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## ORGAN SITE REVIEW COMMITTEE RECOMMENDS CONTINUING PROGRAM DESPITE SOME WEAK AREAS, SUGGESTS CHANGES

The National Organ Site Program Ad Hoc Review Committee has recommended that the four projects presently in the program be continued despite a number of weaknesses the committee said it found in the review.

Major changes recommended by the committee include phasing out

*(Continued to page 2)*

*In Brief*

### HENNEY PERMANENT NCI DEPUTY DIRECTOR; 17 REGIONAL COOPERATIVE GROUP APPLICATIONS GET FIRST REVIEW

**JANE HENNEY'S** status as acting deputy director of NCI was changed to permanent by HHS Secretary Richard Schweiker, who signed off on her appointment last week. She has been acting deputy for more than a year and before that was special assistant for clinical affairs in the Div. of Cancer Treatment. Henney, 34, received her M.D. at Indiana Univ. School of Medicine and training in medical oncology at M.D. Anderson. . . . **SEVENTEEN APPLICATIONS** for the regional cooperative group awards received an initial round of review last week by the ad hoc cooperative group review committee (sometimes called "CCIRC B"). A final review by the committee is scheduled for March 29-30, after responses from applicants to questions generated in the first review. The committee is chaired by Richard Kempson, pathologist with the Northern California Oncology Group. Two of the applications are for specialty groups—a pediatric group covering the New England area and centered around Boston Children's Hospital, and a urologic group in New York City. NCI had hoped to fund three this year with a total budget of $1.5 million. Some of the applicants are asking for less than $500,000 in the first year, so it is possible that more than three will be funded. . . . **JOHN MACDONALD**, director of the Cancer Therapy Evaluation Program in the Div. of Cancer Treatment, is leaving NCI for private practice. His deputy, Daniel Kisner, will be acting director. . . . **APPROPRIATIONS SUBCOMMITTEE** hearings on NCI's 1983 budget will be held Feb. 22 by the Senate and March 2 by the House. . . . **FOUR NCI** senior scientific and senior executive service staff members received outstanding performance awards ranging from $4,000 to $10,000 in 1981. They are Richard Adamson, director of the Div. of Cancer Cause & Prevention; Mones Berman, chief of the Laboratory of Mathematical Biology in the Div. of Cancer Biology & Diagnosis; Tibor Borsos, acting chief of the Laboratory of Immunobiology in DCBD; and Paul Van Nevel, director of the Office of Cancer Communications. Calvin Baldwin, former NCI executive officer and now NIH associate director for administration, also received one of the awards.

## REVIEW GROUP SAYS KEEP FOUR ORGAN SITE PROJECTS, DON'T START ANOTHER

*(Continued from page 1)*

of long term clinical trials supported by the projects; consolidation and streamlining of headquarters services; reducing cost of review perhaps by consolidating the four review groups into one or two; reducing the length of grant awards to no more than three years with limited renewals, permitting more awards to new and innovative investigators; and eliminating awards to individual members of project working cadre during their tenure on the cadre.

The committee reported it found deficiencies in basic research ("a number of research projects would probably not compete favorably if reviewed by an NIH study section"), in development of biological models, in tumor markers and immunology, molecular biology, carcinogenesis, and epidemiology. Perhaps the most serious weakness, the committee report said, is in the area of clinical research. Exceptions were noted in each case where high quality work was found.

The review committee was established at the request of the National Cancer Advisory Board on the recommendation of its Subcommittee on Organ Site Programs. Previous reviews by NCAB members had supported continuation of the program. The subcommittee recomended this time that it be done by an independent team of scientists and clinicians who were not members of the Board nor affiliated with any of the projects in the program.

NCI Director Vincent DeVita had initiated discussion of the Organ Site Program's future by reducing its budget and by suggesting that the time may have come to start phasing out some or all of the projects. The subcommittee called for an outside review with the following charge:

A. Critique of the guidelines and objectives of each project–

1. To what extent are guidelines and objectives still viable?

2. To what extent have they been met?

3. To what extent are programs being planned and priorities set?

B. How effective has the project been in attracting new investigators and has this been sufficient to the needs of the problem?

C. Has the research been unique and specific to the needs of the organ site projects?

D. Could the activities, including planning, recruitment of investigators, review, setting priorities, and scientific investigations, have been accomplished as effectively by conventional grants, with or without the use of RFAs, Task Force, or other mechanisms?

E. Has the project resulted in increased interdisciplinary action between basic and clinical scientists?

F. Is the administration of the project efficient and is it cost effective?

G. Are appropriate steps being taken to plan programs for future efforts?

H. Should each of the organ site projects be continued in its present format? Should it be phased out, changed to a Task Force, or be reviewed and administered as a conventional research grant? Should new organ site projects, e.g., one for respiratory cancers, be initiated?

On the last charge, the committee said it was "not prepared to recommend that any new cancer sites be added to the program."

The report was discussed in closed session last Sunday by the subcommittee and again in closed session by the full Board Tuesday. The subcommittee's recommendation and the report were scheduled for discussion in open session Wednesday. The subcommittee had agreed to recommend acceptance of the report and its recommendations.

The complete report of the review committee follows:

The National Organ Site Program consists of four grant supported projects of targeted cancer research. Each project is a planned research effort oriented toward cancer of a specific organ. At present, there are organ site projects concerned with cancers of the urinary bladder (1972), large bowel (1972), prostate (1972), and pancreas (1975). A headquarters institution other than NCI plans, directs and coordinates each project. A national project director–not an employee of NCI–is assisted by a headquarters staff and by a working cadre of research scientists recruited from institutions throughout the nation. Grant applications are received by the headquarters and are reviewed by the working cadre and later by the National Cancer Advisory Board. Scientifically meritorious and relevant applications are recommended to the NCI for funding.

The National Bladder Cancer Project (NBCP) is directed by Dr. Gilbert H. Friedell, St. Vincent Hospital, Worcester, Mass.; the National Large Bowel Cancer Project (NLBCP), by Dr. Edward Copeland, M.D. Anderson Hospital & Tumor Institute, Houston; the National Pancreatic Cancer Project (NPaCP), by Dr. Isidore Cohn Jr., Louisiana State Univ. School of Medicine, New Orleans; and the National Prostatic Cancer Project (NPCP), by Dr. Gerald P. Murphy, Roswell Park Memorial Institute, Buffalo. The organ site projects also constitute a branch of the Div. of Resources, Centers & Community Activities of NCI, where three professionals and staff conduct the business necessary to the maintenance of the National Organ Site Program (NOSP).

At the request of the Organ Site Subcommittee of the NCAB, a review of the program was conducted on Nov. 22-25, 1981, at NIH, with each project director and his five or six selectees participating in a one-half day review of each of the projects. The nine reviewers included senior physicians in clinical practice and senior physicians or scientists engaged in basic research.

Each of the organ site groups supplied programmatic material to the reviewers; NCI staff furnished fiscal data. The review focused largely on organizational elements of the organ site projects and compared their accomplishments with the objectives initially developed in 1972. These included the following: 1) pursuit of targeted research through investigator initiated efforts; 2) application of a spectrum of research disciplines to cancer at specific organ sites; 3) encouragement of accomplished investigators to study cancer at specific organ

sites; 4) recruitment of administrative expertise from the biomedical community for planning and implementing targeted research; 5) funding of targeted research through a grant mechanism; 6) retention of the NIH system of peer review.

Because of time limitation, scientific and clinical accomplishments were not presented in depth at the meeting but spokespersons for each project were encouraged to highlight areas of substantial progress. Based on this, the publication record and the reviewers' perspective on the field, general comments were prepared concerning the relative quality of several elements of the program. What follows is meant to convey some view of individual elements that have helped frame the several conclusions. There was not unanimity in evaluating the quality of certain elements. Considerable attention was directed toward comparison of the activity of the projects with nontargeted research under other auspices.

**BASIC RESEARCH**

Participants in each of the organ site programs presented reports covering highlights of basic research and summarized their research efforts. These included models, biological markers, immunology, molecular biology, carcinogenesis, epidemiology, and diagnosis. The consensus was that most of the research being supported did not originate in the individual project, but was "derivative" of work accomplished elsewhere. Although much of it is well done, a number of the research projects would probably not compete favorably if reviewed by an NIH study section. In many cases, investigators have not asked questions specific to the organ site of interest but have approached their research with too broad a view. In general, the quality of science was uneven within as well as between each of the projects.

Biological Models. Several biological models, such as DMH-induced colon cancer, are being used but the research is not outstanding. Most of the models were developed before the inception of the NOSP and major conceptual developments cannot be attributed to this program. Furthermore, this model and others are not equivalent to the human disease in that they do not produce a CEA equivalent or parallel some of the other properties of the human disease.

Four transplantable tumors have thus far been identified by investigators supported by the NPCP and arrangements have been made for their dissemination as models for tumor biology and immunology. These models are the only ones available for the prostate, and their maintenance and use have been made possible by the NPCP. Studies of prostate tumor biology are less well defined, more limited in their application, and offer less potential than models for other organs.

No useful models for bladder cancer have been developed in this project. There is definite potential for study, however, based on the results of investigators active in this area.

The development of models may be the most promising segment of the pancreatic cancer project. Although these tumor models did not originate in the project, they have been effectively developed under its sponsorship. Efforts to develop an understanding of the phenomenon of progression and promotion in this model are considerably behind the skin and liver models of carcinogenesis.

Tumor Markers and Immunology. In general, the NLBCP does not appear to have stimulated new or imaginative research focusing on tumor markers or immunology. It ranks behind the bladder program in marker research and well behind the prostate project in immunology. There are several marker studies under way in the prostate project but as in the other projects, immunological research has not developed from evidence of organ specific responses or new findings related to tumor-host responses.

The bladder project is supporting important research in markers, including DNA and RNA cytophotometry, blood group antigens and karyotyping to predict invasiveness. Since the 1970s, it supported a major effort in immunology. Although this work was done thoroughly and carefully it, like many other similar studies elsewhere, has not generated evidence of a tumor specific immune response. To its credit, the working cadre recognizes the need to change direction, and is phasing out current studies in favor of new approaches.

Although a primary goal of the pancreatic project is to uncover a diagnostic marker, research on markers and immunology in general is weak. The project is supporting a potentially useful evaluation of the pancreatic oncofetal antigens as diagnostic markers for human disease.

All the projects have attempted to develop radioimmunoassays at some time but none of the studies has been fruitful. The reviewers noted that the NLBCP has already stopped supporting such efforts, and they recommended that the other projects be wary of continuing their support in this area. All the projects are either currently supporting or planning to support the development of monoclonal antibodies. Major developments in this field have not originated with the NOSP but the value of this approach is acknowledged if proper attention is paid to characterization and purification of the antigens. Until human monoclonal antibodies are available it may be premature to initiate the clinical trials that are under discussion.

Molecular Biology. Molecular biology studies in the four projects have not been very productive. For example, a major focus of molecular biology in the prostate project as presented was a study of the control of expression of the prostate-specific spermine binding protein, but its application to the diagnosis or control of prostate cancer was not clear. In order to take advantage of the technology available, especially in the area of carcinogenesis, the NOSP must attract more outstanding scientists with a molecular biology orientation, or at least demonstrate innovative approaches that utilize current advances in this discipline.

Carcinogenesis. Only a few models for carcinogenesis, such as the production of isolated colon epithelial cell cultures, originated with support from the NOSP; many were developed before inception of the program and originated elsewhere. The reviewers were concerned that despite the existence of many models there was not sufficient emphasis on exploiting them to understand the potentially unique properties of neoplasms in a specific organ or establishing the human equivalence of these models.

For the most part, carcinogenesis research conducted with these models is not outstanding. There are some exceptions, however, especially in the Bladder Cancer Project which supports some highly regarded scientists with long experience in this area.

Epidemiology. As a group, the four organ site projects are supporting relatively little in the way of classical descriptive epidemiology. What is supported appears to be of acceptable technical quality, but has not resulted in any major advances.

**CLINICAL RESEARCH**

It was the unanimous and strong opinion of the reviewers that the organ site programs should limit their support of long term, expensive phase 2 and 3 trials. Instead, they should emphasize innovative site specific developmental therapy and phase 1 studies, leaving further trials to the clinical cooperative groups supported by NCI through other mechanisms. The reviewers agreed that clinical studies undertaken by the NLBCP were valuable because of the way in which they were conducted and in their potential for new treatment regimens. They also agreed that the pancreas studies were of doubtful value because of their fundamental design and lack of specificity. They disagreed on the value of the prostate and bladder studies from the standpoint of originality and exploitation of new information.

Large Bowel. Recognizing that other organizations have

concerned themselves with clinical therapeutic trials, the NLBCP is focusing on the design, development, and early clinical evaluation of newer cancer drugs such as quinazoline derivatives. The investigators use various cell and tissue culture systems, murine transplantable tumors, chemically induced autochthonous tumors, and human xenograft models as guides. Radioimmunotherapy will be studied in the future, and further exploration of antioxidants as chemopreventive agents will be carried out using large bowel adenomas.

In general, treatment research sponsored by the NLBCP seems appropriate and of good quality, and the investigators rank well among their peers nationally. Efforts are being made to develop treatments more specific for large bowel cancer.

Prostate and bladder. In the opinion of some of the reviewers, the NPCP has conducted a series of well controlled clinical trials guided in large measure by experimental findings from their animal models. These include studies of hormonal treatments as well as cytotoxic therapies. Although response rates have not been impressive, these efforts represent the first organized, well controlled interinstitutional (13 institutions) clinical trials in this area. These are important beginnings by leaders in the field.

The NBCP headquarters staff is not directly involved in therapeutic trials except to administer grants to the National Bladder Cancer Cooperative Group A (NBCCGA), a multidisciplinary group with membership from 13 major institutions centered at the Massachusetts General Hospital. NBCP members have developed the FANFT murine bladder cancer model as a guide to therapeutic trials. They have also developed biological and pathological concepts of progression of human bladder cancers as a guiding framework for therapeutic interventions.

The preclinical studies leading to the design of clinical trials are good and the FANFT model has been put to good use. However, the administrative relationships between the NBCP and the clinical trials groups, including the NBCCGA, are tenuous, making it difficult to predict what impact the preclinical studies would have on clinical trials. Reviewers were also concerned about the accession of suitable patients to studies. Enhancing these relationships would improve the potential for future productivity.

The assessment of the other reviewers was not as positive for the two groups. They considered the clinical trials programs of the Prostate and Bladder Projects mediocre and pedestrian, and, for the most part, repetitive of studies done by other groups. They did not feel that the clinical investigators were exploiting marker or receptor studies to full advantage.

It was suggested that, at a minimum, these two clinical programs be consolidated. This would be significantly cost effective since seven of the 13 institutions participating in the bladder studies also serve as a source of patients for the prostate studies, but without any coordination of effort such as uniformity of administrative forms and sharing of statistical centers.

Pancreas. The NPaCP goals in the clinical area are limited to the development of novel therapies and the conduct of pilot studies. Because other organized groups are involved in more extensive therapeutic trials, these goals are reasonable. Plans to exploit any leads coming from basic animal research are not well developed, however; nor do present studies appear promising or specific to the treatment of pancreatic cancer.

**NATIONAL ORGAN SITE PROGRAM ADMINISTRATION**

In evaluating the National Organ Site Program, aside from scientific accomplishments, the reviewers critically examined certain administrative characteristics: management of headquarters site, cost effectiveness, the review process, and communication.

Headquarters. A unique feature of this program is the decentralization of management. Each organ site project is administered at a headquarters facility outside the National Cancer Institute under the leadership of a project director assisted by a headquarters staff and a working cadre of research scientists.

The reviewers were impressed with the high quality of leadership provided by the project directors. The directors are all knowledgeable scientists dedicated to the NOSP and enthusiastic about the program. In addition, they give a great deal of their time and energy with little or no monetary compensation.

An important issue is the degree to which management and direction of the program should be decentralized, in contrast to a program centralized at NCI. Decentralization was chosen originally to provide greater flexibility, broader vision, more rapid response to research leads, and stimulation of new activities. Such an arrangement was to lend itself to development of a center of knowledge and competence in an atmosphere of stability, relatively free of bureaucratic uncertainties.

Although these goals have been at least partially met, recent trends have diminished the autonomy that the four specific organ site projects once had. Problems include a substantial burden of governmental regulations and restrictions, requirements for the National Cancer Advisory Board to review every grant, delays in informing specific programs of funds available, and too frequent review of headquarters operations. Program personnel viewed the latter point as particularly limiting because of the great diversion of effort and resources needed to respond to a full scale review each year, as well as the loss of autonomy inherent in frequent adjustments required by central direction.

Headquarter costs for review was a disturbing feature of the NOSP. The following table summarizes these costs as well as the number of grants reviewed and active in FY 1981.

| FY 1981 | Large Bowel | Prostate | Bladder | Pancreas |
|---|---|---|---|---|
| Support for entire project | $5,245,000 | 4,095,000 | 4,617,000 | 2,005,000 |
| Support for headquarters | 603,847 | 577,490 | 310,923 | 265,779 |
| Number of active grants | 60 | 42 | 48 | 32 |
| Number of applications reviewed | 66 | 36 | 26 | 35 |

The reviewers contrasted the number of NOSP review sessions—three or four per year for each of the four projects, a total of 13 for FY 81 to review 163 applications—with the two sessions that would have been required by an NIH study section for the same workload. All things considered, the NOSP review costs are significantly in excess of what they would have been had the 163 projects been channeled through the ongoing study sections.

Reviewers were also concerned with the high cost of personnel and the cumbersome administrative structures of the headquarters. The four offices vary in their budgets and staff size, but without exception are overstaffed, especially in terms of associate and assistant program directors; they also enjoy a luxurious level of clerical and secretarial support. Travel costs are generally excessive in all four projects and a careful evaluation of travel costs for the administrative and professional staffs would be appropriate. The reviewers agreed that a major effort should be made to reduce the numbers of professional and support personnel in order to improve the administration and cost effectiveness of the projects.

In weighing the possible advantages of administering the program from NCI instead of from headquarters, the following factors were considered. Costs would be reduced somewhat, though not by the full amount because of the need to continue functions such as review of proposals, state of the art conferences and reviews, and communication with investigators. Activities now in the NOSP could be integrated with other organ specific activities of NCI, and management and re-

porting would be streamlined and simplified.

On balance, the reviewers believe that there is substantial advantage to the original concept of a true decentralization of management of the National Organ Site Program. However, the present situation of partial and diminishing decentralization of authority as well as some areas of inappropriate administrative growth places a limit on the realization of these advantages.

Review Process. The review process employed to assess the quality and project relevance of research grants is similar for all four of the organ site projects. A "letter of intent" is mandatory for two of the projects, Large Bowel and Prostate, optional for the Pancreatic Project and not used by the Bladder Project. This vehicle serves as the major access to three of the projects and determines the subsequent course of action by the applicant.

A working cadre, one for each project, convenes three or four times per year to review applications, previously sent to 2-6 reviewers for comments. Applications are recommended for approval, disapproval, or deferral at the cadre meetings and a priority is assigned to each one. As a final step, these reviews are submitted to NCAB for secondary review by mail ballot.

The working cadres are comprised of scientists from a wider variety of disciplines than are found in NIH study sections. This is essential to the multidisciplinary nature of the NOSP and its objective of interplay between basic and clinical science.

Currently, members of the working cadre may also be grantees of the NOSP. Most reviewers found this situation unacceptable and recommended that it not be continued.

In general, the limiting priority score that is funded is about the same as that for R01 grants. However, priority scores in the Organ Site Program were judged to be generous for the quality of the science in these projects. This is because program relevance, as well as scientific merit, is an important consideration in arriving at the priority score, while scientific merit is the overriding consideration in NIH peer review.

After a grant has been awarded, it is usually monitored more closely than those in the R01 program. Principal investigators are required to submit a progress report annually; these are read and carefully considered at the time of annual grant renewal.

In examining funding priorities in the NOSP, the projects, except for pancreas, have made many long term commitments, funding some studies for as long as nine years. As a result there is now little support for new projects and thus little opportuny for initiation of more innovative research.

Although the review process has been adequate, a major restructuring is in order to help make it more cost effective and to improve the quality of research sponsored by the NOSP. For example, the study and clinical management of bladder and prostate cancers overlap in the discipline of urology and many aspects of these two programs could be combined. Large bowel and pancreas projects also overlap in several areas, particularly general surgery and gastroenterology. Alternatives to the present review system are thus recommended later in this report.

Communication–Recruitment and Interaction. The NOSP is charged with recruiting highly competent scientists for research directed toward a specific organ site and with fostering interaction between basic scientists and clinicians. The groups have been successful in recruiting scientists into their specific areas and have indeed stimulated interaction among investigators. In the opinion of some reviewers, this interaction is one of the most positive features of the NOSP.

The groups have used various means to communicate program information to the scientific community. These include announcements in professional journals; notices to various departments of academic institutions; newsletters; exhibits; meetings held jointly with other organizations; a variety of liaison activities; publications; seminars; and workshops.

The workshops have been a particularly effective tool of the NOSP in their communication efforts. They are attended by grantees and other scientists and are sometimes international in scope. Most importantly, the workshops facilitate interaction between basic and clinical investigators. They provide investigators with an opportunity to develop future research strategies and set priorities; to analyze topics of growing interest; to be instructed in special topics; and to update, review, and resolve certain issues. They frequently result in the development of new ideas and in cooperative efforts between heads of institutions and departments.

Still more effective communication is needed on a regular basis to attract additional qualified investigators from a broader scientific base. Currently more than one half of grantees have been funded for six years or more, except in the more recently formed pancreas group. Information on the availability of funds often depends on "word of mouth," especially in the NBCP, and this situation needs to be corrected.

Communication between headquarters staff and grantees, as well as between headquarters staff and NCI staff is effective. On the other hand, there is little if any communication and coordination among the four project directors with respect to program development and resource sharing. It was the understanding of the reviewers that the projects were initially encouraged to develop along separate lines in order to nurture innovative and diverse approaches to organ site oriented research. Now, however, interaction between project directors is vital to overall program effectiveness and efficiency.

**RECOMMENDATIONS**

The review committee unanimously endorsed the concept of the organ site approach to cancer research and acknowledged the dedication and effective leadership of the project directors. They recognized, however, that the progress sought from the National Organ Site Program has not been achieved, primarily because essential basic knoweldge does not yet exist. Although progress has been minimal in the first decade, it was felt that continuation of the interdisciplinary efforts relatively unique to the NOSP approach might accelerate progress to a degree not possible by any other mechanism. Although the topic was addressed in general terms, the reviewers were not prepared to recommend that any new cancer sites be added to the program.

The reviewers made the following recommendations with the hope that the National Organ Site Program could be made more productive and cost effective:

1. The program should maintain the objectives formulated in 1972.
2. The program should continue to constitute only a small fraction of the NCI budget (approximately 5 percent).
3. The program should phase out support for long term clinical trials which place a disproportionate burden on its resources and are often repetitious. Instead it should support highly innovative pilot studies in patients and focus attention on basic research.
4. Management of the program should continue to be decentralized, with headquarters at institutions outside of NCI. Attempts should be made to restore the diminishing autonomy of the projects.
5. Headquarter services, such as statistical evaluation, should be consolidated, the number of personnel reduced, and the review process modified to cut costs, eliminate duplication of effort, and made headquarter operations more efficient.
6. Communication among project directors should be improved in order to foster exchange of scientific information and sharing of resources.
7. Means of communicating program and funding informa-

tion to the scientific community at large should be improved and standardized in an effort to recruit a broader range of highly competent scientists.

8. The review process should be streamlined in order to reduce the costs and time required by busy scientists for grant review and to foster communication among the groups. Following are some alternatives suggested by the review committee for further consideration in the near future: a) Form one review committee for all NOSP grants, with representatives expert in each of the sites; b) consolidate the review into bladder-prostate and large bowel-pancreas groups; c) use the established study sections at NIH for review.

9. To bring more new innovative investigators into the program, projects should be supported for a limited period, perhaps one to three years. Subsequent renewal should only occur in exceptional cases where continuity of support was essential to complete an objective.

10. As soon as possible the review process must be separated from planning.

11. A board of 3-5 uninvolved scientific advisors knowledgeable in the pertinent organ site should be appointed for program planning for each of the projects.

12. To avoid conflict of interest in the review process, most of the reviewers felt that grants should not be awarded to individual members of the working cadres during their tenure on the cadre. At present this is emphasized only in the pancreas project. Some members felt that the current practice of ad hoc reviews of the cadre member application was satisfactory and that their active support by the project might be important to the success of the project goals.

On the basis of evidence available at the meeting, the reviewers ranked the degree to which the projects had been successful in fulfilling the original goals in this order: (1) large bowel, (2) bladder and prostate (equivalent), (3) pancreas. There was least agreement on the value of continuing the large bowel project since it had successfully stimulated interest in and recruited scientific talent to this serious clinical problem. Some reviewers believed, despite the progress during the first eight years, that future impact of this project would warrant continued effort. Inasmuch as the pancreas project has only recently become adequately staffed and organized, the recommendation for its continuation was unanimous since the opportunity for development of new knowledge remains. In addition, studies focused on pancreatic cancer might affect the impact of this growing problem in the population.

## DRCCA BOARD, SUBCOMMITTEE APPROVE EDUCATION PROGRAM REORGANIZATION

The Board of Scientific Counselors of NCI's Div. of Resources, Centers & Community Activities approved recommendations of its Education Subcommittee which call for:

- Reorganizing DRCCA's education component, dropping one branch, creating another and combining two more into one, all under an upgraded Education Program.
- Giving DRCCA's Education Program oversight responsibility for the education projects supported by other divisions as a mechanism for "quality assurance."
- Adopting six criteria for appropriateness of education projects to be supported by DRCCA, based on a matrix of target groups and the intervention area, from prevention to terminal care.

Christine McGuire, chairman of the subcommittee, presented the recommendations to the Board.

DRCCA's present organization includes the Education Program, with three branches—Clinical Manpower, headed by Margaret Edwards; Research Manpower, headed by Barney Lepovetsky; and Educational Research & Evaluation, headed by Arlene Barro.

The subcommittee proposal would combine the Clinical and Research branches into one Professional Education Branch, with separate sections for Manpower Training and Career Development. The Educational Research & Evaluation Branch would be dropped, and a new Liaison & Oversight Branch would be established.

Excerpts from the subcommittee report follow:

The matrix defines, on the vertical axis, the relevant audiences to which educational programs should, in our view, be directed. You will note that the audiences include both professionals in clinical and basic science disciplines and various lay publics.

| Target Groups* | | Prevention | Screening | Detection | Diagnosis | Treatment | Rehabilitation | Terminal Care |
|---|---|---|---|---|---|---|---|---|
| Professionals: Specialist "Dedicated" | Generalist "Casual" | | | | | | | |
| Physician | | | | | | | | |
| Nurse | | | | | | | | |
| Nutritionist | | | | | | | | |
| Other Allied Health Professionals | | | | | | | | |
| Behavioral/Social Scientist | | | | | | | | |
| Epidemiologist | | | | | | | | |
| Biostatistician | | | | | | | | |
| Basic Scientist | | | | | | | | |
| Etc. | | | | | | | | |
| High Risk | General | | | | | | | |
| Public | | | | | | | | |
| Patients | | | | | | | | |
| Families | | | | | | | | |
| Workers | | | | | | | | |
| Students | | | | | | | | |
| Legislators | | | | | | | | |
| Etc. | | | | | | | | |

Within each of the groups of professionals named, two categories of personnel are identified: first, those who are specialists in oncology and whose work is dedicated primarily to clinical practice or research concerned with cancer; second, those professionals who, from this point of view, are generalists (i.e., they do not specialize in either clinical practice or research devoted to cancer) and whose assocation with the area is "casual." Similarly, the various publics are thought of as being composed of two groups: the high risk group and the general public. The horizontal axis of the matrix defines the various points on the spectrum, from prevention to terminal care, which educational programs should address.

In order to develop a comprehensive statement of the nature and kinds of educational activities which should be provided or promoted by DRCCA, the subcommittee recommends that this entire matrix be

considered and that six criteria be applied in making a decision about the appropriateness of supporting a project in any cell of the matrix. The six criteria are enumerated below.

Criterion One: Is there a need and a demand for an educational program in the defined area for the designated group? Note that the criterion includes the concept of "demand for," as well as "need for." By this specification the Subcommittee wishes to call attention to the fact that irrespective of the urgency of a particular social need, the impact of an educational program designed to meet it will be minimal unless there is also a demand for such a program, and, in the case of professionals, career opportunities for persons who complete it.

Criterion Two: Is education an appropriate type of intervention to meet the need? Clearly, social needs may be met by many different kinds of interventions and education is not always the most cost-effective. For example, consider the area of prevention for a target group of high risk workers. Various mechanisms, including regulation, inspection, equipment modification, etc., might be used to meet this need. Criterion Two requires that these alternative mechanisms be considered and a determination made as to the probable relative effectiveness of educational activities in meeting the need.

Criterion Three: Are there existing programs either within NCI or elsewhere designed to meet the identified need; if so, are they adequate?

Criterion Four: What is the priority for establishing a program in the specified area? Resources will never be adequate to provide programs in all the cells that meet the first three criteria. Consequently, it is essential that priorities be assigned and that the priorities represent an informed judgment about the relative urgency and the potential benefits of competing alternatives.

Criterion Five: Is a specific proposed project such that it is likely to fulfill the objectives (i.e. meet the need) for which it is designed? The subcommittee noted numerous examples of well intentioned programs which, though developed in accord with the preceding four criteria, were of such a nature as to have relatively little impact. It was the subcommittee's judgment that such failures occur, in part, because available educational and social-psychological expertise is inadequately utilized.

Criterion Six: For those programs which meet all of the preceding criteria, one final set of questions must be asked, namely: Is this program appropriately located within NCI? If so, where? If there is no existing mechanism which is appropriate, what kind of mechanism should be created? It is the subcommittee's view that NCI should have a very limited, if any, role in the support of basic educational research or in the continuing support of regular undergraduate medical or dental education.

Approval of the model outlined above clearly implies the need for an Education Program Area within DRCCA. As noted earlier, it is recommended that the functions of that program area be twofold: to develop, design and administer certain educational projects; and to serve a liaison or oversight function for purposes of quality assurance on projects administered by other program areas within the division and by other divisions within the institute.

**Professional Education Branch**

It is further proposed that projects in the Professional Education Branch be of two types: manpower training activities designed to provide or expand pools of needed specialists; and activities in support of a career development program.

With respect to manpower training, the subcommittee recommends that the activities include three major categories of projects: projects designed to serve the conventional purpose of bringing new persons into the pool of specialists; a variety of projects involving brief, intensive instruction designed to provide already trained professionals with new knowledge and skills as new fields or new requirements open up within a specialty; and projects designed to retrain previously trained professionals in related specialties or subspecialties so as to enable them to meet changing manpower demands.

It should be clear from the foregoing that the subcommittee regards both clinical and research manpower training as proper functions of the institute and appropriately located in a program area of DRCCA. However, the specific areas in which clinical and research training are to be supported should be reviewed and the areas of genuine need identified so as to assure that the programs are consonant with current needs. It is further recommended that there be an annual report to the Board of Scientific Counselors regarding specific manpower needs and that documentation of need be made prior to concept approval of any proposed project and prior to expert review of continuing projects. Secondly, the subcommittee recommends that creative and innovative mechanisms be considered for meeting the needs identified as genuine.

In addition to the manpower training program outlined above the subcommittee recommends that special attention be given to the creation of a systematic career development program to facilitate the flow of trained professionals between academic and institute research programs or between both of these and industrial programs for the mutual enrichment and revitalization of all. The subcommittee recognizes that implementation of such a program will require the institute to establish various types of linkages with the academic community and with industry.

**Liaison, Oversight Branch**

In the above statement of mission and elaboration

of the recommended model it has been repeatedly implied that many, perhaps most, educational projects supported by the institute will be developed and administered by divisions other than DRCCA and by program areas (within DRCCA). It has also been noted that, in the past, much of the educational activity has been pedestrian, unimaginative and ineffective, and that this may have been due, at least in part, to consistent failure to apply expertise from the educational sciences in program development. To correct this situation and to provide a mechanism for quality assurance the subcommittee recommends that a branch be established in the Education Program for administration of liaison activities and that this branch be responsible for providing expert resources for consultation, liaison, oversight, analysis and evaluation of educational projects administered in other program areas within the division and in other divisions within the institute.

Elimination of basic educational research as a function of NCI and assignment of responsibility for project evaluation as an integral part of each project, obviates the need for a separate Research & Evaluation Branch in the Education Program.

## OHIO STATE SCHEDULES CCOP WORKSHOP

**NCI is tentatively planning more workshops on the Community Clinical Oncology Program, following the one at St. Vincent's Hospital in Los Angeles last week, but locations and dates have not yet been determined.**

**Ohio State Univ. is sponsoring a CCOP workshop Feb. 19 in Columbus, at the Stouffer's Dublin Hotel. Charles Cobau, member of the committee which helped draft CCOP guidelines, will be the principal speaker. A limited number of out of state attendees will be accepted. Call Shirley Moen, 614-422-1382.**

## RFPs AVAILABLE

*Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.*

### RFP NCI-CM-27537-24

**Title:** *Biochemical genetic monitoring of rodents*
**Deadline:** *April 2*

NCI's Animal Genetics & Production Branch of the Div. of Cancer Treatment is seeking proposals from qualified organizations having the capabilities, resources and facilities to provide a genetic monitoring resource. Twenty-four inbred strains of mice are routinely received from the NIH repository. Genetic monitoring for quality assurance will accompany the long standing efforts in microbiological quality in order that each animal produced from rederived stock under our production contracts is as well defined as possible. Genetic monitoring will be accomplished by biochemical means, i.e., testing for loci involved in producing cellular enzyme or protein variants. Interested organizations must be able to:

Monitor between seven and 12 designated loci for each strain by electrophoresis of erythrocyte lysates and kidney homogenates. The conditions for electophoresis for each enzyme or protein such as support medium, buffer systems, etc., as well as visualization of proteins and enzymes will be subject to review and approval by the project officer. The contractor will receive 10 inbred mice per week from each of two strains. Reports and photographs of the electrophorograms will be submitted within 14-21 days, after the receipt of the mice, for a total of 104 reports per year.

In addition, the contractor will be required to submit annual and semi-annual progress reports.

Selection of loci to be monitored will originate from the following:

| Locus | Chromosome | Description |
|---|---|---|
| Idh-1 | 1 | isocitrate dehydrogenase |
| Pep-3 | 1 | dipeptidase |
| Car-2 | 3 | RBC carbonic anhydrase |
| Gpd-1 | 4 | glucose-6-phosphate dehydrogenase |
| Pgm-1 | 5 | phosphoglucomutase |
| Ldr-1 | 6 | lactate dehydrogenase regulator |
| Gpi-1 | 7 | glucose phosphate isomerase |
| Hbb- | 7 | hemoglobin-beta chain |
| Es-1 | 8 | esterase |
| Mod-1 | 9 | malic enzyme |
| Es-3 | 11 | esterase |
| Es-10 | 14 | esterase |

Organizations must be capable of detecting the proteins or enzymes encoded by each of the above loci by electrophoretic methods.

The strains to be monitored on an annual basis for this effort are: A/He, AKR/N, BALB/c AnN, BALB/c-CMC, C57BL/6N, C57BL/10ScN, C56/L, CBA/J, C3H/HeN MTV-, C3H/HeN MTV+, C3Hf/He, DBA/2, DBA/8, RFM, SJL/J, NZB, NZW, GR/N, B10.A, B10.A (2R), B10.A (4R), B10.A (5R), B10.129 (5M), and B10pd/Cz.

**Contract Specialist:** Marlene Haywood
RCB Blair Bldg. Rm. 228
301-427-8737

**The Cancer Letter** _Editor Jerry D. Boyd

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