

THE

CANCER NEWSLETTER

11800 Sunrise Valley Drive, Reston, Virginia 22091 Phone 703-471-9695

Vol. 1 No. 25

July 26, 1974

© Copyright 1974
National Information Service Inc.

Subscription \$100 per year

NEW RESEARCH TRAINING ACT MAY PERMIT NCI TO HELP FILL CLINICAL GAPS IN RADIOTHERAPY, MEDICAL ONCOLOGY

The National Research Act will open an entirely new era in NIH manpower training, and NCI hopes to take advantage of provisions in the new law that will permit the cancer program to support training of students in clinical disciplines.

Under the old NIH training grant and fellowship programs, clinical training, except in certain very limited cases, was prohibited. An exception at NCI was the clinical education program, which is aimed at institutional improvement, although under the old guidelines it did include some trainee stipends. That program was ended by order of HEW two years ago, but NCI modified it, dropping trainee stipends (except when trainees are paid for services rendered), and HEW went along with it.

The new law removes restrictions against clinical training support by NIH. The payback requirement implemented by the act applies to all trainees and fellows, removing the most compelling argument against support for future clinicians - that too many of them go immediately into lucrative private practice with the government not realizing any return on its investment in them.

Like all other recipients of support under the new program, clinical
(Continued to page 2)

In Brief

NCI AWARDS \$1.2 MILLION TO MT. SINAI TO ESTABLISH SPECIALIZED CANCER CENTER

MT. SINAI School of Medicine in New York City has received a \$1.2 million grant from NCI to establish a specialized cancer center. James F. Holland is director of the center, which will have a research ward with a four-bed laminar airflow unit and a research clinic, where outpatients will be treated. The grant partially supports salaries, equipment and supplies and also provides partial core support for programs in chemotherapy, immunotherapy, biochemical diagnosis, and supportive patient care . . . **ROSWELL PARK** will lay the cornerstone Aug. 1 for its Cancer Cell Center, a \$7.8 million basic research facility. NCI put up \$5.5 million, New York State the rest . . . **INTERNATIONAL WORKSHOP** on the clinical usefulness of cell kinetic information for tumor chemotherapy is scheduled Oct. 14 and 15 in Rijswijk, The Netherlands, at the Radiobiological Institute . . . **SECOND ANNUAL Hellenic Congress on Oncology** is scheduled for April 20-23, 1975, in Athens. Main topic will be breast cancer, with additional symposia on cancers of the lung, colon, bone, and male genitalia; virus-induced tumors in humans; and experimental chemotherapy. Panels will be held on organization for cancer control, charlatanism and cancer and euthanasia and cancer . . . **JEREMIAH B. SULLIVAN** has moved up from director of Hazleton Labs' product safety division to vice president of Program Development . . .

Contract Awards

.... Page 6

NCI REPORT LISTS CANCER MANPOWER REQUIREMENTS OVER NEXT FOUR YEARS

(Continued from page 1)

training graduates may opt for private practice without serving the required time in research or teaching, but they will be required to repay the government for all stipends they received unless they work a designated period in medically-underserved areas or in HMOs.

NCI has been warning that one of the cancer program's major weaknesses has been the fact that too few medical students were going into the cancer clinical specialties. The most urgent need is for radiotherapists and medical oncologists.

NCI's Div. of Research Resources & Centers reported to NIH on projected cancer program manpower needs through fiscal 1978. The report was compiled by John T. Kalberer Jr., acting associate director for program planning, and was signed by DRRC Director Thomas J. King.

Since at the time the report was filed there was no authority for training in the clinical disciplines, detailed figures on those needs were omitted. However, Kalberer told *The Cancer Newsletter* that the Committee on Radiotherapy had estimated that more than 2,400 radiotherapists would be needed by 1978. There are now only 560 physicians practicing radiotherapy full time.

Figures on medical oncologists are more difficult to determine, since there is no general agreement on what that category includes. Kalberer estimated that at least 2,000 medical oncologists would be needed by 1978, and the best guess is that now there are only a few hundred.

In the research disciplines, the report estimates that by 1978 a total of 9,300 scientists will be needed by the cancer program. There are approximately 5,000 now, so the program will have to recruit and train about 4,300 in the next four years if the needs are to be filled.

The report breaks out the requirements by program (figures are total scientists needed, including those already working in the respective fields):

Carcinogenesis, 2,551; epidemiology, 240; radiation physics, 80; viral oncology, 1,521; immunology, 1,665; drug development, 1,152; chemotherapy, 641; and tumor biology, 1,450.

The report anticipated that training support in the current fiscal year would be only through the Weinberger fellowship program (training grant programs that were in the process of being phased out were not included). To date, NCI has awarded about 400 Weinberger fellowships. Because the new law and its payback requirement applies to that program, NIH is notifying recipients and asking them to sign the payback agreement.

The report lists the number of anticipated individual awards and estimated funds supporting them in each of the program areas for fiscal 1975 and 1976.

Viral oncology – 1975, 134 awards, \$1.8 million; 1976, 229 awards, \$3 million.

Carcinogenesis – 1975, 120, \$1.6 million; 1976, 203, \$2.6 million.

Chemotherapy – 1975, 33, \$441,000; 1976, 59, \$767,000.

Drug development – 1975, 76, \$1 million; 1976, 131, \$1.7 million.

Epidemiology – 1975, 25, \$338,000; 1976, 35, \$455,000.

Immunology – 1975, 153, \$2 million; 1976, 255, \$3.3 million.

Radiation – 1975, 50, \$669,000; 1976, 83, \$1 million.

Tumor biology – 1975, 126, \$1.7 million; 1976, 199, \$2.6 million.

NIH executives were meeting this week to resolve some of the questions raised by advent of the new act:

– Will the new authority be used to fund at least some of the applications approved under the old program but unfunded? Is that practical considering that two years have elapsed and conditions probably have changed at the applicant institutions?

– Will the old review bodies be recalled, or new groups constituted?

– How soon can new programs be implemented?

As far as NCI is concerned, any new programs put into operation in the current fiscal year will have to be funded out of the \$4 million allotted to training from the extra \$60 million given NCI in the House appropriations bill. William A. Walter, DRRC deputy director, said that NCI had tentatively planned to use most of the \$4 million to fund training grant programs previously scheduled for phasing out. About \$2 million would go to institutional support, \$2 million to trainee stipends, picking up about 175 additional trainees.

NCI has created a new position, that of associate director for manpower development, and is in the process of recruiting someone to fill it.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute, unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP. Some listings will show the phone number of the Contract Specialist, who will respond to questions about the RFP. Contract Sections for the Cause & Prevention and Biology and Diagnosis Divisions are located at: NCI, Landow Bldg. NIH, Bethesda, Md. 20014; for the Treatment and Control Divisions at NCI, Blair Bldg., 8300 Colesville Rd., Silver Spring, Md. 20910. All requests for copies of RFPs should

cite the RFP number. The deadline date shown for each listing is the final day for receipt of the completed proposal unless otherwise indicated.

RFP NCI-CB-53857-33

Title: Construction of a projection data base for testing algorithms for computerized transaxial reconstruction

Deadline: Sept. 16, 1974

Computerized transaxial X-ray reconstruction has recently become commercially available for studies of lesions of the brain and of the torso or parts thereof. Usually the commercial equipment combines hardware and software in a unit that is beyond the financial reach of many radiological centers. It has become apparent that improvements in software as well as hardware may reduce radiation hazard to the patient without loss of resolution in the reconstruction, improve the detection, localization and diagnosis of lesions, and minimize the deleterious effects of distortion and artifacts in regions of medical interest in the reconstruction.

The contractor shall have the capability and interest in constructing standard data bases consisting of unprocessed projection data from various body sections. Specifically:

a. The offerors must establish expertise and responsibility in the use of equipment for digital transaxial X-ray projections on phantoms and human subjects.

b. They must furnish physical specifications for the equipment they propose to use.

c. The projection data must be digitized and recorded on industry-compatible magnetic tape for delivery to NCI.

d. Offerors agree to have NCI furnish the data to contractors for evaluation and comparison of reconstruction algorithms.

e. Offerors agree to have the composition of the data base decided upon by the project officer and other representatives of NCI.

The goal of this project is to obtain information (that can be supplied to radiologists) that can be utilized to more readily establish techniques that will improve the possibility of recognizing cancer in its earliest (smallest) stage.

The government anticipates that the proposed contract will last one year. However, offerors should furnish their own estimates of the time required to achieve the objectives of this project.

Contract Specialist: J. H. Reynolds
Biology & Diagnosis
301-496-5565

RFP NCI-CB-53858-33

Title: Development and evaluation of computerized tranaxial x-ray reconstruction

Deadline: Sept. 16, 1974

The project objective is to develop an improved

method of x-ray imaging to aid in the diagnosis of early cancer and to evaluate it in comparison with conventional x-ray methods. It is expected that the radiation dosage to the patient may thereby be reduced as well.

While computerized transaxial x-ray reconstruction has recently become available commercially for study of brain lesions, it has become apparent that there may be institutions that are developing this technique and are building or have built equipment that is capable of performing the same function for the torso and parts thereof.

The contractor shall have or be working with a prototype machine with the capability of providing such a scan within the ten-second breath holding interval. In addition:

a. The contractor agrees to furnish NCI with the machine as developed and the algorithms thereto pertaining.

b. The contractor will have clinical facilities for the diagnosis and treatment of patients considered to be abnormal by the techniques employed.

c. Comparable radiation dosages will be determined for the two techniques, namely, the scanning radiogram and the conventional diagnostic radiograms obtained in the usual manner with and without contrast media.

d. It is desirable that a high-risk group be identified so as to justify the use of the increased radiation exposure occasioned by the use of the two techniques.

e. The contractor will establish the capability of independent reading of these films as well as sound experimental design for evaluation of the performance of the two different techniques.

f. It is expected that these pared films will be delivered to a recognized panel of experts named by NCI for their randomized reviewing and interpretation including the quality of each of the films.

g. It is expected that digitized projection data and digital reconstructed images will be delivered to the National Cancer Institute on industry compatible magnetic tape.

The government anticipates that the proposed contract will span a three-year period, permitting a year for further development of equipment and two years for clinical trial.

Contract Specialist: J. H. Reynolds
Biology & Diagnosis
301-496-5565

RFP NCI-CB-53861-33

Title: Application and evaluation of self-obtained vaginal smear

Deadline: Sept. 16, 1974

The project objective is to promote the use of self-obtained smears to see if this modality has greater acceptance by the group of women who do not avail

themselves of the ordinary screening facilities for cervical cancer. It is also the objective to evaluate the effectiveness of this type of screening in detecting cervical cancer or its precursors and in lowering mortality from cancer of the cervix.

While cervical cytology studies have established themselves as a mechanism for the detection of early cancer and precancerous lesions, it is at the same time recognized that this modality has not involved a large segment of the American population. In an attempt to reach those women who do not seek regular screening clinics, and who do not attend with any degree of regularity medical clinics of any sort, it has been suggested that the use of self-obtained smears may reach a large part of this unscreened population.

The contractor is expected to establish a self-obtained vaginal smear technique in screening a high-risk group that has not in the past availed itself of cervical screening programs to an appreciable extent. Specifically:

- a. The techniques they offer to use will have been established as giving a high positive correlation and a low negative correlation with the actual existence of cancer or carcinoma-in-situ of the cervix.
- b. It is expected that the offerors will have had past experience with the techniques.
- c. It is expected too that there will be established within the cohort or a demographically similar cohort an adequate control to establish the validity of the testing as a means of reducing deaths from cervical cancer. In this effort, the offerors will have the advice and support of accepted demographers and biostatisticians.
- d. Suitable history and laboratory forms will be established so that further demographic and epidemiologic aspects not yet demonstrated may be inferred if they exist.
- e. Offerors will be expected to keep records that will allow them to recall patients with suspicious and positive smears and to have clinical facilities to adequately establish the diagnosis and to adequately treat those that need treatment at no cost to the government.
- f. Offerors will have established the mechanism whereby negative screenees will be recalled within one year, and then screenees with two consecutive negative annual screenings will be divided randomly so that one-third are continued on annual screening, one-third are screened every two years into the sixth year and the remaining one-third are screened again in three years and repeated in the eighth year.
- g. Offerors will establish the mechanism whereby upon completion of the screening study they will be able to determine the annual status of each of the patients, study and control.

The goal of this project is to extend a cervical screening for cancer mechanism to women who do not ordinarily avail themselves of such screening fa-

cilities; by this means it is intended to reduce the number of deaths from cervical cancer in these women. This project will demonstrate the feasibility of such a mechanism and will also demonstrate the comparative values of screening at various time intervals.

RFP NCI-CB-53862-33

Title: The use of screening technique for blood in the stool as a means of detecting early cancer of the bowel.

Deadline: Sept. 16, 1974

The project objective is to detect cancer of the colon at a time when it is localized and can be encompassed and hopefully cured by a surgical procedure.

Cancer of the colon-rectum in 1972 was estimated to have caused over 36,000 deaths and 90,000 new cases were estimated to have occurred. At this time the survival rate is low; yet the survival rate from lesions that are recognized at an early stage is quite good. It has been known that the detection of blood in the stool is often useful to direct one's attention to cancerous lesions in the large intestine. It is proposed to screen a large high-risk population by means of stool examination for the presence of blood, to follow these patients for a routine re-screening at various intervals for a period of five years and a continual follow-up for another five years in order to determine the effects of such screening on survival.

The contractor shall establish a screening procedure for blood in the stool in the population to be decided upon consultation with demographers.

- a. The contractor after consultation with demographers will establish high-risk characteristics and seek a method of attracting individuals with these characteristics to their institution.
- b. The contractor will determine the number of patients to be entered into this study by epidemiological and biostatistical consultants; the number should be adequate to give valid comparisons.
- c. The contractor, again with epidemiological and biostatistical consultation will establish a control cohort that will not have stool screening for blood, but which will be able to be followed for the same period of time.

The government anticipates that the proposed contract will span an eight-year period. However, offerors should furnish their own estimates of the time required to achieve the objectives of this project. Offerors should submit budgets on an annual basis for the total period of their estimates of the time required to achieve the objectives of this project. It is anticipated that the proposed contract will be awarded as a 12 month contract with annual renewal based on performance and an incrementally funded contract.

Contract Specialist: J. H. Reynolds
Biology & Diagnosis
301-496-5565

d. The contractor will have clinical facilities to be able to establish the diagnosis of large bowel cancer when such suspicion exists.

e. The contractor will have clinical facilities for the treatment of such patients.

f. The contractor will have a high follow-up potential for all the patients entered in the study, so that the negative patients can be recalled for re-screening and so that the occurrence of interim disease as well as status can be established.

g. The contractor will establish history, physical, laboratory and other necessary forms that are suitable for conversion for computer storage and that can be used upon retrieval for evaluating pre-disposing factors and findings not yet established.

h. The contractor agrees that if and when a more sophisticated test for human blood is developed, NCI may request substitution of the new test if the contractor agrees to creation and adoption of a common protocol with collaborating contractor.

The government anticipates that the proposed contract will span a five-year period and a subsequent five-year follow-up. However, offerors should furnish their own estimates of the time required to achieve the objectives of this project.

Contract Specialist: J. H. Reynolds
Biology & Diagnosis
301-496-5565

RFP NCI-CB-53863-33

Title: Determination of optimal frequency of screening strategies

Deadline: Sept. 16, 1974

The project objective is to develop a means for determining a frequency of screening more realistic, scientifically more accurate and with least cost and with least hazard to the patient.

Determining an optimal screening strategy for a specific disease in a target population involves looking at several inter-related questions including the frequency, choice, and sequence of screening tests. This requires information on several factors:

- The natural history or development of the disease.
- The incidence of the disease in the target population.
- The effectiveness (sensitivity and specificity) of the various available screening tests at each stage of the disease.
- The effectiveness (on mortality) of intervention (treatment) during each stage of the disease.
- The cost and hazards of the various screening tests.

The contractor will create a team of clinicians, pathologists, statisticians, operations researchers and epidemiologists. Specifically:

a. This team will be expected to work closely together in order to obtain the objective.

b. It will be necessary for the team to carry out an extensive investigation and documentation of the level of present knowledge, both empirical and theoretical, on each of the five factors mentioned.

c. All assumptions made in developing the model must be explicitly identified.

d. It should be known that the government may wish to conduct an independent ad hoc review of the proposed model before extensive testing and simulation is carried out.

e. A method of validating the models should also be proposed.

f. The contractor should supply models for diseases for which screening data exist. However, the contractor will be expected to supply to NCI preliminary models for diseases with less complete data such as colon, lung, bladder and prostate cancer.

g. These preliminary models mentioned in "f" will be used by the contractor to help identify additional information that is needed to completely develop the model and through parametric analysis to suggest general ranges or minimum limits on the performance of screening tests if they are to be effective in early cancer detection and reducing cancer mortality.

The government anticipates that the proposed contract will span a one to two year period.

Contract Specialist: J. H. Reynolds
Biology & Diagnosis
301-496-5565

RFP NCI-CB-53864-33

Title: Design of an experiment to assess the impact of multi-site screening on total cancer mortality

Deadline: Sept. 16, 1974

The project objective is to establish models of multi-site screening so as to give us the best possible likelihood of effectively reducing cancer mortality in general at a cost that can be acceptable.

It is not known whether screening for all sites that are available to us at this time should be done indiscriminately or with selection based on risk, together at one time or individually; nor is it known that such screening will reduce our cancer mortality. A model or models to help to determine whether the answers to these questions can be obtained is sought.

The contractor shall establish a team having expertise in the fields of clinical oncology, radiology, epidemiology and statistics. Specifically:

The contractor shall develop an experimental design on the basis of available knowledge of high risk factors, quality of screening procedures, variability in the effectiveness of present day treatment, cost, compliance with follow-up examinations and follow-through procedures, side-effects of treatments, incidence rates, prevalence rates, and case fatality rates.

b. The contractor must be able to express the rationale for the experimental design in a format

which makes explicit their use of available information and their accepted assumptions.

The government anticipates that the proposed contract will span twelve months. However, offerors should furnish their own estimation of the time required to achieve the objective of this project and submit budgets accordingly.

Contract Specialist: J. H. Reynolds
Biology & Diagnosis
301-496-5565

SOURCES SOUGHT

Responses to these solicitations will be technically evaluated by NCI to determine R&D capabilities and potential sources for solicitation. RFPs are not yet available. Reference the synopsis number.

SYNOPSIS 12

Title: Chemical Repository

Deadline: July 30, 1974

CHEMICAL REPOSITORY. NCI is soliciting source information from organizations having the capability and facilities for the establishment of a repository and distribution center for the handling of carcinogenic and radioactive chemicals. Activities to be carried out in the repository include the opening of shipments received and inventory of hazardous materials, mixing the bulk chemicals, the removal of aliquots for chemical characterization, the submission of bulk materials into smaller packages of convenient size, long-term storage, and repacking into containers suitable for shipment.

Methods for the safe disposal of such materials should be available. The analytical support laboratory would be expected to perform chemical characterization studies which would validate that the material received was in fact the material desired. It is assumed that such measurements might include melting points, boiling points, refractive index, infrared spectroscopy, and gas-liquid chromatography.

The storage area should have provision for the storage of chemicals in a variety of package sizes stored at room temperature, at 5 degrees C, or at -20 degrees C. An area must be available in which materials are packed in a suitable manner for shipment and logged out of the facility. It is anticipated that these activities might ultimately require the dedication of some 6,000 sq. ft.

It is expected that facilities devoted to this purpose would meet the OSHA standards for the handling of carcinogenic materials. In immediate proximity to these facilities it may ultimately be desirable to have space, equipment, and personnel available for

the performance of some synthesis and purification activities in support of the repository; the availability of such facilities is desirable but not essential.

Resumes are invited from organizations having the capability and facilities required to carry out the above activities.

All information submitted shall address the following areas:

Experience - An outline of any previous projects of specifically related in-house activities which have been performed in the past or are presently being performed.

Personnel - Name, professional qualifications, and specific experience of key technical personnel who could be assigned to this activity.

Facilities - A description of the special facilities available at this time for the conduct of the work as well as a discussion of facilities which might be made available in the future.

Include in your submission any other pertinent data that would enhance our understanding or assist us in evaluating the information submitted.

Contract Specialist: D. J. Dougherty
301-496-6361
Cause & Prevention
Room B-401 Landow Bldg.
NCI
Bethesda, Md. 20014

SOLE SOURCE

Proposals listed here are for information purposes only. RFPs are not available.

Title: Molecular studies of human and animal cancer with emphasis on breast carcinoma
Contractor: Meloy Laboratories, Springfield, Va.

Title: Study of structural properties of cancer therapeutic agents
Contractor: Pomona College, Claremont, Calif.

Title: Study mycobacteria as inhibitors of tumor cell growth
Contractor: The Trudeau Institute, Caranac Lake, NY

Title: Studies on Marek's disease as a model for human herpesvirus oncogenesis
Contractor: Life Sciences, Inc., St. Petersburg, Fla.

CONTRACT AWARDS

Title: Coordinating center for the clinical study of melanoma
Contractor: Istituto Nazionale per lo Studio e la Cura dei Tumori, Milan, Italy, \$46,400.

The Cancer Newsletter—Editor JERRY D. BOYD

Published weekly by National Information Service Inc., 11800 Sunrise Valley Drive, Reston, Va. 22091. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without the prior written permission of the publisher.