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Tight Budget, Turf Battles Kill One Project, Threaten Popular CGOP Clinical Trials Effort

The destructive impact of increasingly restrictive budgets on various elements of the National Cancer Program has ended for the moment one promising cancer center collaborative effort and is threatening a key element of the clinical

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In Brief

House Subcommittee Adds 15-17% to NIH 1987 Budget; NCI To Fund Lombardi, KY Centers

HOUSE APPROPRIATIONS Subcommittee for HHS added enough money to the NIH FY 1987 budget to lift it 15-17% over the 1986 level, according to reports filtering out of the closed door markup session last week. If that percentage holds for NCI through the rest of the appropriations process, NCI would get an increase of up to $200 million over its post Gramm-Rudman 1986 total of $1.177 billion. The subcommittee, chaired by William Natcher (D.-KY), also included language in the bill that would take away the Office of Management & Budget's authority to restrict flexibility of NIH institute directors in reprogramming money. If that survives, it would be better news for NCI Director Vincent DeVita than the additional dollars. The subcommittee set a level of 6,200 competing grants for NIH. NCI's projections under the President's recommendations for 1987 are a payline of 160 funding about 27% of approved competing grants; the Natcher budget would lift that to about 165 and over 30%. . . . **SUPPLEMENTAL APPROPRIATIONS** bill for FY 1986 approved last week by Congress which includes an additional $6 million for cancer centers probably will be signed by President Reagan (if it hasn't by the time this isssue is delivered). Congressional Republicans reportedly struck a deal with the White House to get the bill through. Meanwhile, NCI executives have decided to use that money to fund all the approved centers, including Georgetown's Lombardi Cancer Center and the new Univ. of Kentucky Cancer Center. There had been speculation that those two, with priority scores beyond the payline, might be sacrificed to permit funding other centers at closer to their recommended levels. That would have been grossly unfair, since Lombardi Director John Potter was instrumental in getting Congress to add the extra money for centers.

NCI Cancels MRI Contract While Issuing RFA For Similar Effort

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trials program. It has also precipitated at least two "turf" battles within NCI, the Div. of Cancer Treatment Vs. the Div. of Cancer Prevention & Control. This is not your usual turf fight over who gets to do what; it's who has to do what, and who has to pay for it.

Battle No. 1: The MRI Network.

Three years ago, the Assn. of American Cancer Institutes proposed to NCI that a group of cancer centers with expertise in magnetic resonance imaging be funded to carry out multi-institution collaborative clinical trials. NCI staff members worked with AACI members in those planning efforts.

In 1984, NCI issued an RFP, the AACI group competed for the contract and won. The contract was awarded in October, 1985, with first year direct costs of about $150,000. The contract supported a central operations office at AMC Cancer Reserch Center, a statistics and data management component at Fox Chase Cancer Center, and the headquarters at UCLA Jonsson Comprehensive Cancer Center. Marvin Rich, John Durant and Richard Steckel, respective directors of the three centers, were coprincipal investigators.

The group recruited prominent radiologists, oncologists and other scientists, established committees, and started writing protocols. Studies under five protocols were in the process of being implemented, when the group was tersely informed by NCI that the contract was being canceled "for the good of the government."

"The only reason they gave us was that the project was considered low priority," Rich said. It wasn't that the contract proposal had received a low priority score in peer review--"it was an excellent score," Rich said.

The three PIs brought the issue to the AACI meeting last week in San Diego, hoping to get some better answers from NCI staff, and to try to get NCI to reinstate the contract. They were particularly infuriated by the appearance soon after cancelation of the contract of a request for applications issued by DCT to establish a diagnostic imaging cooperative group. The RFA set aside $600,000 for first year funding.

The contract with the AACI members had been issued and funded by DCPC, the division which houses the Cancer Centers Program.

DCPC Director Peter Greenwald; his associate director for cancer centers and community oncology, Jerome Yates; and his coordinator for the Community Clinical Oncology Program, Robert Frelick, were the only NCI staff members at the AACI meeting. No one from DCT was there to respond (or defend themselves).

When Steckel described the situation and asked Yates for an explanation, his response was, "I guess another way to ask that question is, do we know what we're doing?" He mentioned the Gramm-Rudman enforced cuts and the fact they had forced DCPC to drop some other projects. Greenwald said only, "I have no comment on the new RFA," then added that when the Gramm-Rudman 4.3 percent cut was imposed on NCI, DCPC has very few contracts which could be cut.

The decision to kill the MRI contract was made by the NCI Executive Committee, which consists of Director Vincent DeVita, his deputy and administrative officer and the five NCI division directors. But that group also had to approve the new MRI RFA before it could see the light of day. So what gives? Was Yates correct? Even if DCT minions don't know what their DCPC counterparts are doing, the all powerful Executive Committee certainly should know.

DCT Director Bruce Chabner offered an explanation to **The Cancer Letter**, which tells at least part of the story. "The RFA is not the same thing they were doing under the contract," Chabner said.

Chabner said the contract project "was similar to something we already had done" through large multi-institutional efforts his division had been supporting. He noted that DCT has primary responsibility for diagnostic imaging, but denied that he had instigated the contract's demise. "That was an Executive Committee decision, although I can't say, if the decision were mine, I wouldn't have canceled it."

Rich, in his comments at the AACI meeting, insisted the new RFA "involves essentially the same elements as the (contract) but reduced in scope to only two cancer sites, and with a first year budget four times that of the one canceled."

AACI unanimously approved a resolution calling on NCI to reinstate the contract. That isn't likely to happen, but there is no reason the Rich-Durant-Steckel group can't compete for the new DCT award. "I hope they do join in the competition," Chabner said.

The unfortunate situation came about

because DCPC, faced with the tough choices imposed by Gramm-Rudman, has been forced to reserve most of its funds for cancer control research. Its budget, except for cancer center core grants and manpower training, is funded entirely by the cancer control line item in the congressional appropriations. In the past, such projects as the MRI contract were loosely defined as cancer control, but those days are gone.

Greenwald apparently decided that the MRI project was one that could go and tried to sell it to DCT, where as Chabner agreed, it really belonged. But Chabner had had his own RFA under way, the concept for which had been approved by his board of scientific counselors in June, 1985. The RFA, incidentally, is not limited to MRI but also includes other new imaging techniques (Discussion and approval of the concept were reported in **The Cancer Letter** June 14, 1985). Copies of the complete RFA and additional information may be obtained fronm Dr. Matti Al-Aish, Diaggnostic Imaging Research Branch, Radiation Research Program, NCI, DCT, Landow Bldg Rm 8C09, Bethesda, MD 20892, phone 301-496-9531.

Battle No. 2: The Fate of CGOP.

When chairman of the clinical cooperative groups met in Bethesda Monday to hear the current status of NCI's plans to "streamline" the groups, they were appalled to learn that the Cooperative Group Outreach Program may be heading for extinction. This is the program through which DCPC has, for nearly 10 years, been supporting efforts by some groups to extend their clinical research into community hospitals. It costs $4 million a year and has become vital to some groups in patient accrual. It generally reaches smaller hospitals than those participating in the Community Clinical Oncology Program.

CGOP is another effort that more properly belongs in DCT, Greenwald has decided, especially when DCPC has run out of money. He has proposed that his contribution be cut in half for the third and final year of the current awards, starting next December, and that DCPC's obligation cease entirely thereafter. If it is to be continued subsequently, Greenwald has suggested, it should be a DCT responsibility.

The Executive Committee is considering dropping it entirely and placing all the comunity eggs in the CCOP basket. The final decision may be made at the NCI executive retreat July 9.

HHS Proposes Changes In Lymphoma, Leukemia Payment In Six New DRGs

The Prospective Payment Assessment Commission is pleased with a recent HHS proposal that will establish six new DRGs (diagnosis related groups) for lymphoma and leukemia cases. ProPAC is especially delighted with the department's proposal to establish a separate DRG for acute leukemia, ProPAC health analyst Nancy Merrick told **The Cancer Letter.** Both the commission and HHS agree, however, that further work needs to be done on the DRGs in the future. The HHS proposal was formally discussed at a ProPAC meeting held in Washington last week.

While agreeing with the recent recommendations by the Prospective Payment Assessment Commission that diagnosis related groups for lymphoma and leukemia "are more heterogeneous than most DRGs and . . . reclassification of cases within these DRGs is appropriate," HHS fell short of accepting all of ProPAC's recommendations for reclassification.

In its annual report to the department in April, ProPAC recommended the reclassification of DRGs 400 through 404 (**The Cancer Letter,** March 21). The new groupings would have created separate DRGs for acute leukemia patients and those with lymphoma/leukemia. They would have also thrown out the age grouping included in the current DRGs for the diseases.

The department is accepting ProPAC's recommendation that the reclassification separate acute leukemia from the other DRGs because of acute leukemia patients' greater needs during hospitalization.

In a notice of proposed rulemaking published in the June 3 "Federal Register", HHS said it agreed with ProPAC's conclusion that the DRGs are more heterogenous than others, but said it was "particularly concerned, however, with ProPAC's proposed reconfiguration of DRG 403, which combines about 7,000 surgical cases of lymphoma and non-acute leukemia with complications or comorbidities." HHS analyses "indicate that the latter group of cases are about 25 percent more resource intensive than the surgical cases without complications or comorbidities. Moreover, the basic logic of the Grouper program is structured so as to establish DRGs that are either medical or surgical." The predominant exception to the logic occurs in cases where a principal diagnosis alone explains resource use, with-

out regard to whether or not a surgical procedure is performed, generally when cases with a specific principal diagnosis virtually always entail surgical treatment or virtually never entail surgical treatment. "We have found the latter to be the case with acute leukemias in that fewer than 4 percent of the cases in our data base involved surgical treatment," it said.

Although HHS accepts the basic premise of the ProPAC recommendations, it asserts that "similar improvements in the homogeneity of these DRGs may be achieved without disrupting the logic inherent in the current classification structure."

Specifically, HHS accepts ProPAC's suggestion that acute leukemia cases without major operating room procedure be classified into a single DRG, and has added acute leukemia not otherwise specified (code 2080) to the other acute leukemia codes included in the recommendations. HHS also accepted the suggestion that age consideration be eliminated from the decision tables for classification of lymphoma/leukemia cases.

HHS proposes to establish the following classifications for lymphoma/leukemia patients:

*DRG 401--lymphoma/nonacute leukemia and other operating room procedure with complications and/or comorbidities.

*DRG 402--lymphoma/nonacute leukemia and other operating room procedure without complications and/or comorbidities.

*DRG 403--lymphoma/nonacute leukemia without operating room procedure with complications and/or comorbidities.

*DRG 404--lymphoma/nonacute leukemia without operating room procedure without complications and/or comorbidities.

*DRG 405--acute leukemia without major operating room procedure, age less than 18.

*DRG 473--acute leukemia without major operating room procedure, age greater than 17.

Acute leukemia is defined as patients with a principal diagnosis of: acute lymphoid leukemia (code 2040); acute myeloid leukemia (code 2050); acute monocytic leukemia (code 2060); acute erythremia (code 2070); and acute leukemia not otherwise specified (code 2080).

"Although the reclassification we are proposing is somewhat different from that proposed by ProPAC, we have found similar improvements in homogeneity," HHS said. "We believe it is appropriate to create an additional DRG for acute leukemia cases without major operating room procedure and to maintain the distinction between surgical and medical lymphoma and non-acute leukemia cases."

ProPAC plans further analysis of the heterogeneity of DRGs involving lymphomas, leukemias and chemotherapy and developing alternative classification(s) of discharges.

The commission will decide which specific DRGs to focus on at its next meeting in September following the identification of problem DRGs by a systematic survey of all DRGs, Merrick said. The current chemotherapy DRG is likely to be identified as one of the problem DRGs. An earlier analysis found some payment problems with the chemotherapy DRG, but those were "less striking" than with the other DRGs recommended for reclassification.

During a public comment session at the meeting, Albert Owens suggested that payment for oncology patients be linked to the course of therapy chosen and the medical factors involved, not on nonmedical factors such as inpatient or outpatient status. Director of the Johns Hopkins Oncology Center, Owens presented the commission with a letter and a six page statement about oncology DRGs. "In general, when the full diagnosis is established and when a treatment decision is made, one is in the best position to anticipate the patient management costs involved," he stated. "Treatment is the main factor which determines costs."

Owens noted that the selection of a treatment course for a patient is dependent on many variables, such as age, stage of disease, prior therapy, and major organ system failure. "Therefore, it would be simpler and more appropriate to register the prospective payment process with the treatment course chosen," he said.

Following a complete patient assessment and the possible existence of other disorders, life threatening situations, treatments fall into the category of emergency, definitive antitumor and palliative treatment as well, he said.

Definitive antitumor treatments may be further categorized to give an indication of the expected clinical course and costs involved, such as: surgical resection (with no long lasting functional impairment or with permanent functional impairment); radiation therapy (with or without complication); chemotherapy (with or without severe aplasia, mucositis, etc.); biologic (cellular thera-

pies such as bone marrow transplantation or LAK cell therapy; and combined modality therapies.

The Hopkins center has experienced major problems with ICD-9-CM-based DRG coding being inadequate to reflect the clinical course of patients, especially complex cases. He specifically cited the history of malignancy (diagnosis); treatments not specifically coded for; no quantitation of patient impairment; series of admissions coded separately not reflecting overall treatment course; and coding that does not adequately express changes in or the extent of disease.

Owens presented data on the length of stay and charges of lymphoma, leukemia and related cases treated with and without bone marrow transplantation at Hopkins. While the mean length of stay for patients who received no bone marrow transplant was 15.84 days (20.08 for acute leukemia patients), those who received BMTs had a mean length of stay of 50.51 days (42.78 for acute leukemia patients).

Similarly, the mean charges for patients who received no BMT was $23,004, ($32,697 for acute leukemia patients), compared to $88,261 for those who received BMTs ($73,067 for acute leukemia patients).

14 Institutions Awarded $100 Million For AIDS Therapy Evaluation Units

A total of $100 million over the next five years has been awarded to 14 institutions for AIDS treatment evaluation units. The units are expected to treat as many as 1,000 patients with acquired immune deficiency syndrome.

The institutions are Johns Hopkins, Harvard, Memorial Sloan-Kettering Cancer Center, New York Univ., UCLA, Univ. of California (San Diego), Univ. of California (San Francisco), Univ. of Miami, Univ. of Pittsburgh, Univ. of Rochester, Univ. of Southern California, Univ. of Texas/M.D. Anderson, and the Univ. of Washington.

Initial plans call for the testing of six drugs, with more agents to be tested as they become available. The drugs to be tested are azidothymidine (phase 1 and 2 studies); foscarnet (phase 1, with phase 2 trials to be conducted later); HPA-23 (phase 1 or planned); ribavirin (phase 1 and 2); interferon alpha (phase 1 and 2); and dideoxycytidine (may be available for phase 1 clinical trials in late 1986, but is still in preclinical studies). Combinations of antiviral and immunomodulating drugs are also planned for evaluation and testing.

The awards are funded by the National Institute of Allergy & Infectious Diseases, which has been jointly sponsoring a number of other AIDS related activities with NCI, including the establishment of national cooperative drug discovery groups for anti-AIDS agents (**The Cancer Letter,** Oct. 11).

Studies Of Molecular Probes In Colon Cancer Patients OKd By DCBD Board

NCI's Div. of Cancer Biology & Diagnosis Board of Scientific Counselors has approved a concept that would fund up to five awards for the characterization and relevance of specific molecular probes in unique subsets of colorectal cancer patients. The estimated total cost of the awards would be $875,000 in the first year. The grant period is anticipated to be three years for each award.

The concept was one of three generated by the Organ Systems Program that were approved by the board. The DCBD board approval of the concepts completes the current round of Organ Systems concept proposals submitted for research the working groups determined necessary. All of the Organ Systems concept proposals presented have been approved with the exception of two that were turned down by the Div. of Cancer Etiology board.

The colorectal studies are intended to integrate newly available molecular probes with the clinical aspects of relatively rare subgroups of colorectal cancer patients whose prognosis is poor, and whose poor prognosis is pre- dictable by conventional morphologic analysis of primary tumor biopsy. Specific objectives of the studies are: a) to identify and characterize phenotypic markers and probes associated with subsets of clinically predictable colorectal cancer patients; and b) to determine structure/function relationships in these pathologic subsets with predictable clinical outcome.

The overall goal is to obtain leads that could be applied to the general population of colorectal cancer patients in whom morphologic analysis of tumor is not predictive of the clinical course.

According to the concept statement, "it is hypothesized that definitive clinical subclasses of colonic carcinoma will demonstrate a type of growth regulation that is different from other identifiable subclasses as well as

pies such as bone marrow transplantation or LAK cell therapy; and combined modality therapies.

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The overall goal is to obtain leads that could be applied to the general population of colorectal cancer patients in whom morphologic analysis of tumor is not predictive of the clinical course.

According to the concept statement, "it is hypothesized that definitive clinical subclasses of colonic carcinoma will demonstrate a type of growth regulation that is different from other identifiable subclasses as well as

to make the study feasible. It is very important that the pathologic criteria of such clinical subsets be clearly defined. To do this quantitatively may require that more than one pathologist be involved.

4. In defining the central theme of this concept that unifies both the clinical studies and the molecular markers and probes, the basic need is to determine what establishes prognosis of patients who live five years versus those who do not, and to then apply what is learned to the general population of colorectal cancer patients. The broad base of this initiative is intended to meld together existing and new technology from a variety of scientific disciplines in responding to the clinical question.

Since these are relatively rare tumors, structure-function relationships should be studied by investigators who have a capacity to accrue adequate numbers of patients, by multi-institutional study or collaboration with one or more cooperative clinical groups. In addition, successful projects would require a capacity to perform adequate serial clinical followup with correlative studies utilizing an array of possible biochemical, immunologic, biophysical, cell and molecular biology studies. Eventual extension of probe applications to the most well to moderately differentiated colorectal tumors would be necessary to define differences in structure function relationships compared to the rarer morphologic subsets.

Other concepts approved by the board are:

Markers of exfoliated bladder cancer cells correlated with tumor progression and recurrence. The board approved a concept that would fund three to five three year awards aimed at predicting bladder tumor progression. Estimated first year funding per single award would be $112,000.

Goals and major objectives of the new concept are:

a). Form a network of several currently active cell marker laboratories in order to coordinate the major expertise available in bladder cancer exfoliative cytology.

b). Test chemical and immunologic cell markers and determine their application in distinguishing populations of exfoliated bladder cancer cells.

c). Extend the research base in exfoliative bladder cell marker technology, and apply the new findings in studies of bladder tumor progression and recurrence after diagnosis.

d). Redefine marker characteristics of exfoliated bladder cancer cells, and factor the data into a tumor classification that is useful in patient management.

e). Engage qualified automated cytometry expertise and facilities to quantitate and document biochemical and immunologic markers of exfoliated bladder cells.

f). Engage qualified expertise in urology in order to acquire samples of exfoliated cells from adequate populations of bladder cancer patients.

The Div. of Cancer Prevention & Control proposes the establishment of a network of three to five cell marker laboratories--each with an image analysis, flow cytometry or slit scan capacity--for carrying out collaborative studies of exfoliated bladder cells in cancer patients. The goal is to establish a team of cell marker investigators who are already leaders in the identification of bladder cancer characteristics using exfoliated urinary cells. It would be expected that this cell marker team, once established, would interact with the ongoing efforts of the existing NCI funded network of collaborating flow cytometry laboratories. The flow cytometry network is charged with the goal of establishing the best clinical methods and instrumentation for the flow cytometry of bladder cancer cells. The two networks, in order to further their respective efforts of transferring cell marker technology and cell automated procedures to answer specific clinical needs, would meet together two times a year.

Each cell marker applicant would be required to propose 1) research projects on cell markers to be done independently, 2) projects to be carried out collaboratively within the cell marker network, and 3) projects to be carried out collaboratively with the existing flow cytometry network.

Cell marker network members would acquire samples of exfoliated cells from populations of bladder cancer patients and would propose methods for preservation and shipment of exfoliated cells to members of the flow cytometry network. Cell marker network members would carry out chemical or immunologic processing of cells prior to flow cytometric analysis, or would specify the process for the flow cytometry network members.

The major aim of the concept is to combine expertise in bladder cell marker technology with an existing network strength in flow cytometry. There is high potential that this collaborative effort will provide the automated system needed for reducing costs in the area of bladder cancer diagnosis and prognosis. Flow cytometry quantitates and documents cell marker characteristics of bladder cancer cells rapidly, accurately and objectively. Flow cytometry of appropriate bladder tumor markers might be practical as an outpatient urologic examination; its increased use could reduce the need for cystoscopy. In sequential examinations of a patient, three-dimensional flow cytometry scattergrams provide an objective documentation of changes in the entire bladder epithelium, which cannot be obtained by any other means.

In order for an application of flow cytometry to become routine in clinical practice, there is a need to standardize cell processing, staining and analysis, and a need to achieve close interaction among experts in urology, cell marker and flow cytometry techniques. This interdisciplinary collaboration must be established if flow cytometry is to be developed as a powerful prognostic tool in patient management. The proposed collaborative approach would make the best use of patient resources and would make it possible to correlate different kinds of markers, do multi-parameter analyses, test and compare techniques and interpretations in different clinical settings, and assess general applicability for bladder cancer patients.

Studies on the molecular biology of pancreatic cancer. A second DCPC concept approved by the DCE board would fund five three year awards, with estimated first year funding of $112,000 per award.

The goals and major objectives of the concept are:

a). Major goal of the proposed RFA is to increase understanding at the molecular level of the regulation of cytodifferentiation and morphogenesis in the

normal and transformed exocrine pancreas.

b) Identify the cell(s) of origin of pancreatic cancer and develop molecular biology tools including probes for genes, oncogenes and gene products that are specific for exocrine pancreatic tumor cells.

c). Develop and use appropriate molecular biology probes for defining growth and differentiation of exocrine pancreatic tumors and of cells of the normal, fetal and adult pancreas.

d) Apply appropriate probes to the diagnosis and classification of human pancreatic tumors and correlate findings with the clinical course of the disease.

e). Produce transfected or infected cell lines selectively expressing human genes and gene products related to growth, differentiation, and transformation of exocrine pancreatic tumors.

f). Correlate studies of human tissues with existing animal models and with cell lines from human and animal material currently used in pancreatic cancer research.

Although considerable information is accumulating on the regulation and expression of genes related to the secretory process of the pancreas, little information is available concerning the onset, control and expression of the gene programs that drive normal cell differentiation in the gland.

Identification and regulation of genes specifically related to pancreatic cancer have not been elucidated. Some reports have described detection of amplified or mutated oncogenes in pancreatic tumors or cell lines. In most studies, only one or two tumors or cell lines were used and not all available oncogene probes were used. Many of the probes used were of viral origin and not their cloned human homologues. For example, one study reports the presence of transforming genes in one of two pancreatic tumors, tested by NIH-3T3 transfection assay, and using a v-ras probe, identified the oncogenes as k-ras.

Another report concludes that the transforming gene in one human pancreatic tumor cell line is a human homologue of k-ras. A variety of human tumors have been probed with a larger panel of oncogene probes with the result that one pancreatic tumor tested negative for k-ras, src, myb, abl, and fes, but positive for h-ras, myc, fms and fos.

The question of the cell of origin of pancreatic cancer is an important issue not yet answered. Over 90% of pancreatic tumors are classified as of ductal origin. In contrast, most animal carcinogenesis models of the disease result in acinar cell tumors. The designation of ductal origin for human tumors by pathologists is based on the ductular appearance of the tumor cells at the light microscopic level.

Using three dimensional reconstructions of the pancreas, it has been concluded that both ductular and acinar cells in the normal pancreas have tubular arrangements, and thus on this basis, acinar cells cannot be eliminated as possible cells of origin for adenocarcinoma. Other studies indicate an apparent interconvertibility of acinar and ductal cells.

Applicants must demonstrate access to sufficient numbers and amounts of normal pancreatic and tumor tissues. Cooperation of surgeons and pathologists may be required to ensure that clinical and pathologic features of patients and specimens are carefully documented and followed up. Material should be processed quickly following excision or frozen in liquid nitrogen for subsequent extraction of DNA and RNA. Applicants would be expected for certain studies to develop cDNA and/or expression libraries form normal pancreas and neoplasms.

For other studies it would be necessary to fix and/or freeze tissue for immunocytochemical and in situ hybridization experiments, as well as for electron microscopy. Some protocols might include transplantation of tumor or metastatic cells into nude mice and/or establishment of cell lines.

Establishment of cDNA libraries and probes using RNA from the human pancreas requires safeguards against degradation by endogenous RNA hydrolases. It should not be necessary to duplicate the array of cDNA probes for the defined oncogenes.

Applicant should indicate mechanisms and approaches for applying the probes described above to diagnosis and classification of pancreatic tumors. Reactivities of the probes should be correlated with histopathologic types and the clinical course of the disease.

RFPs Available

Requests for proposals described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda MD 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring MD, but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI CPEB 71004-21

Title: Industrial hygiene and biochemical monitoring of exposures encountered by anatomists and embalmers

Deadline: Approximately Oct. 1

The Occupational Studies Section of the Environmental Epidemiology Branch, Div. of Cancer Etiology, is seeking a contractor to perform a study which is a toxicologic investigation to gain detailed information on exposure to formaldehyde and other chemicals which will be integrated with information obtained by interview in the case control study.

The contractor will not engage in independent research. The National Institute of Occupational Safety & Health is collbatoring with NCI on this project.

The contract will be completed in three phases with initiation of each subsequent phase dependent upon the outcome of the preceding phase.

The objectives of this project are (1) to identify chemicals used now and in the past by embalmers and anatomists to perserve, fix, stain and handle biologic tissues; (2) to document, through environmental monitoring, levels of exposure of embalmers and anatomists to formaldehyde, glutaraldehyde, phenol and other selected chemicals; and (3) to obtain blood and urine samples on a limited number of anatomists and embalmers to assess delivered dose and early evidence of biologic damage from those selected chemicals.

The project manager must be certified by the American Board of Industrial Hygiene and all air samples must be analyzed by a laboratory accredited by the American Industrial Hygiene Assn.

This will be a total small business set aside.

Contract Specialist: Barbara Shadrick
RCB Blair Bldg Rm 114
301-427-8888

The Cancer Letter _Editor Jerry D. Boyd Associate Editor Patricia Williams

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