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CCOPS UNHAPPY WITH NCI POLICY LIMITING THEIR PARTICIPATION IN EARLY PHASE 2 CLINICAL TRIALS

Community Clinical Oncology Program principal investigators and some of their research base partners are not happy with NCI policies on their participation in phase 2 trials, policies which would prohibit CCOPs from taking part in early phase 2 studies. The controversy came to a head last week when representatives of all 62 CCOPs gathered in Washington for discussions on implementation

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In Brief

OLDHAM TO LEAVE NCI, HERBERMAN ACTING HEAD OF BRMP; LANSKY APPOINTED DIRECTOR OF ICC

ROBERT OLDHAM, director of NCI's Biological Response Modifiers Program, has decided to leave NCI, probably by the end of the year. Ronald Herberman, chief of the Biological Therapeutics Branch of BRMP, has been named acting director. The Div. of Cancer Treatment is initiating a national search for Oldham's replacement, with DCT deputy director Saul Schepartz chairman of the search committee. Persons interested may contact Schepartz or DCT Director Bruce Chabner. Oldham would not comment on why he is giving up one of the most prestigious jobs in the field of biologicals, but it is no secret that he has been dissatisfied with what he felt was the lack of emphasis his program has been getting from DCT. . . . SHIRLEY LANSKY, who has been acting director of the Illinois Cancer Council Comprehensive Cancer Center since Jan Steiner resigned last March, has been appointed permanent director by the center's Board of Trustees. Lansky, an M.D., holds a concurrent academic position at the Univ. of Illinois School of Medicine. . . . PAUL WOOLLEY, professor of medicine and pharmacology at Georgetown Univ. Medical Center, has been appointed acting chief of the Div. of Medical Oncology, replacing Philip Schein, who left Oct. 1 to join SmithKline as VP for clinical research. Schein also was scientific director for the Lombardi Cancer Center, and Center Director John Potter is in the process of recruiting someone to fill both jobs. . . . BARRY SAKULSKY, surgical oncologist at St. Vincent Medical Center, Los Angeles, has been appointed chairman of the Committee on Approvals of the American College of Surgeons Commission on Cancer.

CCOPS IRKED AT NCI DECREE THEY CAN'T DO EARLY PHASE 2 STUDIES

(Continued from page 1)
the program in which community institutions will enter patients on NCI approved protocols in cooperation with cancer centers and the cooperative groups.

Most CCOPs have developed their relationships with the cooperative groups with the understanding that they will be considered equal partners with the other members of the groups. They have heard over and over, from NCI, each other, and various observers that community oncologists are as capable as anyone in administering clinical research protocols. Now NCI seems to be telling them that they are not to be trusted with phase 2 studies, at least in the early portions of those trials.

Dorothy Macfarlane, CCOP program director, sent out the following memo to all CCOP PIs and research bases prior to last week's meeting:

"During the past few weeks a number of questions have arisen about the appropriateness of protocols for CCOP participation. Some of these questions were addressed in the CCOP request for applications; others have required decisions by the Div. of Resources, Centers & Community Activities staff and by the Div. of Cancer Treatment staff who have been working together to review cancer center protocols and develop policies for investigational drug use by CCOPs. These decisions were based on the intent of NCI in establishing the program which was to involve community physicians in high priority protocols, especially those for early stage common cancers. To bring you up to date, the following policies have been established to carry out the intent of the program:

"1. Phase 1 trials are not appropriate for CCOP participation and such participation will not be counted toward CCOP accrual.

"2. Early phase 2 trials should only be carried out by institutions with phase 1 expertise and capability. CCOP participation is unnecessary and may not adequately address lingering toxicity issues commonly found as these drugs are moved to efficacy studies. Only after 40 to 50 patients have been studied should consideration be given to extending late phase 2 studies to CCOP participation. Research bases may make exceptions to this rule on an individual basis with notification to DRCCA staff, but this will generally be discouraged.

"3. CCOPs may participate in contract phase 2 protocols as long as they meet the criteria for late phase 2 studies stated above.

"4. All protocols in which CCOPs participate must be joint ventures between the research base and the CCOPs. There should be no protocols in which only CCOPs are participating.

"5. Although the initial cancer center protocols in which CCOPs will participate are receiving NCI review primarily for safety, the DCT/DRCCA reviewers will not approve any protocols for CCOP use which are either unlikely to answer questions or provide only state of the art options yielding no new scientific information (those which are generated solely for accrual purposes).

"6. Drug orders from CCOPs must be submitted through the research bases, which will verify the CCOP's participation in an active protocol. The drugs will be sent directly to the CCOP physician. Each CCOP should be prepared to describe its drug accountability system to staff of the Investigational Drug Branch in DCT. This system is necessary to meeting FDA requirements.

"7. Research bases should determine which protocols they consider 'high priority' for CCOP participation. Participants are encouraged to enter patients with early stage disease with common cancers and to enter or refer, if appropriate, patients with uncommon cancers.

"8. When protocols are sent for review by NCI, the research base should designate which CCOPs will participate and whether the protocol is for referral to a group member/center (e.g. bone marrow transplanation, hyperthermia) or for direct CCOP participation.

"9. The question of distribution of investigational agents to satellites of CCOPs (i.e. physicians without a form 1573 on file) is under study. We will inform you as soon as a policy has been developed."

NCI's position is that early phase 2 studies should be limited to a few patients at no more than three or four institutions, where toxicities can be closely monitored and quickly reported. No one is arguing with that policy, but at least some of the cooperative groups make it a practice to rotate early phase 2 studies among its members, three or four at a time. They have assured their CCOP partners that they would be included in that rotation.

NCI did agree, in item 2. above, that research bases may make exceptions to this rule on an individual basis with notification to DRCCA staff. However, immediately following was the statement, "this will generally be discouraged."

Despite strenuous objections from those at the meeting, NCI will expect CCOPs to follow those rules, for now. Macfarlane told The Cancer Letter that modification of the rules may be considered later.

Meeting participants also expressed concern over NCI's requirement for maintaining patient logs. They consider that rule to be too cumbersome and difficult to follow in detail, and some felt it may be in violation of state laws. Nevertheless, the requirement was not modified.

Alan Hatfield, PI for the Carle Clinic CCOP in Urbana, Ill., was one of those who questioned NCI's policies on phase 2 studies. He is chairman of the Cancer Control Committee of the Eastern Cooperative Oncology Group, which has more than 160 community hospitals involved in its outreach efforts. Those efforts are supported by a Cooperative Group Outreach Program contract with DRCCA.

Hatfield said that data published by ECOG from its experience with the community affiliates shows that there is no difference in administration of phase 2 protocols between the community and university based institutions.

Hatfield said that for some cancers, including front line therapy for colon cancer, melanoma, and renal cell cancer, the best treatment is that available through use of new agents. Most of those who went into CCOP did so because they felt it would help them gain access to NCI Group B drugs (those in phase 2 studies, usually available only to cooperative groups and cancer centers) and other new therapies, Hatfield contended.

About 50 percent of ECOG's patient accrual now comes from the community affiliates, Hatfield noted. ECOG has an extensive pilot program for early phase 2 studies in which a university based member works with several community affiliates on a study.

"I understand the sense of NCI's policies, and I can't disagree with it completely," Hatfield said. "But I don't believe they are necessary." Community physicians who do not feel qualified to participate in early phase 2 studies, or whose institutions are not properly equipped, generally do not ask to participate, he said. "It's a self selection process and it seems to work. But to make the pronouncement that a community is not qualified is something we have not been able to do and I doubt if anyone else can. We haven't had to put up barriers to participation."

Hatfield said the policy would limit the accessibility of patients to new investigational drugs in a program which was designed to broaden that access.

Hatfield emphasized that he believes "it is clear NCI staff wants to work with the communities, and he supports the staff proposal to establish a CCOP advisory board made up of community physicians. "Their hearts are in the right place. I've been impressed by the staff. But I'm not sure they are as knowledgeable as (the group) cancer control committees on what the communities can do."

Hatfield urged NCI not to be inflexible, and noted the provision which would permit community participation in early phase 2 studies if the research base so desires. "If it is left up to us, we plan to continue as we have been," he said.

ALL CIS OFFICES EXCEPT FOUR NOW HAVE ONE NUMBER: 1-800-4-CANCER

NCI has established a new, single toll free phone number for most of the 22 offices in its nationwide Cancer Information Service. That number is 1-800-4-CANCER. For those who prefer numbers for their phone numbers, it is 1-800-422-6237.

Until now, each CIS office had a different phone number, depending on the state in which it was located.

Four of the nation's CIS offices do not share the new number: Washington D.C., 202-636-5640; New York City, 212-794-7984; Alaska, 1-800-638-6070; and Hawaii, 808-524-1234.

NCI CONTRACT AWARDS

TITLE: Task order managed computer programming support
CONTRACTOR: ORI Inc., Silver Spring, Md., $241,875.

TITLE: In vivo screening for antitumor activity; five year awards
CONTRACTORS: IIT Research Institute, Chicago, $5,188,955; Southern Research Institute, Birmingham, Ala., $4,103,203; EG&G Mason Research Institute, Worcester, Mass., $4,584,367; Battelle Memorial Institute, Columbus, Oh., $3,466,544.

TITLE: Development of human tumor models for correlating in vitro drug sensitivity with in vivo response rate
CONTRACTOR: Univ. of California (San Diego), $2,210,894.

COOPERATIVE GROUPS NOT INCLUDED IN GRANTS GETTING FULL BUDGETS

Those members of the NCI supported clinical cooperative groups who may have been thinking that some of the extra $90 million Congress gave NCI over the President's request for FY 1984 would rub off on them can forget it, for the most part.

The Div. of Cancer Treatment's Cancer Therapy Evaluation Program which administers funding of the groups intends to stay with its plan to fund new and competing renewal groups at 80 percent of the study section recommended levels.

Both House and Senate Appropriations Committees directed that NIH stop the practice of "supporting an increased number of research projects at the expense of existing grants." The committees ordered grants to be paid at or close to recommended levels.

That directive will not apply to cooperative groups. NIH long since has interpreted congressional language referring to "research projects" to mean only RO1 and PO1 grants. Even when the cooperative group mechanism was the R10 grant, groups were not considered to be in that category. They are now supported by cooperative agreements, which are reviewed like grants, scored like grants, but are not in that privileged category.

So the plan to fund competing cooperative group applications at 80 percent of recommended levels will stand. However, a small portion of relief may be on hand for those groups not up for renewal this year. DCT had planned to fund them with a four percent increase over their 1983 budgets, rather than the previously negotiated six percent. Consideration is being given to allotting a little of the additional money to the groups to pay the full six percent.

The five groups being recompeted this year are Cancer & Acute Leukemia Group B, Gynecologic Oncology Group, Radiation Therapy Oncology group, Southeast Oncology Group, and Southwest Oncology Group.

DCT expects applications as new groups from the Brain Tumor Study Group and from a multi-institutional head and neck cancer consortium. New groups also would be funded at 80 percent of recommended levels under the original funding plan.

DCT's original budget for the cooperative groups for FY 1984 was $43.6 million, up only slightly from $43.2 million in 1983. Robert Wittes, director of the Cancer Therapy Evaluation Program, told the division's Board of Scientific Counselors that he was faced with three options: Decrease funding substantially for one group; not fund any new groups; or "spread out the pain" by reducing budgets of all groups.

The option was to cut everyone because "we don't want to freeze out new groups," Wittes said; neither did he want to disable an existing group with a drastic reduction.

Wittes listed his priorities, if more money were to become available: First, increase the amount available for new applicatons. Second, pay competing and noncompeting renewals at close to recommended levels; and third, increase the number of state of the art meetings.

Wittes said the priority score paylines for the groups would be "essentially" the same as in 1983—200 for competing renewals, 150 for new and supplemental applications.

The Brain Tumor Study Group in years past had been supported by DCT through a contract. When the other contract groups were converted to cooperative agreements, BTSG was not. The group continued operating with other support, and submitted a new application for a cooperative agreement. It received a fundable score and will be supported beginning in the 1984 fiscal year.

Other cooperative agreements supported by the Cancer Therapy Evaluation Program in FY 1984 include two continuation clinical research projects in Kaposi's sarcoma, totaling $429,000, which were initially awarded in FY 1983; and the Bladder and Prostate Organ Systems Program groups, totaling $2.6 million.

DCT Director Bruce Chabner told the Board that under the President's budget, the division's budget would increase about three percent over FY 1983. That increase includes the $2.6 million transferred from the Organ Systems Program, so the real increase for DCT would be 2.1 percent. The additional money to be added for full funding of RO1s and PO1s will increase that, however.

Chabner noted that PO1s and RO1s were funded through priority scores of 178 and 175, respectively, in FY 1983. He said it is anticipated that in 1984, the cutoff for both mechanisms would be about 170 (others have estimated in will be closer to 175). Since much of the extra money was earmarked for full funding of grants and for payment of full indirect costs, NCI does not expect to

have much more available to lift the payline, although there is a substantial amount of nonearmarked money. How that will be distributed remains to be determined (The Cancer Letter, Nov. 4).

SAMUELS OBJECTS TO WITHHOLDING NEWS RELEASE ON QRA PROPOSALS

Sheldon Samuels, member of the National Cancer Advisory Board and chairman of its Committee on Environmental Carcinogenesis, stirred up a flap at the Board's meeting last month when he charged that NCI Director Vincent DeVita was withholding a news release on the committee's recommendation regarding quantitative risk assessment.

DeVita denied any ulterior motives in holding back on the news release and said he was merely waiting until the full Board could approve it.

Samuels' committee had been given the task of developing policy recommendations on the controversial topic. A draft of those recommendations was presented to the Board at its May meeting, and subsequently approved by the Board in a mail ballot. Samuels then had sought to have NCI distribute a news release describing the recommendations.

(A summary of the recommendations was published in The Cancer Letter, July 8).

The news release follows:

The National Cancer Advisory Board has recommended that the National Cancer Institute continue to investigate new ways to quantitate cancer risks. Such a quantitative risk assessment goes beyond identifying a cancer hazard and tries to predict the possible number of cancer cases or deaths from exposure to a cancer causing agent.

The Board recommended that the Institute continue, in the meantime, to use present methods of risk assessment. It urged, though, that "uncertainties apparent at each stage of the risk assessment process be clearly and explicitly stated." It also recommended that the process of risk assessment be kept separate from that of risk management, and that risk assessments, regardless of where or by whom performed, be peer reviewed and made available to the scientific community.

(The release noted that the report was approved unanimously by the Board in the mail ballot).

The report contained explicit recommendations concerning "institutional arrangements" for quantitative risk assessment. It recommended, for example, that if a particular institution within the Dept. of Health & Human Services were to have information pertaining to a particular risk assessment, the surgeon general or the assistant secretary of health "should be responsible for marshalling whatever resources and individuals in the government are available to perform risk assessment."

And when the data used by the government for risk assessment originate outside of government, the report recommended, "a special committee should be established by the surgeon general or assistant secretary to evaluate the data." Finally, the report said, when an assessment is challenged, responsibility for dealing with it "must be remanded to the most neutral mechanism" without unreasonable delay.

Assessments of qualitative risk, the report notes, deal with the identification and characterization of substances that may be hazardous to humans. Assessments of quantitative risk attempt to define the degree of risk of disease or death in a population exposed to a toxic agent, based on exposure patterns, including both intensity and duration.

Evidence that a substance is carcinogenic is derived from animal studies, or bioassays, and from studies of human populations exposed to that substance. Those exposed populations are often workers. Other ways to assess the carcinogenic potential of a compound include studies of structure activity and relationships, metabolic studies, tissue culture and cell transformation assays, and characterization of the physical and chemical properties of a compound.

Quantifying the risks in populations exposed to toxic substances is far more difficult and inexact. Such an assessment must first look at the qualitative assessment and then consider exposure. Any analysis of exposure, the report notes, "must take into account various routes of exposure, different concentrations, human activities, biological conversions, chemical reactions, environmental transport mechanisms, and analytical limitations in the ability to quantify chemicals at trace levels."

Quantitative risk assessment then applies data from the first two steps to describe "the relationship between dose of the substance and the probability of toxic response."

In May, 1982, NCAB Chairman Henry Pitot asked the committee to review quantitative risk assessment methods and to report its

findings back to the Board. Specifically, the committee was asked to examine which models might be most useful in terms of data fit, testability, and predictability; to determine their practicability; to determine if the regulatory issues can be separated from the scientific areas; and to weigh who should do quantitative risk assessment.

(That concludes the news release).

Copies of the 24 page report, titled "Policy of Risk Assessment of the Health Effects of Hazardous Exposures to Populations," is available from the Office of Cancer Communications, NCI, Bldg. 31 Rm. 10A18, Bethesda, Md. 20205, phone 301-496-5583.

CCRU, CCSP PROJECTS DESCRIBED; APPLICATIONS BRANCH PLANS LISTED

Two of the major new programs in the dynamic evolution of the Div. of Resources, Centers & Community Activities (soon to be renamed the Div. of Cancer Prevention and Control) are the Cancer Control Research Unit and the Cancer Control Science Program. They were initiated with the emphasis switching from outreach to cancer control research, and were intended to encourage collaborative multidisciplinary programs at cancer centers and universities.

To say that DRCCA staff was disappointed with the first round of applications generated by the request for applications (for CCRU) and program announcement (for CCSP) would be an understatement. Only one of eight CCRU applications was approved (it was funded) and only two of 25 CCSP applications scored high enough to be funded. The CCRU went to the Fred Hutchinson Cancer Research Center, and the two CCSPs to the Fox Chase Cancer Center and the Illinois Cancer Council. Subsequently, after another review, a third CCSP was awarded to UCLA.

Staff was not that discouraged, however, and the DRCCA Board of Scientific Counselors was asked for and gave concept approval to reissuance of the RFAs for the two programs. Applications generated by the new RFAs are due Jan. 15, with letters of intent due by Dec. 1.

Thomas Kean, acting chief of the Cancer Control Applications Branch, described some aspects of the first CCRU and CCSP applications at the recent meeting of the division's Board of Scientific Counselors:

—151 research projects and 75 developmental projects were proposed.

—Approximately 85 percent of the investigators were newly recruited to cancer control, indicating a surge of interest in this new research mechanism.

—70 percent of the proposed projects were prevention (as opposed to management) oriened. This represents a reversal of prior cancer control program emphases.

—22 percent of the total projects were defined population studies (Cancer Control phase IV), whereas previously there were none.

The Hutchinson CCRU is a multidisciplinary research program, involving a critical mass of investigators from FHCRC and the Univ. of Washington School of Public Health & Community Medicine. It was approved for five years. The major research focus is prevention. The five research projects, four developmental studies, and supporting resources which were approved provide a well integrated cancer control research base for the CCRU, Kean said. The approved research projects are:

—Cancer prevention with retinol in persons with asbestosis (phase IV).

—Chemoprevention of lung cancer with retinol.

—Prevention of cervical cancer with folic acid.

—Efficacy of breast self examination.

—Worksite smoking cessation and relapse prevention (pase IV).

—Smoking cessastion and relapse prevention: A community intervention project (developmental).

—Low serum selenium levels and subsequent risk of cancer (developmental).

—Primary prevention against cancer risk from industrial exposures to composite fibers (developmental).

The Fox Chase grant was approved for five years, Illinois Cancer Council's for three. Approved projects included:

—Cancer control in an urban neighborhood.

—Cancer education program for older citizens.

—Secondary prevention: Comparing traditional and self directed CME.

—Cancer education and management for patients.

—Compliance with referrals for evaluation of possible malignancies.

—Swallowing rehabilitation in cancer patients.

—School attendance intervention in pediatric cancer patients.

—Physical therapy evaluations of select head and neck cancer patients.

Kean listed major plans for the 1984 fiscal year, in addition to the new CCRU and CCSP round:

*Continuation of seminars, colloquia, workshops, and program reviews for the Career Development Program.

*Additional emphasis on cancer control traineeships through increased recruitment of scientists from a wide variety of disciplines.

*Initiation of a small grant program for dissertation research in cancer control.

*Initiation of academic and programmatic placement to afford DRCCA staff additional training in disciplines related to cancer control research.

*Sponsorship of regional workshops on cancer control research methods.

*Completion of the development of a DRCCA data base to characterize cancer control resource expenditures.

*Expansion of the resource tracking data base to include information on allocations at the state and local government levels.

*Development of a standard process, Cancer Control Grand Rounds, for working with communities to identify problems and plan programs for solving them.

*Selection of one high priority cancer control problem and initiation of interactions with appropriate communities to address it.

*Recruitment of eight professionals and six support staff to undertake new branch responsibilities and initiatives.

DRCCA BOARD APPROVES CONCEPTS FOR NONCOMPETITIVE CONTRACTS

The Board of Scientific Counselors of the Div. of Resources, Centers & Community Activities gave concept approval to the following noncompetitive contract supported projects at its recent meeting:

Nutrition intervention study of esophageal cancer in Linxian, China. The Chinese Academy of Medical Sciences Cancer Institute, five years, total cost $1.9 million.

Dietary techniques for beta carotene trials. U.S. Dept. of Agriculture, four months, $14,655.

Data management and analysis center for the Breast Cancer Detection Demonstration Program followup. Univ. City Science Center, two years, $650,000 per year.

Radiation dose reduction strategies in mammography and computed tomography. FDA National Center for Devices & Radiological Health, two years, $175,000 per year.

Chemoprevention of cervical cancer (increase in funding). Univ. of Arizona and Albert Einstein College of Medicine. Two year supplement totaling $400,000 for Arizona and $200,000 for Einstein.

The Board deferred consideration until its January meeting on a concept for a competitive contract for a study of correlations between chest x-ray abnormalities and development of lung cancer and mesothelioma in asbestos exposed populations. Board members felt more staff work was needed on determining the populations to be studied and on the sample sizes needed. One contract would be awarded for a coordinating center, with subcontracts as needed to carry out the work.

The project would be carried out in two parts. The first would be to study pleural plaques as a predictor of bronchogenic carcinoma and mesothelioma. It would be a nonconcurrent prospective study. The estimated budget for this study was $600,000 for each of the first two years, $300,000 for the third, and $200,000 for each of the fourth and fifth years.

The second part would be a retrospective case control study of approximately 200 cases of mesothelioma. It would be a two year study, with an estimated cost of $100,000 a year.

The two projects would be competed separately.

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 NO1-CN-45168-03

TITLE: International food and composition data system
DEADLINE: Jan. 12, 1984

NCI is soliciting requests for proposal from organizations interested in developing and implementing an international food data system. This system will facilitate the transfer of reliable data within and between countries. The system shall provide guidelines and constraints for data acceptance including sampling, preparation and methods of analysis, systematic description of foods including parts, processes, maturity and grade as required using standardized descriptions, as well as identification of factors which may influence food composition data such as environmental conditions. This proposed procurement is subject to the availability of funds.

CONTRACTING OFFICER: Shirley Kyle
RCB, Blair Bldg Rm 2A01
301-427-8745

RFP NCI-CN-45172-34

TITLE: Breast cancer bank for animal and human tumors
DEADLINE: Jan. 4, 1984

NCI is soliciting requests for proposals to biologically characterize and maintain transplantable mammary tumors, and tumors of other origins of special interest for use in research projects by selected investigators.

The bank's primary function is to characterize, cryopreserve, store, and provide these animal and human tumors plus antigens and specific antibodies to a-lactalbumin and specific antibodies to various types of collagens and procollagens, to qualified investigators for research purposes.

The bank also maintains in cryopreservation seed samples of certain human and animal, normal and malignant, mammary cell culture lines, all of these well characterized in previous studies. These are for safe storage only and not for distribution.

Purpose of the bank is to provide tumors with a uniform standard of quality, with established biological characteristics, and with proven reproducibility, in order that results obtained can be reproduced from one laboratory to another, and scientists from different disciplines can contribute their expertise in providing additional important information on the biological characteristics of the tissues.

CONTRACT SPECIALIST: E.J. Abbott
RCB, Blair Bldg Rm 2A01
301-427-8745

RFP NCI-CB-44020-53

TITLE: Radioimmunoassays and enzyme immunoassays of immunoglobulins and antibodies
DEADLINE: Jan. 16, 1984

NCI has a requirement for the performance of radioimmunoassays of immunoglobulin molecules and enzyme linked immunoassays for specific antibodies in human mononuclear celll culture supernatants or biological fluids. This project will serve in direct support to a laboratory at NCI. The contractor's facility must be within close proximity of the National Institutes of Health. Many of the assays required under the proposed project will be performed on samples from patients admitted to the NIH Clinical Center for only a few days. Results of these assays determines the research protocols utilized in the clinical evaluation of these patients. A 24 hour turn around time is required.

The current effort is being performed by Hazleton Laboratories Inc. under contract. It is expected that one award will be made for a three year period.

CONTRACT SPECIALIST: Eileen Webster
RCB, Blair Bldg Rm 114
301-427-8888

RFP NCI-CM-47645-24

TITLE: In vivo screening of materials from European sources
DEADLINE: Feb. 13, 1984

NCI's Div. of Cancer Treatment, Developmental Therapeutics Program, Drug Evaluation Branch, is seeking organizations in Western Europe for primary and detailed in vivo testing, in rodent hosts, for anticancer efficacy. Animals, tumors, and testing protocols will be supplied by NCI. Materials to be tested will be supplied by NCI primarily through the NCI Liaison Office based in Europe.

NCI is seeking organizations possessing facilities for housing sufficient numbers of conventional experimental rodents and possessing the capability to maintain and transplant tumor lines, to prepare materials for testing, to conduct a minimum of 11,000 test equivalents per year, and to report all test data for computer processing on forms and format furnished by NCI.

A test equivalent is based on the work effort required to carry out an IP L1210 assay, with IP treatment for nine consecutive days using six mice per test group plus appropriate controls. Organizations must have the capability to conduct testing in a number of in vivo tumor assays, primarily the P388 tumor test system and other systems such as L1210, B16 melanoma, M5076, etc. Testing against human tumor xenograft is not required.

Offerors must possess the capability and resources for in vivo screening at a minimum level of 11,000 L1210 test equivalents per year. The principal investigator must have experience in the in vivo testing of drugs in rodents.

It is anticipated that one award will be made as a result of this RFP. It is also anticipated that the award will be for a five year incrementally funded period of performance. Some form of cost sharing is encouraged. The RFP will be available on or after Dec. 19.

CONTRACT SPECIALIST: Marlene Haywood
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