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## DCT BOARD APPROVES MAJOR CLINICAL TRIALS CHANGES, REGIONAL GROUPS, NEW EFFORT IN SURGICAL ONCOLOGY

Major changes in the manner in which NCI supports clinical trials and a big new effort in surgical oncology were approved last week by the Div. of Cancer Treatment Board of Scientific Counselors. Changes in clinical trials support will have an impact on both the Cooperative Groups and the contract supported single disease groups. The surgery initiative will infuse $5 million through a variety of mechanisms into a program aimed at developing more surgical oncologists.

Key features of the clinical trials changes are:

(Continued to page 2)

*In Brief*

### NCI FUNDED TO DEC. 15, NO SENATE FIGURE YET; SPEEDUP URGED ON INTERFERON MANUFACTURE, TESTING

**CONGRESS APPROVED** the continuing resolution funding HHS and many other federal agencies until Dec. 15 before adjourning for the campaign and election. Those agencies, including NCI, may obligate funds at the rate of the House passed appropriations bill or the 1980 budget, whichever is lower. For NCI, the two figures are virtually identical. The Senate HHS Appropriations Subcommittee did not mark up its bill before the adjournment; the amount the Senate will add for the Cancer Program will not be known until mid-November at the earliest. **ONE MEASUREMENT** of the impact of the National Cancer Program: Four years ago, *Cancer Treatment Reports,* published by NCI's Div. of Cancer Treatment, received 400 manuscripts, for the most part reporting on studies started three to five years previously. Last year, 1,200 manuscripts were submitted. The monthly journal now uses as many as 95 pages an issue. . . . **THIRD INTERNATIONAL** Conference on Adjuvant Therapy of Cancer deadline for abstracts is Nov. 1. The conference is scheduled for March 18-21 in Tucson, chaired by Sydney Salmon and Stephen Jones. Studies with at least three years of followup are of particular interest. Abstract forms will be sent on request, or ASCO forms may be used. Contact Mary Humphrey, Cancer Center Div., Univ. of Arizona, Tucson 85724. . . . **NATIONAL COUNCIL** on Drugs, whose members include the AMA and other professional organizations, and the Pharmaceutical Manufacturers Assn., has called for action to speed public and private efforts to manufacture and test interferons. The Council cautioned against overpromise in reporting to the public on test results. Resolutions approved by the Council also urged Congress and HHS to give high priority to funding of basic and clinical research on interferon, and asked FDA to expedite monitoring and regulation and "minimize those bureaucratic procedures that might delay the availability of this material for clinical investigation."

## COOPERATIVE AGREEMENTS TO REPLACE GRANTS, CONTRACTS IN CLINICAL TRIALS

(Continued from page 1)

• Three new regional cooperative groups will be established, with $1.5 million earmarked in 1981 fiscal year funds to get them started.

• All groups—the existing grant supported Cooperative Groups, the contract groups and the new regional groups—will be supported by the new cooperative agreement mechanism, with the first two to be converted from the present mechanisms as soon as it is feasible.

• All groups will be reviewed by a single peer review body, to replace the existing Clinical Cancer Investigation Review Committee, responsible for the Cooperative Group grants, and the Clinical Trials Review Committee.

The changes are the result of the review of clinical trials by the DCT Board in March, 1979, and the subsequent summary of the review recommendations drafted by a Board subcommittee chaired by Sydney Salmon. DCT presented its response to the subcommittee recommendations in the following paper:

1. A clinical trials study section should be established.

Response: As a result of an indepth analysis of clinical trials by DCT staff that had been presented to the Board in October 1978, the NIH Div. of Research Grants has organized an ad hoc study section which will be meeting in the fall of 1980. If the results of this experimental group study section are satisfactory, a permanent study section will be considered by DRG.

2. Conversion of major clinical trials entities to the cooperative agreement funding mechanism in accord with federal guidelines.

Response: DCT plans to convert the Cooperative Group Program (R10 grants), the Lung Cancer Study Group (contract), the Gastrointestinal Tumor Study Group (contract), the Brain Tumor Study Group (contract), the Melanoma Tumor Study Group (contract), the Head and Neck Cancer Study Group (contract), the parenteral nutrition contracts, phase 2 GI contracts, large bowel contracts and the breast contracts to the cooperative agreement mechanism. These conversions will be implemented within the next year. The only clinical trials groups remaining within the contract mechanism are the two resource contract groups considered critical to the DCT Drug Development Program. These are the Phase 1 and Phase 2/3 Working Groups. It is anticipated that in response to DCT's specific responsibilities to FDA for early drug development, the Phase 1 Group will remain a contract-supported group. As the cooperative clinical trials groups supported under cooperative agreements are developed, it is anticipated that the Phase 2/3 group will be phased out and this work will be performed by the cooperative clinical trials groups.

All clinical trials research supported under cooperative agreements will be reviewed by a single type of review body. It is anticipated that the makeup of this review body will be similar to the existing CCIRC and Clinical Trials Review Committee. It is also anticipated that the workload of this new committee will require at least two subsections.

A. Group members will be required to pass peer review.

Response: As outlined above.

B. The size and nature of individual groups.

Response: DCT staff agrees with the subcommittee that there are definite advantages to having multidisease, multidisciplinary groups with a compact regional organization. However, it is important not to impose rigid criteria re: size or regional distribution of a clinical trials group. The needs of a clinical trials entity to perform effective multimodality studies should be the critical criteria for number and geographic distribution of institutions. Establishing a large adult oncology group for the purpose of having the potential to perform studies in rare tumors will not be encouraged, since such studies may easily be performed under intergroup mechanisms. DCT staff recognizes the necessity of having national clinical trials groups in several specific instances: 1) groups that are specifically disease oriented (NSABP, GOG, 2) groups that are designed to deal primarily with high technology single modality studies (RTOG), and 3) groups dealing in clinical areas where patient resources are limited, and the clinical trials require special expertise of a limited number of investigators (pediatric groups).

**Proposal to Initiate the Development of Regional Clinical Trials Groups**

DCT is proposing to approach the development of regional cooperative clinical trials groups in multidisease, multidisciplinary trials by the development of regional operations and statistical offices. A request for response to a proposed cooperative agreement will be issued to fund regional operations offices. Requirements for these operations offices will be the demonstration of expertise in design and execution of multimodality clinical trials. Adequate patient resources must be demonstrated. It is anticipated that regional groups will utilize some patient resources which currently are not being utilized in multimodality clinical trials including many patients treated by trained oncologists in community hospitals. An institution seeking funding as a regional operations office must have the potential to be a center of expertise in cancer clinical trials. Such expertise may be demonstrated by one or more of the following criteria: 1) regional cancer center status, 2) having grant and contract support for clinical trials, 3) clinical program project grant support, 4) active cooperative group participation including not only patient accrual but also active participation in clinical trials design, and 5) an ability to provide statistical support for multimodality clinical trials.

It is anticipated that regional cooperative clinical trials operations offices will be able to accept into membership current R10 grant holders transferring from an existing Cooperative Group under present guidelines. The commitment of such grant holders, however, will not be a requirement for response to an RFA for regional operations offices. The regional operations offices will serve to demonstrate the functional capability of regional entities supported by cooperative agreements to perform good clinical trials. The size and geographical area encompassed by regional operations offices will be judged on an individual basis.

C. Group Statistical Offices

Currently there is no plan to alter the way in which statistical support is provided to cooperative groups. The only alteration would be that statistical offices also will be funded by cooperative agreements.

D. Adequate Pathology Support

Response: See the guidelines for DCT involvement in clinical cooperative agreements.

E. Gives recommendations for membership in a regional cooperative clinical trials group

Response: The DCT plan as described under B above.

F. Suggest that satellite institutions in Cooperative Groups be carefully scrutinized

Response: DCT staff feels it would be counterproductive to eliminate the use of satellite institutions in funded cooperative clinical trials. It will, however, be important that the satellite institutions:

1. Have investigators with demonstrated oncologic expertise.

2. Be geographically and logistically relevant to the group in which they are functioning.

These relatively simple requirements will insure good protocol compliance.

G: Member institutions of a given multidisease and multidisciplinary group cannot belong to more than one such group

Response: This recommendation is consistent with current DCT policy regarding the Cooperative Group Program.

H. Relates to quality control of clinical trials

Response: See the section in the guidelines for "DCT involvement in cooperative agreements for clinical trials" in which quality control issues are addressed.

I. Addresses the advisability of providing contract funded support to cooperative clinical trials groups operations offices for flexibility and rapidity of response in addressing new clinical trials ideas

Response: DCT staff feels this is an excellent idea and is proposing a task order contract for clinical trials to which operations offices of Cooperative Groups may respond. This would develop a group of master contractors in a cooperative clinical trials program which would have funded task order contracts. When a new idea in clinical trials arises which will require extra financial support or when it becomes apparent with the increasing regionalization of the groups that an appropriate clinical trial can only be done on an intergroup basis, DCT will discuss with the group operations offices development of a plan of execution and funding for such a trial. A protocol would be developed under DCT guidance for a needed study and funds could be awarded for the trial through the task order mechanism. This would allow a very substantial increase in flexibility and responsiveness in clinical trials in the cooperative clinical trials group programs. For example, in the case of intergroup studies, rather than having to develop a new R10 grant or a supplement to an R10 grant to perform the study and wait 12 to 18 months before implementation, awards could be made within three months of the development of the protocol.

J. Addresses issues of protocol review in three major classes of research studies

Response: DCT staff agrees with these guidelines in principle and they are outlined in the document on DCT involvement in cooperative agreements. It should be emphasized that these guidelines in many ways formalize a system which is already in existence. Because of DCT's specific requirements for reporting to FDA on IND drugs, protocol approval is already required for protocols using these drugs. It is important to note that pilot studies and smaller group studies will not be liable to protocol disapproval under the new guidelines. There is also a well defined appeals mechanism that has been set up for review of studies that may be disapproved.

3. Recommendation for transfer of Cancer Control Program monies

Response: Plans for redistribution of control monies are being actively discussed with the DRCCA.

4. Expansion of the CTE program for the evaluation and dissemination of information on cancer therapy evaluation

Response: Expansion of CTEP staff is being evaluated at present. Funding and position constraints will require careful consideration in making decisions regarding CTEP staff size.

**The Board approved the clinical trials changes on an 8-4 vote, with most of the objections relating to the regional groups.**

Salmon, Rose Ruth Ellison, Walter Lawrence and Sharon Murphy voted against Paul Marks' motion to approve. Voting with Marks were Joseph Byron, Gertrude Elion, Alexander Fefer, Carmack Holmes, Enrico Mihich, Theodore Phillips, and Alan Sartorelli. Chairman Samuel Hellman did not vote, and members Philip DiSaia and Carlos Perez did not attend the meeting.

Former Board members who participated in the clinical trials review were invited to the meeting along with Cooperative Group chairmen.

"The Cooperative Groups as they exist now are underfunded," James Holland said. "If additional funding is available to help bring surgeons, pathologists, immunologists, and psychiatrists into clinical research, I don't understand why you want to do that with new entities."

NCI Director Vincent DeVita responded that the institute invests $68 million a year in cancer centers, many of which are anxious to participate more than they do in clinical trials. Regional groups will be developed to a large extent around the centers, DeVita said.

Also, DeVita continued, "I feel there is a major national crisis" in the availability of patients for clinical trials. Most patients now being referred to centers have been previously treated. "We've applied our research findings so widely that mortality is falling. . . It is probably halfway technology, and we must continue to improve. The public is impatient for more improvement," DeVita said.

Barth Hoogstraten pointed out that the Salmon subcommittee did not recommend establishing regional groups, and Salmon agreed. "When the Cooperative Groups were moved into the Div. of Cancer Treatment," Hoogstraten said, "Dr. DeVita encouraged us to develop multimodality capability. We did, and it is beginning to work nicely. Funding is a problem. If NCI has money for new groups, I think that money should be used to strengthen the existing multimodal groups."

Referring to comments that physicians training by group members are now competing with them for patients as practicing oncologists in communities, Hoogstraten said, "That is not true. Our experience is that they want to stay with the groups and participate in clinical research."

Hoogstraten argued that "there are not that many places where you could have regional groups. There was a vacuum in California (where the Northern California Oncology Group was established), and there was a vacuum in the Dakotas (where the North Central Oncology Group has some of its participating clinics). To have regional groups around New York City or Chicago would present enormous difficulties. Where is the scientific expertise?" The regional concept involves "a single institution with scientific expertise working with private physicians," while the national groups involve many institutions with that expertise, Hoogstraten contended.

The key issue, DeVita said, "is whether regional

groups or national groups can better draw in patient resources."

Salmon said his subcommittee felt that satellite members of groups should be geographically relevant, but "there was no evidence that multimodal national groups needed to be geographically relevant. The subcommittee felt there was no distinct evidence that the groups should be dissolved and reformed into regional groups."

Cancer Therapy Evaluation Program Director John MacDonald agreed that the NCI response did not clearly state the subcommittee's position. But, MacDonald said, "Nowhere in our document does it say that groups should be dissolved and reformed into regional groups."

"If the question is, do we dissolve existing groups and do something else, the answer is no," DeVita said. "But regional centers do need to be tested."

"Centers are varied," former Board member Harris Busch said. "Not all are centers of excellence, and within a center, excellence is variable from one area to another. There may be more excellence in the satellites than in the centers."

John Durant asked Salmon if the subcommittee addressed the question of how many groups were required to meet clinical trial needs and where the money would come from to fund new groups.

"We felt that the existing groups have shown they are doing well," Salmon said, "but that some might be more efficient if they were smaller." Reducing some groups in size could "free up money to strengthen existing groups and perhaps fund new ones."

Former Board member Henry Kaplan commented that "the major Cooperative Groups have achieved excellence because some are more equal than others. Some have strong leaders like Jim (Holland). If all the groups were to be dissolved and reformed, Jim would rise to a position of influence in any group. He's unaccustomed to hearing nice things from me." Kaplan and Holland frequently and vociferously were in disagreement when both were members of the Board. "But without strong leaders, you have two strikes against you," Kaplan said.

"Attrition of case accrual has been devastating no matter what the group structure is," Kaplan continued. "With regional groups, as shown by NCOG, we may have a better chance to reach patients. With cooperative agreements, NCI staff may have better input in protocol decisions and also in exchanging information among groups. Those two elements alone justify at least taking a look at reorientation toward the regional concept. But unless one or two very strong leaders within the existing groups are willing to dissolve and go along with the experiment, the regional concept is doomed."

Holland said the Cooperative Groups as they exist now "represent a constellation of major institutions" which could develop satellite programs with community hospitals "which fit the pattern you describe for regional groups." He suggested that the $1.5 million earmarked for the new regional groups be used instead as supplements to group chairmen grants to develop satellite programs.

"I don't agree with Jim that simply putting more money into the hands of the chairmen will solve the problem," Marks said.

Murphy noted that the Board agreed with most of the DCT recommendations except for the regional groups, and asked Marks if he would agree to divide his motion to permit a separate vote on the regional issue.

"The regional issue is what attracts me," Marks said.

"But that's not in the spirit of our report," Murphy replied.

Mihich suggested that funding a few new regional groups would offer the opportunity to compare the concept with the national groups. "We might extract a qualitative difference."

"I sit on both sides of the street," Salmon commented. "We have a very important regional cooperative effort in my state. It works effectively, under a program project. It is not competitive with our participation in a national Cooperative Group."

Ellison objected to initiating the experiment with regional groups at the same time other changes are made, including the switch to cooperative agreements. "If the experiment works, we may never know if it was due to the cooperative agreements or what."

**The switch of some contracts to cooperative agreements may not pose the threat to commercial firms that it once did.**

DeVita told the Board that negotiations are in progress with HHS officials to remove the restriction against awarding grants to for-profit organizations. That restriction has been in effect for nearly 20 years and was one of the reasons for the growth of the contract mechanism.

The cooperative agreement is considered as one type of a grant. If the restriction against grants for commercial firms is lifted, the cooperative agreement probably would be available to them.

DCT described how the cooperative agreement will work as a funding mechanism for the groups, including protocol approval and quality control:

In 1977, Congress passed the Federal Grant and Cooperative Agreement Act. Its purpose was to achieve uniformity in the use of funding mechanisms throughout the federal government. The act characterized relationships of the federal government and funding recipients as either one of procurement or assistance.

A procurement relationship exists whenever the principal purpose of the funding instrument is to acquire property or services for the benefit or use of the government. In this situation, a contract must be the legal instrument reflecting the relationship. In DCT, for example, we contract for such things as the purchase of drugs or the services of a statistician.

Grant agreements are the legal instruments to be used whenever the purpose is to transfer money to the recipient to accomplish a public purpose of support or stimulation. No substantial involvement is anticipated between the federal government and the recipient under the grant mechanism.

When the purpose of the relationship is the same as that of a grant, but the federal government anticipates substantial involvement with the recipient during the course of the activity, a cooperative agreement is the funding instrument to be used.

As a consequence of this legislation, all government agencies are examining their methods of funding various extramural efforts. At NIH, programs such as DCT's research clinical trials have been identified for transfer to the new cooperative agreement mechanism. This is consistent with the recommendations contained in clinical trials subcommittee report.

DCT staff has historically had more involvement with R10 grant holders than is the case with other NIH grants, an involvement partially required by the FDA rules and regulations governing the use of investigational new drugs. In addition, DCT staff has served as a resource for the development of new protocols and a clearing house for information concerning ongoing protocols, to discourage duplication, for example. This is the kind of involvement which will be formalized under the cooperative agreement mechanism.

DCT has, of course, also conducted many clinical trials under the contract mechanism when studies of high program priority are not being conducted by grantees. It is our intention to convert the research clinical trials to cooperative agreements as well, since they would more appropriately fund such government initiated research.

The initial review body for all cooperative agreements will be the same. We would hope that at the start the review body will represent a combination of the Cancer Clinical Investigations Review Committee and the Clinical Trials Committee.

Administrative procedures are currently being established for DCT to transfer these grants and contracts into the new cooperative agreement mechanism. Once they are finalized, we intend to begin the conversion of the R10 grants and our research contract programs to this mechanism. The time frame is such that we expect all our research clinical trials to be funded through the cooperative agreement mechanism by 1983. A complete schedule of conversion dates will be published as soon as it is available.

For grantees, the process of conversion to cooperative agreements will cause little change. Applications and budgets will be submitted in the same format currently used. The difference will be the formal agreement by grantees to the terms of award which will now specify the "substantial government involvement."

Contractors will find the process different from their previous experience. They will prepare applications for funding instead of proposals in response to a specific RFP. Their budgets, as well as their technical competence, will be reviewed by the initial review group. If the CCIRC and CTC are combined, many of the reviewers will be the same persons who perform that function now. In addition to the changes in the budget review, the degree of government involvement with the principal investigator will change. Scientific and administrative direction by NCI staff for these groups will be diminished.

Both contractors and grantees should have to make only minimal adjustments in their current operating procedures. The terms of award for all cooperative agreements will contain the following identification of substantial government involvement:

Terms of substantial government involvement in the operation of clinical trials groups supported by cooperative agreements.

1. Scientific resources—NCI staff will serve as a resource to provide specific scientific information with respect to treatment regimen and clinical trial design. The staff will assist the groups in developing information concerning the scientific basis for the performance of specific trials and also will be responsible for informing the group of the nature and results of relevant trials being carried out nationally or internationally.

2. Protocol design—NCI staff will have an active role in assisting the group in protocol design. The NCI project officer will assist a group's protocol design committee and advise with respect to: a) duplication of proposed study by other groups or institutions, b) scientific rationale, c) design and implementation, and d) availability of necessary drugs and/or other treatment modalities.

3. Protocol review—All protocols prepared by clinical trials groups supported by cooperative agreements will be reviewed by the CTEP protocol review committee. This committee will meet weekly and consist of CTEP professional staff. This committee will be under the overall direction of the associate direc director, CTEP, and be chaired by the Branch Chief, Clinical Investigations Branch (CIB). Protocol review will be accomplished under the following guidelines:

1) All protocols utilizing IND drugs will require NCI approval before activation. 2) All group-wide protocols requiring entry of 100 or more patients will require NCI approval before activation. 3) Group-wide protocols requiring less than 100 patients will be filed with NCI for information purposes but will not require specific approval. NCI staff will review these protocols and supply the groups with suggested modifications. 4) Pilot studies requiring less than 100 patients and participation of less than six institutions will be treated under the guidelines described in No. 3 above.

If a protocol is disapproved by the NCI, specific reasons for rejection will be furnished to the group chairman and the group may submit a revised protocol. NCI will not fund performance of a protocol disapproved within the context of the above guidelines. There will be an appeals process for investigators who wish to appeal protocol disapproval. DCT staff is proposing that a subcommittee of the Board of Scientific Counselors serve as an appeals panel to review such protocols. This subcommittee may uphold the NCI staff decision or overturn that decision and suggest protocol activation.

4. Quality control—NCI staff will approve, in cooperation with each clinical trials group, mechanisms developed for quality control. Quality control in clinical trials should consist of: a) pathology review to establish pathologic diagnosis, b) review of clinical and laboratory data on patients to establish stage of disease and performance status and c) quality control of treatment. It is understood that mechanisms of pathologic quality control should retain considerable flexibility since the degree and sophistication of pathological review will vary with the disease under study and the clinical trials question being addressed. Treatment related quality control should consist of a review of patients' flow sheets for compliance in dosage and scheduling in chemotherapy trials and appropriate review of patient information and port films to establish compliance with radiotherapeutic protocol standards in radiation trials. Surgical quality control will be evaluated on an individual protocol basis when surgical treatment is a critical aspect of the clinical trials question being addressed in a study. It is understood that NCI staff may periodically review with the group compliance with protocol quality control standards.

5. Data management—DCT staff will assist cooperative agreement-supported clinical trials groups in establishing mechanisms for data management and analysis. NCI staff may have access to all data generated by such groups and assist in periodically reviewing data management within the group.

6. Protocol termination—NCI staff may determine when a protocol study should be terminated. Protocol studies may be terminated for such reasons as insufficient accrual or when further accrual of patients on study will not add any informa-

tion of scientific relevance.

7. Investigational drug management–

A. NCI will hold INDs on all drugs undergoing clinical trials which have been developed by the NCI Drug Development Program. For drugs not developed by NCI, permission for NCI to crossfile on an existing IND, if it so desires, must be granted by the drug sponsor, if the drug is to be tested in the NCI clinical trials program.

B. NCI staff will advise investigators holding cooperative agreements of specific requirements and changes in requirements concerning investigational drug management that the FDA may mandate. Investigators performing trials under cooperative agreements will be expected, in cooperation with NCI, to comply with all FDA monitoring and reporting requirements for investigational agents.

C. Investigators holding cooperative agreements for clinical trials will be advised by NCI staff of specific needs of the NCI Drug Development Program to obtain clinical information on investigational drugs that will be acceptable to FDA for inclusion in a new drug application. In cooperation with NCI staff, the cooperative clinical trials groups will develop protocols t obtain such information as needed.

**The Board went along with the thrust of the recommendation of its Surgical Oncology Research Development Subcommittee for a new $5 million a year program.**

The Board agreed to broaden the program from the discrete surgical oncology research development grants proposed by the subcommittee to include planning grants, supplements to cancer center core grants, and program projects.

Board members felt that each of those mechanisms might be used to accomplish the objectives outlined in the proposal presented by subcommittee Chairman Walter Lawrence:

**Surgical Oncology Research Development Grants**

Purpose–Expansion of national capability for laboratory and clinical research in surgical oncology.

Eligibility of applicant institution:

1. A medical center that provides cancer treatment, training and research (only one application will be funded in any one center).

2. There is a surgical oncology (either general or specialty surgery) clinical service with adequate and available surgical caseload.

3. Training and research programs in nonsurgical oncology disciplines must be present in the institution and there should be evidence of an organized interdisciplinary cancer program.

4. The PI (and director of surgical oncology if these are different individuals) should be essentially full time in terms of the surgical oncology programs.

5. The development program should be supported by adequate numbers of professional staff that are committed to the research and the training areas. This staff may be specifically in the surgical oncology unit as well as in outside basic and clinical departments collaborating with surgical oncology in this program.

6. Professional staff directing research laboratories that are a major part of this program will be evaluated partially on the basis of research support awarded on the basis of peer review by major research funding agencies.

7. Presence of an internal peer review mechanism for evaluation of the developmental projects in this program is an important consideration.

8. There should be documentation of adequate laboratory and support space to conduct the proposed program.

Budget–Appropriate requests include partial salary support for professional staff members tha tcontribute significant time and effort to the program. Full time support for research associates involved in the program is justifiable as is clerical and nursing help required by the program. Support required by the PI for laboratory assistance in the various research laboratories utilized can be provided by partial support of laboratory technicians and supply needs. Inappropriate budgetary items, in terms of this specific program, include funds for alterations and renovations, large equipment purchases, and patient care costs.

Note–For budgetary planning it is estimated that a mean level of funding for individual programs will be in the range of $200,000/year. There should be 25-30 such programs funded to accomplish the goal of the proposal.

Donald Morton, former Board member and a member of the subcommittee, said, "When we really got down to considering what needs to be done in surgical oncology, the present state of surgical oncology is such a disaster that we had to start from ground zero. Obviously, what has to be done is train a new generation of surgical oncologists who are scientifically based. We can only do that with the help of our colleagues in medical oncology, radiation oncology, and basic science. We felt it would be better to start building now. We have a brilliant group of young people going into surgery, but if history repeats itself, they will be siphoned off into cardiac surgery and other areas and away from cancer. Our first priority is to develop surgical oncologists at research centers."

"I agree that the state of surgical oncology is a disaster," Marks said. "But I have trouble with the 25 to 30 programs. Who will develop them? Second rate people develop fourth rate people."

Mihich said he agreed that the need is there, "and this is a good approach. I have some hesitation about the number. The quality is as Dr. Marks said. There must be a critical mass in oncology outside the surgical area, where the atmosphere prevails to permit the discipline to grow."

"It's not necessary to get hung up on numbers," Holmes said. "Only those qualified would get funded, those with the nucleus to generate talent."

Marks said the proposal was not clear on the funding mechanism. "Would it be a training grant? Seed money to enrich a program? If it is the former, I have no trouble with it. If the latter, I don't see why we need a special instrument. That instrument is available now, either through a P01 or R01."

"Surgical oncology is a particular problem in universities," Morton said. "A minority have divisions of surgical oncology. I would guess that if you really review the comprehensive cancer centers, less than 20 percent have surgical oncology programs. General surgeons are doing the surgery. The problem not only is can they do the cancer surgery better; the problem is having patients available for research, and participating in research. The general surgeon who does a hernia one day, cancer surgery the next, may be very com-

petent. But he has no time to do research. It is not economically attractive now for a department chairman to say yes, surgical oncology is what we need, so let's expand, do research and training. There is no incentive unless you give them a carrot."

DeVita pointed out to the Board that $4-6 million probably would be the most that the division will have to spend for new programs in the 1982 fiscal year. He compared the proposal to the radiation physics program projects in the 1960s which helped increase the number of radiation oncologists. "I assume P01s in surgical oncology would be developed. Maybe we need a first round of planning grants, to show what can be done with a P01."

Lawrence said, "We did not have a training grant in mind, but felt what was needed was a greater number of surgical oncologists, and more scholars in this area."

Bernard Fisher, former Board member and a member of the subcommittee, said, "I always think of surgical oncology as a discipline searching for a mission, and I'm not sure what the mission is."

Appropriate review is a major factor, Fisher argued. "When I put in an application for a grant to study the immunology of lymph nodes, with surgical implications, it goes to a basic science study section. We need a mechanism where surgery can be funded through competent peer review."

DeVita assured the Board and subcommittee members that surgeons could be added to the NCI review committees and that the DRG ad hoc study section probably would also when necessary.

Former Board Chairman John Ultmann said, "These deliberations make it clear there are mechanisms available, with the assurance of review by bodies with competent surgeons. The word will go out that the interest is there and that their applications will be reviewed competently and fairly."

Lawrence moved to approve an RFA for a program patterned on the subcommittee's recommendation. He amended it at Salmon's suggestion to open the program to planning grants, core supplements and program projects.

That motion was approved, with Marks voting against it and Sartorelli abstaining. A subsequent motion to earmark $5 million from 1982 funds for the program was approved by a 9-2 vote, with Marks and Sartorelli opposed.

## NCAB PONDERS CONTRACT REVIEW, PAY LINE ADJUSTMENT TO REDUCE DUPLICATION

The National Cancer Advisory Board was assured this week by Director Vincent DeVita that whether or not the Waxman bill provision requiring NCAB review of grants totaling $500,000 or more becomes law, the Board will be more closely involved and better informed on NCI contracts than it has in the past.

DeVita described the contract process, particularly the policy now in force which requires all new NCI initiated programs including those supported with contracts to obtain concept approval from the appropriate divisional board of scientific counselors.

Board member Irving Selikoff, who in the past has complained because the Board had little to say about contracts although they account for nearly half of extramural expenditures, said, "You've given us a different sense of what is happening than what I previously felt."

Board member Maureeen Henderson said that NCI staff "has to have the freedom to identify areas to be pursued, and use whatever mechanism is necessary."

"That's my position," Board member Morris Schrier said. "We only advise."

"We should be spending more time on general issues, and I'm willing to delegate some of our responsibility to the boards of scientific counselors," Bruce Ames said.

Mrs. Jules Lederer, new Board member from Chicago and better known as Ann Landers, said, "I'm staggered by the amount of mail sent to us. One batch cost $30.10 to mail. I couldn't lift it. Talk about waste."

Material sent to Board members prior to meetings includes summary statements of grants which must be acted upon. They have been sent by Federal Express since Board members complained about slow mail delivery and asked for more time to review them. When some members agreed with Lederer that it was impossible to read all the summaries, Board Chairman Henry Pitot reminded them, "We have a legal responsibility to review grants. If you do not read all of them completely, scan them. You must be familiar with them."

Selikoff, who said he reads all the pink sheets "and I've seen some elegant science in them," asked if a mechanism exists to identify duplicating projects.

"With contracts, we have almost total control," DeVita said. "With grants, that is something else. Two identical grants may not always be seen by the same study section. Even if they are, they can get identical priority scores and we will go ahead and fund them. Duplication is all right sometimes, and occasionally we can adjust the pay line to eliminate undesirable duplication, but not often."

"That's not good enough," Selikoff said. "Even at 170 or 145 scores, with scarce resources and a limited budget, we shouldn't fund duplications."

"Sometimes, in new fields or controversial ones, we can go to 270," DeVita said. The hot new area right now is cloning genes, he noted. "They are different genes, but it still is essentially duplication. The question is, who do we shut off?"

"That is an issue we have to deal with," Harold Amos said. "There is no doubt, a lot of people are doing pretty much the same thing. We shouldn't give up our prerogative (to adjust the pay lines)."

"Grants policy is the total responsibility of this Board," DeVita said.

"We have to deal with that issue one case at a time," Frederick Seitz said. "The new field versus good scores in other fields."

"Duplication is a good thing within limits," said Margeurite Hays. "The pay line is the key issue."

"We do not have a flat pay line," DeVita said. "It would be appropriate for the Board to make suggestions on pay lines."

## 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. Some listings will show the phone number of the Contract Specialist who will respond to questions. Listings identify the respective sections of the Research Contracts Branch which are issuing the RFPs. Address requests to the Contracting Officer or Contract Specialist named, Research Contracts Branch, National Cancer Institute, Blair Building, 8300 Colesville Rd., Silver Spring, Md. 20910. Deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.*

## SOURCES SOUGHT

### RFP NCI-CB-14339-34, Project CB-14339-S

**Title:** *Biomedical computing software services in support of Breast Cancer Treatment Program*

**Deadline for Statement of Capabilities:** *Oct. 31*

NCI is seeking a contractor to provide computer related support services to the Breast Cancer Task Force Program, Div. of Cancer Biology & Diagnosis. The purpose of this announcement is to initiate competition for continuation of support services which have been in progress for the last four years.

Prospective contractors must have experience and expertise in all phases of software services in support of a group of biomedical research activities. This support involves abstracting large sets of clinical and laboratory data, coordination of multi-institutional biomedical studies, and preparation and execution of computer programs for sophisticated statistical analyses. The contractors should have the capability to use the computer systems of the Div. of Computer Research Technology, NIH, but should have their own computer terminals.

The estimated required level of effort is four and one-half person years: one person year of project management, two and one-half years of programmers and biomedical analysts and one person year of general datatech services. It is desirable that the project manager and one other staff member have biomedical backgrounds. The contractor must have, or be willing to establish at the time of submission of a proposal, permanently established offices within 35 miles of NIH, Bethesda, Md. A four year contract is anticipated.

Respondents should document in four pages or less: (1) their capabilities (a) to generate data bases requiring the design and development of specialized software, and (b) to apply existing general purpose software for data organization, maintenance and analysis; (2) their experience in biomedical research statistical services; and (3) their ability to interact with personnel of the institutions which provide clinical and laboratory data and with NCI staff members.

Ten copies of the resume of capabilities must be submitted.

**Contract Specialist:** Elizabeth Abbott
Biology & Diagnosis
301-427-8877

## NCI CONTRACT AWARDS

**Title:** Evaluation of the impact of the estrogen receptor assay on the treatment of human breast cancer
**Contractor:** Fred Hutchinson Cancer Research Center, $105,073.

**Title:** Evaluation of carcinogenic agents in cigarette smoke, continuation
**Contractor:** American Health Foundation, $64,350.

**Title:** Literature monitoring service
**Contractor:** Enviro Control Inc., $292,102.

**Title:** Immunodeficiency cancer registry, continuation
**Contractor:** Univ. of Minnesota, $77,618.

**Title:** Epidemiological studies in the etiology of cancer in veterans, continuation
**Contractor:** National Academy of Sciences, $246,340.

**Title:** Biomedical computing: Designing and implementation of computer programs and systems, continuation
**Contractor:** Geomet Technologies, $389,780.

**Title:** Support services for epidemiological studies
**Contractor:** Westat Inc., $8,635,833.

**Title:** Risk of cancer following multiple chest fluoroscopies for tuberculosis
**Contractor:** Yale Univ., $498,541.

**Title:** Holding facility for small laboratory animals
**Contractor:** Litton Bionetics, $659,277.

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

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