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AIDS CONCEPTS TOTALING $13 MILLION APPROVED BY DCT BOARD; WILL BE FUNDED BY SPECIAL APPROPRIATIONS

NCI's Division of Cancer Treatment's Board of Scientific Counselors has approved concepts totaling $13 million for research activities related to acquired immune deficiency syndrome (AIDS). One of the largest concepts would provide first year funding of $3 million for the establishment of national cooperative drug discovery groups

(Continued to page 2)

In Brief

FORMER HHS OFFICIAL COULD REPLACE HECKLER; REAGAN SIGNS FEDERAL CIGARETTE TAX EXTENSION

HHS SECRETARY Margaret Heckler's successor when she leaves to become U.S. ambassador to Ireland remains uncertain, but speculation centers on two former department officials. One possible candidate is former HHS undersecretary David Swoap, who recently resigned from his position as California health and welfare secretary. John Svahn, who is currently a presidential assistant for policy development, is also rumored to be a candidate for the job. Heckler will continue to serve as HHS secretary until a replacement is named. ... **CIGARETTE TAX** extension for 45 days was signed by President Reagan following a personal appeal by Sen. Jesse Helms (R-N.C.) last week. Reagan had been expected to veto the measure that extends the 16 cent federal excise tax on cigarettes until Nov. 14. Helms had agreed to support extension of the tax in exchange for tobacco price support legislation (The Cancer Letter, Oct.4). Tobacco price support is likely to be included in any legislation to permanently extend the federal tax... **NIH REAUTHORIZATION** compromise between House and Senate measures could include the establishment of a center for nursing research on a level similar to the Fogarty International Center, NCI legislative liason Mary Knipmeyer told the National Cancer Advisory Board. The House version of the reauthorization bill contains a provision to establish an institute of nursing research, a measure President Reagan is expected to veto.... **CANCER SCREENING** procedures such as mammography, PAP smears and hemocult testing should be reimbursed by third party payors, including the government's Title 18 & 19 programs, the NCAB advises in a resolution adopted Oct. 7. The board unanimously approved a statement calling for reimbursement of such "scientifically established/cost effective screening procedures." The resolution was suggested by board member Rose Kushner in response to an upcoming Congressional hearing on Medicare payment for mammography screening in women over 65 to be held by Rep. Mary Rose Oakar (D-Ohio).... **LEUKEMIA SOCIETY** of America Inc. has recently been surveyed by the Accreditation Council for Continuing Medical Education and awarded two years accreditation as an accredited sponsor of continuing medical education for physicians.

APPROPRIATIONS BILLS DOUBLE HHS REQUEST FOR AIDS FUNDING IN FY '86

(Continued from page 1)
for the treatment of AIDS.

NCI expects to issue an RFA for cooperative agreements in late November, with awards to be made approximately four months later. The project will be jointly sponsored by NCI and the National Institute of Allergy and Infectious Diseases, with each institute providing $1.5 million.

Funding for the national cooperative drug discovery groups and the other AIDS concepts approved by the board will come from Congressional appropriations for AIDS research, DCT Director Bruce Chabner told the board. Chabner stressed that expansion of the division's efforts against AIDS is dependent on new money and will not come from reprogramming funds.

Funding for the effort appears certain, with the House approving a total of $140.7 million for AIDS research. While the House measure does not specify a breakdown within NIH for allocation of AIDS research funds, the report language cites the collaborative drug development program as one of the research activities that can be carried out with the additional funding. The appropriation provides $70 million more than the administration's request for AIDS research for fiscal 1986.

In its markup of the HHS FY 1986 budget, the Senate also provides twice the amount the administration requested for AIDS. The Senate bill also gives NIH an additional $70 million for research on AIDS.

NCI and NIAID have signed a memorandum of understanding for the cooperative effort, which includes the establishment of a Drug Selection Committee to be chaired by DCT Clinical Oncology Program head Sam Broder. The committee, which will include six scientists from NCI and six scientists from NIAID, will have its first meeting in late October.

The anticipated length of the project is five years. The groups will be patterned after DCT's National Cooperative Drug Discovery Groups for cancer treatment.

"In order to maximize the skills to be marshalled for this cooperative effort to discover a treatment aganist AIDS, it is envisioned that a multi-institutional approach be adopted so that in a group of scientists incorporating medicinal, pharmaceutical and synthetic chemists, biologists, molecular biologists, immunologists, and pharmacologists of several kinds, the best talents will be included wherever they are located," the concept says.

The concept notes that "only in the largest institutions might it be possible to find sufficient highly skilled staff to contribute to such a project in a meaningful way." It adds, "In practice, however, differing scientific interests often diffuse any concerted approach to what necessarily must be a closely coordinated effort.

"Operationally, the P.I. will be the conceptual focus of the group, and depending on the perceived needs of the project, will extend invitations to appropriate scientists in other institutions to participate in the project. Since this project will only be as strong as its weakest link, it is important that the P.I. assemble the strongest possible gorup for the work. In an interdependent effort such as this, the competitiveness of the application as a whole will be severely compromised by the inclusion of weak components."

The groups will be charged with the design, synthesis, and preclinical evaluation of treatment entities aimed at blocking development or reversing AIDS and its consequent symptoms, as well as opportunistic diseases. The groups activities will specifically exclude functions related to clinical introduction of a new agent such as bulk synthesis and formulation, animal toxicology, and performance of Phase 1 and 2 clinical trials. Those activities are included in other concepts approved by the board.

Discussing the status of clinical trials underway at the clinical center and Duke University with azido-thymidine, Broder stressed the need for agents that can penetrate the blood brain barrier and be administered orally.

"Any agent that doesn't block replication in the central nervous system will fail," he said.

Broder also emphasized the need for oral formulations of anti AIDS drugs, saying that the oral route is necessary because of the likelihood that such agents will have to be administered over a long time period.

Other AIDS related concepts approved by the board include a $3 million per year project for preparation of investigational dosage forms for AIDS treatment. The agents will be selected by the Drug Selection Committee, and assigned for formulation as injectable or oral products.

NCI expects approximately four new agents to be tested per year involving 2,500 patients per drug for a treatment period of 100 days. The batch sizes for clinical distribution are expected to be initially small for Phase 1 and 2 trials, but escalation for Phase 3 and clinical guideline categories must be anticipated, the concept advises. The project "must be prepared to produce approximately 1 million dosage units of combined injectable and oral tablets or capsules per year."

The three year project will require contractors to test the products for pharmaceutical acceptance, package the dosage forms, and prepare proper batch documentation for NCI and FDA. The products will be delivered to the NCI distribution contractor for subsequent redistribution to clinical investigators.

The concept notes that "it is possible to screen antiviral compounds, such as suramin and ribavirin, that are already in clinical trials against other types of infections, as well as totally new drugs with promising biochemical or biological properties. For example, agents such as 3'-azido-thymidine and a series of novel nucleosides blocked in the 3'-position have been discovered to have potent anti HTLV-3 activity in tissue culture."

Preclinical concepts approved by the board include a $1.8 million per year three year project for preclinical toxicology and pharmacology of drugs developed for AIDS and related illness.

The objectives of the project are: 1. To determine whether the blood levels of anti AIDS drugs required for antiviral activity can be attained in animal systems; and 2. To characterize the toxicity of the agents in vivo at dose levels that produce the desired blood/tissue levels.

The preclinical pharmacologic and toxicologic findings will serve to guide the early aspects of clinical trials relating to starting doses, escalation schedules, and potential adverse effects. NCI expects that four new agents will be tested per year, leading to the submission of IND applications to FDA.

A five year, $350,000 per year project for the analysis of chemicals and pharmaceutical formulations for anti AIDS agents will be responsible for the evaluation of bulk chemicals and formulated drug products for identity and purity. Reports of the analytical testing on bulk drugs and dosage forms will be used as a basis for assessing their suitability for use in screening, toxicological studies, formulation studies or for clinical trials. The data will also be used as part of IND filings submitted to FDA. The project will also develop solubility and stability data and adapt selected assay methods for the quantitation of drug in plasma. The data will be provided to other contract projects to facilitate formulation development and to aid in the analytical aspects of pharmacology and toxicological testing.

The board also approved a three year, $150,000 a year concept for dosage form development to develop acceptable pharmaceutical dosage forms of new compounds. Drugs to be formulated will be selected by the Drug Selection Committee. NCI expects four compounds to require dosage form development per year. The contractor will be expected to provide a small batch of 50 to 100 dosage units for subsequent analytical and biological evaluation by other NCI contractors. The dosage units are not intended for clinical use but to demonstrate the feasbility of pharmaceutical manufacture.

Another concept approved by the board will provide $1.5 million annually for three years for the large scale preparation of anti AIDS drugs for Phase 2 and 3 clinical trials. The chemical preparation laboratories will be service laboratories selected to prepare known chemicals and bulk drugs needed by the program, and will be used to obtain data for the preparation of the necessary quantities of clinically important chemicals and to develop the most economical means for their preparation.

The concept notes that "many methods of synthesis which are practical for small quantities are not technically feasible or economically practical when used for large scale synthesis operation. The conversion of small scale to large scale production often requires developmental studies which will be carried out by these contractors."

A three year $750,000 per year concept for large scale preparation of anti AIDS drugs for preclinical toxicology and Phase 1 clinical studies was also approved by the board. For that project, the quantity of a given material synthesized may range from 50 grams to five kilograms, depending on factors such as the rate of usage, ease of preparation, chemical stability and cost. The compounds will be used for screening, formulation development, toxicology, pharmacology and Phase 1 clinical studies.

NCI expects to eventually establish AIDS treatment centers under a joint agreement with NIAID. Primary responsibility for clinical trials will rest with NIAID, although the institutes will have co-project officers. The treatment centers will probably cost about $20 million to $30 million, Chabner predicted.

Other long range plans for AIDS include a plan for compassionate Investigational New Drug (IND) distribution. Although HHS officials had initially considered the Centers for Disease Control to manage compassionate INDs, the program will probably be carried out either by NCI or NIAID because of the institutes' familiarity with the toxicity and pharmacology of the drugs, he said. The program is expected to cost about $6 million to $10 million in its initial years, with costs increasing as the number of patients and drugs increase.

MONOCLONAL ANTIBODIES PRODUCTION CONCEPT APPROVED BY DCT BOARD

A three year $600,000 a year concept for large scale production of monoclonal antibodies was approved by the Division of Cancer Treatment's Board of Scientific Counselors. The purpose of the contract is to produce large quantities of monoclonal antibodies for preclinical testing and clinical trials.

Upon receipt of a given hybridoma, the contractor will be expected to produce 10 to 50 grams of a given monoclonal antibody by ascites or cell culture procedures. Following production of bulk monoclonal antibody, the contractor will perform the necessary purification, perform MAP test, sterility, general safety, rabbit pyrofen and any specific analysis appropriate such as HPLC, SDS-PAGE, isoelectric focusing, RIA, protein content and Ig isotype testing.

The contractor will also vial and label the MoAb and develop an approved certificate of analysis. In addition to complying with FDA Good Laboratory Practice and Good Manufacturing Practice procedures, the contractor should demonstrate the capability of scaling up production of human monoclonals.

Board members unanimously approved the concept, with an amendment by board member Efraim Racker that deleted a reference to the number of MoAbs that might be obtained under the award. As presented, the original concept said eight to 10 MoAbs could be produced per year.

Board member Alan Rosenthal asserted that the proposed funding for the project was too low to support high quality production of that many monoclonal antibodies. Rosenthal suggested that DCT staff survey industry to estimate the costs of MoAb production. The division will report back to the board at its February meeting, DCT Director Bruce Chabner said.

Other concepts approved by the board are:

Analysis of chemical and pharmaceutical formulations. Two five year awards are anticipated, at an estimated total annual cost of $1.276 million.

Contracts for the project are currently held by SRI International, Research Triangle Institute and Midwest Research Institute. The contractors evaluate the identity and purity of bulk chemicals and formulated drug products.

Results of the evaluations are used to assess the suitability of bulk drugs or finished dosage forms for use in advanced antitumor screening, toxicological studies, formulation studies or for clinical trials. The data are also supplied to FDA as part of NCI's IND filings for new antitumor agents.

Data on solubility and stability are also developed and selected assay methods are adapted for the quantitation of drug in plasma. Data are also provided to other contract projects.

The three contracts have a level of effort of six staff years per year. During the past year, 132 reports were received. NCI expects the major thrust of the project to continue, but will place additional emphasis on the expeditious development of analytical methods to be used in pharmacological and toxicological studies.

Production of clinical doses of antitumor agents. One five year award is anticipated at an estimated annual amount of $900,000.

Currently held by Ben Venue Labs, the contractor performs developmental studies of chemical agents leading to the formulation of clinical dosage forms; large scale production and packaging of parenteral dosage forms for clinical use; and assay and quality control of prepared dosgae forms. All bulk chemicals and final products are evaluated for their conformance to NCI's release specifications. The contractor has supplied the majority of parenteral products, both freeze dried and liquid filled, for DCT's Phase 2 and 3 clinical trials.

The contractor is expected to manufacture 36 production products annually depending on clinical demand. A single production project may include the manufacture of 20,000 to 25,000 freeze dried vials or 15,000 to 20,000 liquid filled ampules. Production projects will periodically include the techniques of low temperature vacum drying from non aqueous solvents, as well as formulation at low temperatures or the use of molecular filtration. All work must be in accordance with FDA current Good Manufacturing Practices.

Funds allocated for the program are $400,000 less than the amount allocated for fiscal 1986 because of the expected cutback in the number of new drugs to be brought to the clinic each year.

Two contracts that support research in Robert Gallo's Laboratory of Tumor Cell Biology were also approved by the board. They are:

Preparation and supply of fresh and cultured mammalian cells. One five year award with annual funding of $132,000 is anticipated. The current contract is held by Biotech Research Laboratories. The contract's major purpose is to provide large quantities of fresh and cultured normal and neoplastic mammalian tissue culture cells to be used to study the effect of viruses on the growth of the cells in culture and other studies related to the pathogenesis of leukemia.

Preparation and purification of viral components. One five year award with an estimated annual funding of $183,000 is anticipated. The contract is currently held by Litton Bionetics, which has provided 30 litres per week of concentrated HTLV-3 for cell biology biochemistry and molecular biology studies.

PB-8510-018765

NCI GRANTS PAYLINE FOR FISCAL 1986 WILL PROBABLY BE 160 OR 165

NCI's grants payline will probably be 160 or 165 in fiscal 1986, according to a budget presentation by NCI Director Vincent DeVita to the National Cancer Advisory Board. DeVita presented calculations based on the administration's funding request for FY 1986, as well as House and Senate markups of appropriations bills.

Under the Senate bill, NCI would receive funding of $1.254 billion, which includes $177.9 million to support "at least 982 new and competing research projects." NCI budget estimates predict that under the Senate measure, 31% of approved grants would be funded, at a priority score of 165.

The House bill would give NCI $1.221 billion, with a $117.9 million increase in research project grants. Under the House measure, NCI would be able to fund 945 competing research project grants. The institute predicts that it would be able to fund about 30% of approved grants, at a priority score of approximately 160.

The House bill does not contain funds for construction and training, which are not authorized. The committee report does note, however, that the appropriations for the programs was $37.3 million in 1985.

Under the Senate bill, $37.3 million is included for construction and training. Of $6.6 million earmarked for construction in the Senate bill, $4.5 million is directed for first year funding of the Mary Babb Randolph Cancer Center in West Virginia.

DeVita told the NCAB that the funds for the center will be placed in the HHS Secretary's office and not within NCI. Discussing the board's refusal to approve the center for funding in May, he told the board, "You did what I would have done, and I thank you for it."

The NCI director later told the board's planning and budget subcommittee that Senate Appropriations HHS subcommittee Chairman Lowell Weicker (R-Conn.) "is very concerned about bypassing the peer review system," and that "this way, the burden's off the institute for bypassing peer review."

The budget figures presented by DeVita do not reflect an additional $70 million appropriated to NIH for AIDS research. Approximately $50 million of the additional AIDS appropriations will probably be shared between NCI and the National Insitute for Allergy and Infectious Diseases, DeVita told the board. NCI expects to receive approximately $17 million, and will share part of NIAID's expected allotment of $35 million to fund the institutes' joint trials contract (See related story).

While the House measure does not specify institute funding for AIDS research, it does mention the joint trials program.

"With the new resources available to the NIH, the committee anticipates that the following AIDS research programs can be implemented: a collaborative program between [NCI and NIAID] for the development and testing of drugs for the treatment of AIDS as well as the opportunistic infections that afflict its victims; the development of candidate vaccines and their clinical evaluation; [and] expansion of ongoing studies on the natural history of the disease," the report says.

Other AIDS research activities that should be performed by NIH cited in the House report include: international epidemiology studies, especially in the Caribbean and in Africa, where there is evidence for heterosexual transmission of AIDS; increased efforts on restoration of the immune system, the search for possible co factors, and the development of an animal model; expanded basic research; and enhanced outreach activities designed to transmit the latest scientific findings to researchers, physicians, dentists, opthalmologists and health care workers.

"The committee expects the NIH to take steps to stimulate greater participation in AIDS research by the extramural research community," it says. It also calls for a report on how the funds will be used within 30 days of enactment, as well as periodic updates.

NCI's role in AIDS research was questioned by President's Cancer Panel Chairman Armand Hammer. In a statement read by panel member William Longmire, Hammer expressed concern on the part of the panel that "serious as the AIDS problem is, the NCI's basic mission should not be threatened by unrealistic demands put upon it by the AIDS problem, nor should the resources it needs to accomplish that basic mission be diluted by the need to provide resources exclusively or specifically aimed toward" AIDS.

Hammer suggested that "the proper and most effective role for NCI to play in dealing with the AIDS problem should be identified by input from members of the NCAB."

NCAB member Rose Kushner also questioned the potential impact the institute's AIDS efforts may have on cancer research.

NCI's role in AIDS research will decrease over the next five years, DeVita told the board. NIH officials forsee a transition in NCI involvement in AIDS from the current 50/50 effort with NIAID to a time when NCI "is involved much less." NCI will be handling the transition "through a series of retreats" in three phases; drug development, vaccine development and natural history and epidemiology, he said.

NCI work in retrovirology associated with the virus can help cancer researchers learn how viruses cause cancer, he said. The institute's expertise in retrovirology led to its lead role in vaccine development. NCI's experience in drug screening and development is also needed in efforts against AIDS, he said.

PB-8510-01876 6

CLINICAL COOPERATIVE GROUPS FUNDING TO DECREASE $2.5 MIL.

NCI will decrease funding for its clinical cooperative groups by about $2.5 million in fiscal 1986, Div. of Cancer Treatment Director Bruce Chabner told DCT's Board of Scientific Counselors last week. The division expects to cut funding for the groups by 5% in FY 1986, from $50.9 million in FY 1985 to $48.5 million in FY 1986. According to background material presented to the board, "it is evident that sufficient funds are not available to maintain funding of all of these competing groups."

The budget decrease was based on the assumption that all of the groups up for competition will not be funded this year, he said. "There are specific recompeting groups next year that we don't think will fare well," he said.

Two groups, the National Bladder Cancer Project and the National Prostate Cancer Project, were disapproved by the Clinical Cancer Investigational Review Committee in June.

Competing applications this fiscal year include the Gastrointestinal Tumor Study Group (GITSG), Mid Atlantic Oncology Program (MAOP), Quality Assurance Review Center (QARC), Pediatric Oncology Group (POG), Piedmont Oncology Association (POA), Northern California Oncology Group (NCOG), and the Southeastern Cancer Study Group.

Excluding bladder and prostate, about 19 cooperative study groups receive the majority of their funding from NCI. NCI support, in the form of approximately 325 cooperative agreements, ranges from about $500,000 to $700,000 per group up to more than $5 million.

Chabner refuted a question by BSC board member Rodrigue Mortel, who asked if the funding decrease represented a change in the division's belief in the importance of the cooperative groups in reaching the year 2000 goals. Chabner said that DCT would like to fund all the groups, but that it believes "it would be a mistake to support groups that are marginal when we have these other projects" that require high priority funding, such as Steve Rosenberg's lymphokine activated killer cell research.

DCT "will make every effort to maintain the funding level of the good performers," he emphasized. Cancer Therapy Evaluation Program chief Robert Wittes also told the board that groups who "survive" peer review "will be in a very good position to get 100% funding." Wittes noted that in the past, DCT assisted groups that fared poorly in peer review in order to ensure funding, but that it "can't afford it anymore" because there are too many other projects that deserve funding.

Discussing a preliminary overview of the division's clinical trials review that is retrospectively examining the performance of cooperative groups over the past five to seven years, Wittes said that larger trials and fewer trials are needed. "It's gotten to be a badge of honor for a cooperative group to do its own trial," he said, adding, "That's the kind of thing that we can't afford anymore."

Wittes also said that clearer priority setting and faster implementation of good ideas are needed in the trials program. Calling for more coordination at the national level, Wittes suggested the formation of intergroup committees. DCT plans to meet with the chairs of breast cancer committees in its first effort at intergroup coordination, he said. "We should get away from the idea it is a birthright of a cooperative group to conduct its own clinical trial."

New board member M.M. Elkind also stressed the need for intergroup coordination, asserting that groups are often unaware if a proposed protocol is duplicative. Wittes said that the Clinical Investigations Branch has informed the groups that concept review is available, but added that it needs to be "much more systematic."

PB-8510-01876 7

UNIV. OF PENNSYLVANIA ORDERED TO REVIEW ALL NIH FUNDED RESEARCH

NIH funding to the Univ. of Pennsylvania's Head Injury Clinical Research Center will remain under suspension because "a thorough review of the situation of the HICRC determined that the Pennsylvania researchers failed materially to comply with conditions of their grant with respect to the care and use of non human primates," HHS Secretary Margaret Heckler announced in a statement released Oct. 4.

NIH Director James Wyngaarden notified the university that it must conduct an institution wide evaluation of NIH funded research involving animals in order to ensure compliance with PHS animal welfare guidelines. NIH will verify the university's evaluation through site visits involving outside consultants, Heckler said.

HHS "will tolerate nothing less than total compliance with NIH animal welfare requirements, which are designed to ensure that animals will only be used when scientifically necessary, and that when they are used, they will be cared for in a humane manner," Heckler stressed.

The Oct. 4 announcement is the latest in a government crack down against investigators who fail to comply with NIH animal care standards. The Beckman Research Institute at the City of Hope had received approval for a $269,000 NCI construction grant in fiscal 1985, but the award could not be made because of restrictions placed by HHS on the institution because of alleged deficiencies in laboratory animal operations (The Cancer Letter, Sept. 20).

The actions come in light of increased public pressures for animal welfare, including the occupation of a floor in an NIH administration building by animal rights demonstrators. Five legislative proposals for animal welfare are currently pending in Congress, and both the House and Senate NIH reauthorization bills contain animal welfare provisions.

An indication of the seriousness with which NIH views the necessity for compliance with animal welfare requirements is its plan to make both announced and unannounced site visits to investigators, Div. of Cancer Treatment Director Bruce Chabner told the DCT Board of Scientific Counselors.

Chabner warned that grantees will face "a serious risk" of losing funding if they do not take the guidelines seriously.

Before NIH will consider any request for further funding of the head injury project involving baboons or other non human primates, the university must meet three conditions. First, the university must file a new animal welfare assurance and obtain NIH approval for all of its animal research facilities and practices, "in accordance with the more restrictive recent revisions of the PHS animal welfare policy," NIH says. NIH will conduct a site visit before any consideration for the approval of the assurance document.

NIH stresses that the first provision applies "to all PHS funded animal experimentation at the university and the assessment could lead to funding restrictions on or suspension/termination of other awards if the OPRR finds additional instances of noncompliance."

Second, the university must provide evidence that it has remedied all unacceptable practices involving research animals through its institutional animal care and use committee. NIH will conduct a full inspection of the Experimental Head Injury Laboratory as part of its evaluation process, including an assessment of the adequacy of implementing the research protocol and complying with the PHS policy.

The university must also show that charges by the Dept. of Agriculture have been fully resolved.

If the university meets the conditions and seeks to resume funding for the head injury project, special conditions will be in place for five years. Those conditions include the requirement that site visits to the lab will include a veterinarian trained in laboratory animal science. The university must also provide on a quarterly basis, all videotapes of research to the National Institute of Neurological, Communicative Disorders & Stroke for evaluation.

If the Agriculture department determines a violation of the Animal Welfare Act, PHS animal welfare assurance or portions of it, will be automatically suspended. In addition, OPRR plans to conduct unannounced inspections of the lab.

The university's grant funds were initially suspended July 18 on the basis of a preliminary report by NIH's Office for Protection from Research Risks (OPRR). The report noted several areas where laboratory procedures were not in conformance with NIH's Guide for the Care and Use of Laboratory Animals. Areas cited in the report were:

1. Management of anesthesia, analgesia and sedation for research animals. The committee cited instances of inadequate pharmacologic management of the animals, and inadequacies in the training and supervision of laboratory personnel.

2. Adequacy of techniques used to achieve a sterile environment. Survival surgery was conducted in a facility that was not equipped for aseptic surgery, and procedures were carried out in the absence of aspetic techniques.

3. Adequacy of the laboratory environment and occupation health program. Staff members failed to maintain high standards of cleanliness, to wear appropriate clothing and to refrain from eating, smoking or drinking during the conduct of laboratory experiments involving animals.

4. Supervision and training of laboratory personnel. Experiments involving animals were not performed under the immediate supervision of a qualified biological or medical scientist. Assistants were either less than adequately or improperly trained to perform important procedures involving animals.

5. Adequacy of veterinary participation in experiments. Adequate records of health status and care of animals were not available. The staff veterinarian was not sufficiently involved in the choice of and/or the use of anesthetics, analgesics and other pharmacologic agents.

The original complaint against the university's animal care standards was lodged by an animal rights group that stole approximately 60 hours of videotape documenting research at the lab during a break-in to the laboratory in which equipment was damaged and records destroyed.

RFPs AVAILABLE

Requests for proposal 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. 20205. 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-CM-57854-09
Title: Primary rodent production centers
Deadline: Approximately Dec. 6

NCI is seeking organizations with the capabilities and facilities for producing large numbers of inbred rodents that are genetically sound and free of pathogenic organisms. To be considered for a contract, respondents should meet the following criteria: 1. Principal investigator and other key personnel must have experience and expertise in the production of highest quality inbred rodents; 2. a facility must be available at the time of contract award, capable of producing highest quality rodents at task specified levels; and 3. organizational experience in pertinent areas of quality inbred rodent production including pedigreeing procedures, isolator production, etc. at a scale commensurate with task performance must be available.

NCI expects to make two awards, with only one award per organization. The RFP is expected to be available after Oct. 18 by written request.
Contract Specialist: William Roberts
Treatment Contracts Section
RCB Blair Bldg Rm 224

RFP NCI-CM-57754-09
Title: Primary rodent production centers
Deadline: Approximately Dec. 6

The proposed procurement is a 100% small business set aside. Award criteria are the same as for the related RFP NCI-CM-57854-09 above, except that the respondent must be a small business, the size standard for which is 500 employees.

NCI expects to make one award for the effort. The RFP will be available after Oct. 18 by written request.
Contract Specialist: William Roberts
Treatment Contracts Section
RCB Blair Bldg Rm 224

NCI CONTRACT AWARDS

Title: Collection of specimens from lymphoma patients and controls for evaluation of viral etiology of Burkitt's Lymphoma
Contractor: University of Ghana Medical School, $135,000

Title: Record linkage study of cancer risk in women treated with radiation for infertility
Contractor: Israel Center for Registration of Cancer and Allied Diseases, Jerusalem, $49,920

Title: Testing feasibility of specific biochemical, immunological or genetic markers or physical detection techniques for the early detection of cancer in humans
Contractor: Enzo Biochem, Inc., New York City, $48,665 for "Biotinylated DNA probe for the diagnosis of cervical carcinoma."

Title: Development of monoclonal test for colon cancer markers
Contractor: Granite Diagnostics, Burlington, N.C., $41,537

Title: Support services for the Office of Extramural Activities, Office of the Director, NCI
Contractor: Technical Resources, Inc., Rockville, Md., $1,022,643

Title: Single purpose calculators: self help approach to nutrition education
Contractor: Capital Systems Group, Inc., Rockville, Md., $45,040.

Title: Development of nutrition education materials, including computer software, which will result in long term adherence to diets thought to reduce cancer risk
Contractor: Research Computing, Houston, $48,897

Title: Record linkage study of occupational and industrial exposures associated with multiple myeloma and cancer of the brain
Contractor: Danish Cancer Registry, Institute of Cancer Epidemiology, Copenhagen, $46,644

Title: Tracing through other sources to ascertain married name, vital status and most recent address of female x-ray technologists
Contractor: Hooper Holmes, Inc., Basking Ridge, N.J., $168,303

Title: Tracing through other sources for former patients evaluated for infertility
Contractor: Hooper Holmes, Inc., $49,367

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