizations and agencies with established links to the target population, will be used. (For example, the health department may have experience with providing or contracting for health services, an area agency may have established networks with elderly women and the American Cancer Society may have experience with providing public education campaigns.) The lead agency must demonstrate experience with disease control, but does not have to be the direct provider of screening services. In many communities, the lead agency is likely to be the health department, however, other public agencies could fill this role.

This approach will permit extrapolation of research results to other communities nationwide. Exceptions to the geographic focus may be proposed, if generalizations can be made from the applicants defined population to the larger community.

Census and/or survey data should permit the characterization of both the female population of a defined service area and their sources of health care. The choice of communities and awardees should provide opportunities to test a variety of promotional strategies. Of particular interest is the effectiveness of approaches that contact women who are already receiving care in public health clinics, or other public facilities, for problems unrelated to cancer screening ("inreach"), as compared to strategies to encourage women who are at risk to come in for screening examinations ("outreach"). Both approaches to the problem should be developed.

Investigators must be able to enumerate unscreened women in the population. They must propose a feasible and technically sound means for measuring the effect of their proposed inreach and/or outreach intervention. A variety of experimental and quasiexperimental designs may be employed in testing interventions, including the use of control communities. An adequate design must be employed to reliably demonstrate the effectiveness of interventions in reaching the target populations. An assessment of current utilization patterns must be conducted before any intervention is undertaken.

Researchers should identify and consider barriers to utilization of mammograms and Pap smears among the high risk groups, as well as mechanisms needed to overcome them.

Investigators will be required to document that they have access to and can recruit a population of unscreened women who are of low socioeconomic or minority status. They will have to provide or arrange for the necessary screening and follow up services. A feasible plan to integrate intervention into the usual practice of the health care facility also will be required.

For cases with any but normal screening results, investigators will be required to plan and implement procedures that will assure compliance with appropriate follow up recommendations.

All clinical, laboratory and radiologic procedures performed in relation to the grant supported interventions must meet state of science levels.

This research will be accomplished by official health agencies or institutions, such as health departments, community health centers or public hospitals, in collaboration with other community agencies or institutions capable of addressing early detection of breast and cervical cancers in the target population. The lead agency must demonstrate experience with disease control and must indicate how coordination of agencies will be conducted.

It is feasible for these agencies to collaborate with research institutions or efforts, such as the Community Clinical Oncology Program, especially when addressing professional education as a means to increase utilization of screening procedures. It is not the intention of this research to offset the cost of screening procedures. However, in order for this research to be of benefit to other communities, applicants must document that they will be able to provide these procedures in significant numbers at low cost.

High priority will be given to research designs that ensure continuation of the project beyond the funded period.

A project steering committee of scientific experts

will provide direction to the project through a series of collaborative meetings with award recipients.

Board member James Holland said he was "disappointed" that the concept did not encourage breast self-examination. Lawrence Bergner of the Cancer Control Applications Branch, who presented the concept, said many health departments are promoting only BSE, and efforts need to be made to promote mammography.

"I don't read in this that BSE should not be taught," said Board Chairman Paul Engstrom. The consensus at recent conferences has been that BSE should be promoted among women aged 20 to 40, and that mammography should be emphasized among those over age 40, he said.

Board member Edward Bresnick suggested the RFA, when it is released, say that respondents should address the "window" for BSE in women aged 20 to 40.

Board member Philip Cole said he was concerned about the requirement for "integrating" the women into the health care system. "These women are very hard to keep in contact with," he said. "If we can show that we can get these women screened just once, that would be a major achievement. Going beyond that is a heavy cross to bear."

Board member Mary-Claire King said the program ought to make clear to women how the screening will be paid, where they will go for follow up, and how follow up will be paid for. "This is a splendid project, but the money for the program is pitifully small," she said.

DCPC Director Peter Greenwald said that the Board could recommend a higher budget for the grant.

"We're always going to have small budgets," said Board member Rumaldo Juarez. "We need to make some progress on cancer among the lower class. This concept deserves support."

Board member Robert McKenna moved that the Board accept the concept as written, with the added provision that BSE be "part of the total package."

The concept was approved unanimously.

Intervention research in Hispanic populations. RFA concept for cooperative agreements, six awards, five years, total cost $7.5 million, estimated $250,000 per award per year. Geographic and Hispanic subgroup representation will be considered in making the awards.

The goal of this concept is to stimulate a wide range of intervention research activities designed to reduce cancer morbidity and mortality in Hispanic populations. The range of research is not limited to any particular aspect of cancer prevention and control, but may include, for example, methods for circumventing barriers to health system utilization, strategies to increase early detection of cancer, or prevention strategies including smoking cessation and diet. The research objectives include:

A. Characterization of the cancer prevention and control needs including health care utilization and risk factor patterns of specific Hispanic populations.

B. Identification or development and pilot testing of new or existing intervention methodologies designed for use specifically in Hispanic populations.

C. Implementation and evaluation of interventions designed to reduce risks or circumvent barriers to cancer control programs in Hispanic populations.

NCI's planning efforts have identified that Hispanic Americans (defined as Mexican Americans, Puerto Ricans, Cuban Americans and Central and South Americans) are underserved are without culturally and language specific cancer prevention and control programs while they continue to experience unique and escalating cancer incidence and mortality rates.

Existing data, though limited, strongly suggest that Hispanics experience an overall lower cancer incidence rate than other ethnic or racial groups. However, the data also show increasing rates for certain cancers in Hispanics when compared to Anglos. Other data show that in the future, smoking may be a problem with Hispanic populations; that knowledge of cancer and of cancer warning signs is not as high as among Anglos; and that certain cancer survival rates are lower for Hispanics.

The data indicate a need for cancer intervention to reduce risk factors, circumvent barriers to early detection and screening of certain cancers and explore the dietary practices of the Hispanic population.

The purpose of this concept is to stimulate developmental and intervention research directed to Hispanic populations. The research is envisioned to progress through two phases.

In the developmental studies the focus should be on developing and validating instrumentation for use in the evaluation of cancer prevention and control intervention research. These instruments will be developed and pilot tested in phase 1 and validated in phase 2 using the population for which it was developed. In intervention studies, during phase one the investigators will focus on identification and analysis of cancer prevention and control program needs for the specific Hispanic population to be studied.

This phase would likely include: 1) a cancer needs assessment, 2) the identifi- cation of attitudes, knowledge levels and the individual health care utilization practices of Hispanics, 3) the identification and adaptation of existing intervention methods for the targeted population, 4) the develop- ment of new intervention methods, and 5) the pilot testing of particular interventions. This phase also would include the development of an implementation and evaluation plan for phase 2. During the second phase, interventions would be implemented and evaluated according to the plans developed in the first phase.

The foci of these projects may include research on all aspects of the intervention implementation designed to address the cancer related needs of specific Hispanic populations, for example: 1) studies to identify of validated strategies which would increase early detection and circumvent screening barriers, 2) interventions designed, developed and adapted to reduce or prevent smoking among Hispanic youth, 3) studies to explore dietary interventions, 4) methods to remove the barriers to state of the art cancer treatment among Hispanic populations, or 5) research to address other cancer control factors such as exposure to chemical carcinogens.

The cooperative agreement mechanism is considered the most appropriate for this research for the following reasons. First, interventions developed for the general population have not effectively reached the Hispanic populations. Second, the consensus of three working groups convened in 1988 by the Hispanic Cancer Control Program determined that interventions initiated in Hispanic communities have not been sufficiently studied to allow NCI to specify the precise content and approach of prevention and control interventions for Hispanics. Third, current data suggest that intervention research targeted to Hispanics would profit from the consistent application of certain behavioral and organizational principles. The use of the cooperative agreement mechanism would allow program staff to work cooperatively with investigators to sharpen current intervention designs, building on the expertise and experience of the researcher, to create programs most likely to effect behavior change in Hispanic populations.

In addition, some common principles, data elements, procedures and evaluation instruments could be developed to maximize the usefulness of the research for other Hispanic communities. Researchers would respond to the RFA with a detailed study plan for both phases of research. Involvement of NCI program staff would include the normal stewardship responsibilities,

participating in the design of interventions, advising on the selection of investigators and consultants, participating in the coordination of survey and reporting instruments, convening steering committee meetings as well as advising and reviewing interventions models and strategies for language and cultural relevancy.

This research will place a special emphasis on access to Hispanic populations and sensitivity to cultural issues. Special consideration will be given studies that focus on the cancer control needs of specific Hispanic groups and that target particular geographic locations with known heavy concentrations of Hispanic populations, including South Texas, Illinois, New Jersey, Florida and Southern California.

Board member Donald Hayes immediately made a motion for approval of the concept. "I was an expert on cancer control--until I dealt with the Hispanics and found I didn't know a thing," he said.

Holland noted that several institutions involved in the Cancer Centers Program are located in areas with large Hispanic populations.

Elva Ruiz, program director in the Special Populations Studies Branch, said while Holland was correct, it appears that Hispanics are not being reached. Even higher income level Hispanic women are less likely than whites to get cancer screening, she said.

Board member Frank Meyskens agreed. "Except for Univ. of Southern California, very little is being done," he said.

Greenwald said the concept is not directed at centers, though they can apply.

Engstrom asked how the money would be split among six awards. Ruiz said each awardee would receive $250,000 a year.

Juarez said he supported the concept and opposed making the program "an appendage" to the Cancer Centers Program. "The problem is there is zero representation of Hispanics in the centers," he said.

Board member William Darity agreed. "I do not see this being carried out by centers. Once it got going, then if they want to do this, fine."

Bresnick and Board member Shirley Lansky both said they supported linkages between centers and public health agencies to carry out this program.

Board member Alfred Haynes said he supported the concept because of his own experience as a resident in obstetrics in a Hispanic area of New York City. "No one spoke Spanish, so we shouted in English, thinking they would understand," he said.

McKenna said he supported the concept, but that it was "trying to solve the total problem with a Band-Aid." He said that in Los Angeles, where his practice is, many minority groups are underserved. "I do think comprehensive cancer centers ought to address this. This is a start, and I strongly endorse it, but don't forget all the other minorities."

The concept was approved unanimously.

Data based Intervention research for public health agencies. Reissue of an RFA for cooperative agreements, approximate budget per award is $765,000 for the data gathering phase and $645,000 for the intervention phase, over a seven year period. Total number of awards not specified and will depend on priority scores.

The goals of this program are to fully utilize existing data for the planning and execution of cancer control programs on the state level which are consistent with the NCI Year 2000 goals and to develop demonstration projects in the use of such data for planning and execution of cancer control intervention programs.

This RFA was first issued in 1986 as a five year grant. Seven state health departments were funded for the first phase, and six of the grants have now continued into the intervention phase. Subsequently, the program was changed from a grant to a cooperative agreement mechanism, and the time period was extended from five years to seven years. This request is for approval to reissue the concept for a third time.

The data based intervention grants have been directed to state health departments to accomplish the following:

1. Reviewing the state specific cancer data in order to provide an understanding of the unique cancer problem in that state.
2. Forming and working with a coalition or council of individuals and organizations which can assist in the assessment of the data and the development of a state cancer plan.
3. Undertaking interventions as proposed in the plan, including the education of state legislators as to the cancer problem in the state, what can be done about the problem and what resources are necessary to respond.
4. Evaluating the grant activity and the total cancer prevention and control effort as defined in the plan.

This is to be accomplished in four phases:

Data review and evaluation: Data for the state population should be evaluated both for cancers and risk factors for cancers related to the NCI Year 2000 goals. This phase may last for up to nine months. In some states, some states, some of this information may already have been collected. In such cases, applicant may request to move immediately into the appropriate later phase.

Planning: The data is to be interpreted and incorporated into a specific cancer plan for the state that can be endorsed by a variety of agencies and institutions throughout the state. Plans also will be developed for the specific interventions that are to be part of the grant process. This phase should last about nine months, overlapping somewhat with the first phase. Where this work has been previously accomplished, applicants may chose to begin at a later phase. At the end of the planning phase there will be a formal review process using both NCI and other reviewers to evaluate progress.

Pilot testing and initiation of intervention activities: Interventions determined in the planning phases to be defined by the data and important within the priorities of the state will be pilot tested and initiated within this phase. Such interventions might include demonstration projects within certain geographic areas such as counties or major efforts to organize and facilitate intervention statewide. For those applicants having to go through all phases of the project, the intervention phase obviously cannot be described sufficiently for adequate review; however, because the cooperative agreement mechanism will be used, NCI staff will be able to verify the validity and likelihood of success of the effort. It is anticipated the review will include both a site visit and formal review.

A key aspect of this phase is the education of state legislators as to the cancer problem that exists within the state including its risk factors, what can be done about the problem and what resources are necessary to respond to the problem. This phase should be no longer than three years, and the combined first three phases no more than four years.

Leslie Boss, program director in the Cancer Control Applications Branch, told the Board that this program has been successful. Half of the states responded to the RFA the last time it was issued, and seven health departments received funding. She said a number of "excellent" applications had just missed the payline.

The number of applications that will be funded this time is not clear, although some Board members suggested that five be funded. The actual number will depend on the priority scores.

The concept was approved unanimously.