

NIH GUIDE

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for **GRANTS**
and **CONTRACTS**

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Vol. 3, No. 1, January 4, 1974

BLADDER CANCER RESEARCH

ANNOUNCEMENT

The Program Director and the Working Cadre of the National Bladder Cancer Project wish to extend an invitation to qualified investigators to apply for grant support of bladder cancer research in those areas which have been designated as high priority for immediate implementation. Several such project areas are presented for consideration.

All applications for research grants to be reviewed by and funded through the National Bladder Cancer Project must be prepared on the standard National Institutes of Health forms (NIH 398) and must be mailed to: National Bladder Cancer Project, St. Vincent Hospital, 25 Winthrop Street, Worcester, MA 01610.

Applications received will be reviewed by the Working Cadre of the NBCP and must receive final approval of the National Cancer Advisory Board and the National Cancer Institute. In addition to the usual assessment of scientific merit, technical adequacy of the experimental design, competency of the investigator, adequacy of resources, appropriateness of the level and period of support, all grant applications submitted to the NBCP will be evaluated for relevance to the program needs and as to whether or not the work proposed is important to the achievement of the NBCP goals.

The National Bladder Cancer Project cannot accept applications which are being considered by the Division of Research Grants or other divisions of the NIH. Also, any application which has been disapproved by NIH cannot be considered by the NBCP unless it has been appropriately changed.

Letters of interest and capability or inquiries for additional information are welcomed.

HIGH PRIORITY RESEARCH AREAS

Etiology and Prevention

Available evidence suggests that in a majority of cases, the etiology of cancer of the urinary bladder is related to environmental factors. Further information about such causal factors, and about possible differences in the reaction of different

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populations to such factors is badly needed. In a few occupations epidemiologic research has revealed a relationship between the high incidence of bladder tumors and a specific job, or even to the exposure to specific chemicals. Under such circumstances, an ideal approach to prevention would be to replace the identified carcinogen with a non-carcinogenic compound or, if this is not possible, to alter the response of the exposed individual to such carcinogenic compound and thus protect the population at risk.

There remains a need for more world-wide information about possible differences between the histories of individuals who have developed bladder cancer as compared with those who have not. Further studies are also needed on the relationship between suspected etiologic factors and the incidence of bladder cancer in selected populations. Because the distribution of verified or suspected carcinogens is now known, new tests need to be developed for measuring such agents or their metabolites in the environment or in exposed individuals. Similarly, improved methods of evaluating host susceptibility to known bladder carcinogens are also needed in order to define more precisely those individuals and populations at high or low risk. These more precise biological and chemical evaluations of risk will become more important with the development of techniques for counteracting identified carcinogens or interfering with the carcinogenic process itself.

Consideration of bladder cancer studies in humans reveals the need to develop or improve in vivo and in vitro model systems. Since no one system is likely to parallel the process in the human, studies in various experimental systems, including human tissue culture systems, must be carried out. The ultimate objective of such studies is to provide means of (1) interfering with the absorption of possible carcinogenic compounds, (2) preventing the formation of proximate carcinogens, (3) modifying the metabolism or excretion of a carcinogen by the host so as to reduce the effectiveness of the carcinogen, (4) interfering with the initiation of malignant transformation or (5) inhibiting the growth of transformed cells into visible tumors.

The following high priority areas of research are proposed for implementation:

- A. To conduct studies for identifying factors (hazards) and to identify populations with differing risks.
 1. International case-control studies on factors suspected of being etiologic for carcinoma of the bladder.
 2. Cross sectional studies in metropolitan and semi-rural areas of the U.S. seeking further information on factors suspected of being etiologic for carcinoma of the bladder.
 3. One or two limited studies to identify more specifically the selected high risk populations, e.g., correlation between provincial bladder cancer rates in Canada and human bracken fern consumption.
 4. Retrospective cohort studies on special exposure groups such as workers in the rubber, leather, and dye industries.
 5. Analytical studies to develop more suitable qualitative and quantitative methods for detecting known bladder carcinogens and for evaluating the environmental levels of carcinogens to which humans are exposed.
 6. Studies to measure the level of carcinogenic compounds to which humans are exposed in selected environments.
 7. Studies utilizing quantitative analytical methods to determine more definitively the absorption, metabolism, and excretion of known bladder carcinogens.

- B. Studies to develop methods for interfering with the formation of tumors.
1. Biological studies to develop more suitable cell and organ culture methods for transitional cell tumors of the bladder.
 2. Biochemical and physiological studies in suitable in vivo and in vitro model systems to investigate growth regulation and characteristics of cellular membranes in normal and neoplastic tissue.
 3. Studies in model systems of susceptible and nonsusceptible species of known bladder carcinogens following the co-administration of the carcinogen with metabolic stimulating or trapping agents or following modification of other organ systems.
 4. Studies in suitable model systems of the effect of known bladder carcinogens administered at various periods during the development of the animal.
 5. Biochemical studies of the influence of stimuli applied during various stages of bladder carcinogenesis through the use of (1) initiation-promotion systems or (2) inhibition, summation or synergistic effects of co-administration of a variety of stimuli concurrently or sequentially by systemic routes.
 6. Preliminary field trials attempting to prevent primary or recurrent bladder cancer with such compounds as vitamin B6 given orally, or thiotepa instilled at intervals in the bladder, by modifying the carcinogenic process in high risk populations with a known exposure to a carcinogen or a previous history of bladder cancer.

Detection, Diagnosis, Prognosis, Treatment

The initial lesions seen in the bladder are often small and of "low grade" malignancy, but with our present state of knowledge we cannot predict--on an individual patient basis--which patients will have subsequent tumors or recurrences. Lesion removal by the transurethral route often serves as the definitive treatment as well as the diagnostic procedure, so that it is not really possible to follow an untreated patient. Any method for improving the evaluation of the biological potential of a bladder lesion to recur after removal, or to progress to more advanced grades of malignancy, or for measuring the patient's abilities to resist such changes, would contribute to the selection of the most appropriate treatment.

Unfortunately, many lesions recur and/or progress in spite of the most skillful use of the treatment regimens presently available. The functional importance of the bladder and the multifocal nature of many bladder lesions make local treatment difficult and often futile. New treatments are needed which are applicable to the entire bladder mucosa or are systemic in approach. Immunotherapy or chemotherapy offer the greatest promise at the present time.

(Continued)

The following types of studies have been given high priority for initiation at this time:

1. Immunological studies attempting to identify and isolate specific antigens and antibodies for bladder tumors;
2. Clinical studies to determine the ability of selected patients with small quantities of tumor, but with a known poor prognosis, to develop antibodies to their tumors following the use of non-specific reagents; and
3. Studies of new and innovative treatments in appropriate animal models.

In general, therapies to be evaluated should have shown promise for other human tumors, or should have special advantages for the treatment of bladder cancer. Those demonstrating promise should, in some instances, be further tested in animals in combination with other therapeutic modalities or agents for toxicity, effectiveness, side effects and probable acceptability to subjects.

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

No. 10, January 18, 1973

DEMONSTRATION OF CANCER
REHABILITATION FACILITIES
AND/OR DEPARTMENTS

A N N O U N C E M E N T

The Cancer Control Program of the National Cancer Institute is soliciting proposals for a project(s) to develop a workable model system of rehabilitation services for cancer patients. The system shall provide for the education of rehabilitation team personnel and the development of new approaches to the rehabilitation of cancer patients. Prospective offerors must have at least the rudiments of a rehabilitation department including physical facilities for active cancer rehabilitation, equipment for making prosthetic devices, and access to a wide range of medical specialties, as well as vocational, psychological, and social rehabilitation services. The contract program is primarily directed toward major medical centers, teaching hospitals and cancer centers. Other rehabilitation projects may be supported through the solicitation just below, entitled "Integrated Cancer Rehabilitation Services." RFP No. NIH-NCI-CD-73-5 will be issued in late February 1973.

INTEGRATED CANCER
REHABILITATION SERVICES

A N N O U N C E M E N T

The Cancer Control Program of the National Cancer Institute is soliciting proposals for project(s) to develop and demonstrate the effectiveness of integrated cancer rehabilitation services in community hospitals. This

effort includes selection and training of nurse co-ordinators and other staff, definition of patient selection criteria, and program evaluation. It is anticipated that a total of 200 new cancer patients per year will be required over a 30 month period. Prospective offerors must have access to trained rehabilitation professionals, staff and facilities for training of supporting personnel, and the ability to develop a patient information system meeting the needs of this project. This contract program is primarily directed toward community and non-speciality hospitals. Other cancer rehabilitation projects may be supported through the solicitation just above, entitled "Demonstration of Cancer Rehabilitation Facilities and/or Departments." RFP No. NIH-NCI-CD-73-6 will be issued in late February 1973.

CANCER TRAINING PROGRAMS
FOR PHYSICAL AND/OR
OCCUPATIONAL THERAPISTS

A N N O U N C E M E N T

The Cancer Control Program of the National Cancer Institute is soliciting proposals for the development and implementation of programs to upgrade and supplement the education of occupational and/or physical therapists with respect to the rehabilitation of cancer patients. Special attention must be given to evaluation and follow-up procedures which determine the effectiveness of the training. Offerors must have or have access to the necessary physical facilities and teaching staff, as well as accessibility to prospective trainees. In addition, they must have the capability to provide practical experience to the trainees. RFP No. NIH-NCI-CD-73-7 will be issued in late February 1973.

TRAINING PROGRAMS FOR
MAXILLOFACIAL PROTHODONTISTS
AND LABORATORY TECHNICIANS

A N N O U N C E M E N T

The Cancer Control Program of the National Cancer Institute is soliciting proposals for the development and implementation of comprehensive programs to upgrade and supplement the training of maxillofacial prothodontists and laboratory technicians with respect to specialized techniques and practices used in the rehabilitation of patients with cancer of the head or neck. Offerors must have or have access to the necessary physical facilities and teaching staff, as well as accessibility to prospective trainees. RFP No. NIH-NCI-CD-73-8 will be issued in late February 1973.

Requests for copies of an RFP should be received by the National Cancer Institute not later than February 15, 1973. RFP availability is limited and will be furnished to requestors on a first-received, first-served basis. Requests must be in writing, citing the particular RFP number. Copies of the RFP may be obtained by applying to the Contracting Officer, Room 10A24, Building 31, National Cancer Institute, 9000 Rockville Pike, Bethesda, Maryland 20014.