

# NIH GUIDE

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## For Grants and Contracts

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## NOTICE

### NIH POLICY RELATING TO REPORTING AND DISTRIBUTION OF UNIQUE BIOLOGICAL MATERIALS PRODUCED WITH NIH FUNDING

P.T. 36, 16; K.W. 1014002, 1016004, 1200140, 1200490, 1200570, 1200820, 1201190

National Institutes of Health

Scientific and technological advances attributable to biomedical research frequently result in unique biological materials, of which some are patentable inventions. Some examples are: specialized and/or genetically defined cells, including normal and diseased human cells; monoclonal cell lines; hybridoma cell lines; microbial cells and products; viruses and viral products; and recombinant nucleic acid molecules. In accord with the policy of the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH) takes the position that such products, when they are developed through the expenditure of NIH funds, should be made available to other research workers and the general public. While the circumstances may vary, the NIH offers the following guidelines concerning materials developed through its awards. (This Notice was first published in March 1984, and again in October 1986. It is reprinted for the benefit of those who did not see it then.)

#### A. NIH policy on Distribution of Newly Developed Materials

The practice of sharing research results--not only information but also the actual biological materials--has been a major strength of our nation's biomedical enterprise. The NIH recognizes that the vast majority of scientists currently make these newly developed materials readily available to other research workers. The purpose of this announcement is to emphasize the NIH policy that all unique biological materials developed with NIH funding be readily available to the scientific community after publication of the associated research findings or announcement at conferences. Restricted availability of these materials can impede the advancement of basic research and the delivery of medical care to the nation's sick.

In order to facilitate the availability of unique or novel biological materials developed with NIH funds, the investigator may distribute the materials through his/her own laboratory or institution, or submit them, if appropriate, to facilities such as the American Type Culture Collection or similar repositories. In some instances sharing of such material may be impractical, but these are expected to be only infrequent exceptions. Investigators are encouraged to consult the appropriate Health Scientist Administrator at NIH who may be of assistance in determining an appropriate distribution mechanism.

#### B. NIH policy on Reporting of Newly Developed Materials

Investigators are reminded that unique or novel biological materials and their products are considered to be inventions and therefore are subject to the various laws and regulations applicable to patents. Accordingly, the NIH requires that grantees and contractors adhere to grant regulations and contract clauses, respectively, pertaining to the reporting of inventions to the NIH. Only those cell lines or their products for which a demonstrated use exists or which have a potential for commercial development need be reported. However, when reporting is indicated, it should occur at the earliest possible time and should not await the end of the budget period or the expiration of the award. Examples of potentially reportable inventions in the areas of molecular and cell biology include synthesis of molecules with unique properties; special tests, assays or components (diagnostic tests); and cells or products of cells. Some investigators may wish to attempt to patent these materials; if so, the usual criteria for reporting and patenting inventions should be used. All not-for-profit institutions and small businesses should be aware that, as a consequence of Public Law 96-517 and OMB Circular A-124, they have first right to all inventions developed at their institutions with funds from the Federal Government.

For further information on the reporting of inventions and the filing of patent applications contact:

Messrs. Leroy B. Randall or Thomas G. Ferris  
Patent Branch, Office of the General Counsel  
Department of Health and Human Services  
Westwood Building - Room 5A03  
Bethesda, Maryland 20892

DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

CULTIVATION OF MARINE ANAEROBIC BACTERIA

RFP AVAILABLE: NCI-CM-87238-16

P.T. 34; K.W. 0780005, 1002003

National Cancer Institute

The Division of Cancer Treatment (DCT), National Cancer Institute (NCI), National Institutes of Health (NIH), is interested in receiving contract proposals from offerors with the capability to furnish and operate a microbiological and small extraction laboratory to isolate various groups of anaerobic bacteria from the marine environment.

The specific objectives of this project are: to (1) collect source samples, (2) isolate various species of marine anaerobic bacteria, (3) determine their taxonomic identity, and (4) grow them under conditions suitable to produce at least 100 mg of whole culture extracts. The Principal Investigator (P.I.) should be trained in microbiology at the Ph.D. level, or equivalent, with at least 3 - 5 years' experience in research with marine anaerobic bacteria and in their taxonomy. The successful offeror will be expected to provide and grow approximately 250 isolates of marine anaerobic bacteria over a period of three years.

Request for Proposal (RFP) No. NCI-CM-87238-16 will be issued, upon written request, to Dorothy M. Coleman, Contracting Officer, on or about October 19, 1987, and proposals will be due approximately six weeks thereafter. To expedite requests for the solicitation, please furnish three self-addressed labels with your request. The contract period is to be three years, beginning approximately August 15, 1988, and one completion-type contract is expected to be awarded.

Copies of the RFP may be obtained by sending a written request to:

Dorothy M. Coleman  
Contracting Officer  
Treatment Contracts Section  
Research Contracts Branch  
National Cancer Institute  
National Institutes of Health  
Blair Building, Room 216  
Bethesda, MD 20892  
Telephone: (301) 427-8737

CULTIVATION OF MARINE PROTOZOA

RFP AVAILABLE: NCI-CM-87239-16

P.T. 34; K.W. 0780005, 1002027

National Cancer Institute

The Division of Cancer Treatment (DCT), National Cancer Institute (NCI), National Institutes of Health (NIH), is interested in receiving contract proposals from offerors with the capability to furnish and operate a microbiological and small extraction laboratory to isolate various groups of protozoa from the marine environment.

The specific objectives of this project are to: (1) collect source samples, (2) isolate various species of marine protozoa, (3) determine their taxonomic identity, and (4) grow them under conditions suitable to produce at least 100 mg of whole culture extracts from each culture used for this contract. The Principal Investigator (P.I.) should be trained in microbiology at the Ph.D. level, or equivalent, with at least 3 - 5 years' experience in research with

marine protozoa and in their taxonomy. The successful offeror will be expected to provide and grow approximately 600 isolates of marine protozoa over a period of three years.

Request for Proposal (RFP) No. NCI-CM-87239-16 will be issued, upon written request, to Dorothy M. Coleman, Contracting Officer, on or about October 19, 1987, and proposals will be due approximately six weeks thereafter. To expedite requests for the solicitation, please furnish three self-addressed labels with your request. The contract period is to be three years, beginning approximately August 15, 1988, and one completion-type contract is expected to be awarded.

Copies of the RFP may be obtained by sending a written request to:

Dorothy M. Coleman  
Contracting Officer  
Treatment Contracts Section  
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National Cancer Institute  
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Blair Building, Room 216  
Bethesda, MD 20892  
Telephone: (301) 427-8737

#### HYPERTHERMIA QUALITY ASSURANCE PROGRAM

RFP AVAILABLE: NCI-CM-87245-11

P.T. 34; K.W. 0706000, 0706020

National Cancer Institute

The Radiation Research Program, Division of Cancer Treatment, National Cancer Institute requires the development of criteria, guidelines, procedures and ancillary equipment for hyperthermia systems which have become or have the potential of becoming commercially available, i.e., have FDA pre-market approval. Ultrasound and interstitial devices in particular need to be addressed. The successful offeror shall also conduct a hyperthermia quality assurance program based on the above and shall conduct on-site examinations of the hyperthermia systems and procedures at government-supported institutions requesting this service. The preparation and distribution of educational materials that describe recommended standard procedures for the use of hyperthermia systems are also required.

This is a full and open competition acquisition for a continuation of the work currently being performed by Allegheny-Singer Research Institute under contract number N01-CM-37512.

It is anticipated that a cost-reimbursement incrementally funded type contract will be awarded as a result of the RFP for a period of thirty-six (36) months, beginning June 30, 1988. All responsible sources may submit a proposal which shall be considered by the agency. RFP No. NCI-CM-87245-11 will be available on or about November 9, 1987. Responses will be due by January 8, 1988.

Copies of the RFP may be obtained by sending a written request to:

Frank Leon, Contracting Officer  
Treatment Contracts Section, Research Contracts Branch  
National Cancer Institute  
Blair Building, Room 225  
Bethesda, MD 20892  
Telephone: (301) 427-8737

PRESCREENING OF COMPOUNDS AS POTENTIAL RADIOSENSITIZERS  
AND/OR RADIOPROTECTORS

RFP AVAILABLE: NCI-CM-87246

P.T. 34; K.W. 0785190, 0415000

National Cancer Institute

The Radiation Research Branch, Division of Cancer Treatment, National Cancer Institute, requires the development of a pre-screen (series of in-vitro tests) to select compounds for screening as potential radiosensitizers. These tests should measure the physical characteristics, i.e., solubility, partition coefficient, electron affinity, etc., as well as specific metabolic endpoints, i.e., binding or inactivation at the molecular or macromolecular levels, cellular oxygen consumption, cellular toxicity, thiols, DNA synthesis, enzyme systems, electron transfer pathways drug inactivation, etc., that may be useful as indicators that the compound is worth evaluating as a potential radiosensitizer. It is anticipated that 8-10 tests will constitute the pre-screen. The pre-screen is expected to remain constant over the length of the contract for the prime objective of the contract is to evaluate the effectiveness of the pre-screen. This will be accomplished by sending the compounds selected by the pre-screen for further testing as radiosensitizers. Cell survival or tumor response assays are not being solicited. The successful offeror would then utilize the developed pre-screen to evaluate 300 compounds each month during the lifetime of the contract. Since the tests will be in-vitro, it is expected that the offeror will have these procedures (tests) on line at the time of contract award. All compounds to be tested will be supplied by the National Cancer Institute. The results are to be formatted in tabular form with a remarks column indicating the Contractor's recommendation for evaluation of radiosensitizing activity. If the recommendation is made for no further testing, the primary reason for this recommendation should be so stated. It is anticipated that a cost-reimbursement incrementally funded type contract will be awarded as a result of the RFP for a period of thirty-six (36) months, beginning June 30, 1988. All responsible sources may submit a proposal which shall be considered by the agency. RFP NCI-CM-87246-11 will be available on or about November 9, 1987.

Copies of the RFP may be obtained by sending a written request to:

Frank Leon, Contracting Officer  
Treatment Contracts Section, Research Contracts Branch  
National Cancer Institute  
Blair Building, Room 228  
Bethesda, MD 20892  
Telephone: (301) 427-8737

PREVENTIVE CARDIOLOGY ACADEMIC AWARD

P.T. 34; K.W. 0715040, 0745055, 0502024

National Heart, Lung, and Blood Institute

Application Receipt Date: April 1, 1988

The Division of Epidemiology and Clinical Applications (DECA) of the National Heart, Lung, and Blood Institute (NHLBI) has initiated the Preventive Cardiology Academic Award (PCAA) to provide a stimulus for the development of a preventive cardiology curriculum in those schools of medicine and osteopathy that do not have one and to strengthen and improve the preventive cardiology curriculum in those schools that do. Each school of medicine or osteopathy in the United States and its possessions or territories is eligible to compete for one award for a project period that does not exceed five years. The number of awards made each year will depend upon the merit of the applications received and availability of funds.

For the purpose of the PCAA, the term preventive cardiology is used to define the area of cardiovascular medicine having a special concern with the development of knowledge and the application of knowledge directed at the prevention of heart and vascular diseases. This includes the area of primary prevention of cardiovascular diseases in infants, children, and adults who are at risk of developing such diseases and the reduction of preventable complications or disability in persons who have already developed cardiovascular disease.

This award is intended to:

encourage the development of a high-quality preventive cardiology curriculum in schools of medicine and osteopathy that will significantly increase the opportunities for students and house staff to learn both the principles and practice of preventive cardiology;

develop promising faculty whose interest and training are in preventive cardiology teaching, research, and practice;

develop established faculty who have a major commitment to and possess educational skills for teaching preventive cardiology;

facilitate interchange of educational ideas and methods applicable to teaching preventive cardiology among awardees and institutions; and

develop at the grantee institution the ability to strengthen continuously the improved preventive cardiology curriculum, with local funds, subsequent to the award.

Requests for copies of the Preventive Cardiology Academic Award Program Guidelines should be directed to:

Associate Director  
Clinical Applications and Prevention Program  
Division of Epidemiology and Clinical Applications  
National Heart, Lung, and Blood Institute  
Federal Building, Room 6A-14  
Bethesda, Maryland 20892-4300  
Telephone: (301) 496-1706

This program of the NHLBI is identified in the Catalog of Federal Domestic Assistance No. 13.837. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

#### MINORITY HIGH SCHOOL STUDENT RESEARCH APPRENTICE PROGRAM

P.T. 44, FF; K.W. 0710030, 0720005

Division of Research Resources

Application Receipt Date: December 1, 1987

#### BACKGROUND AND OBJECTIVES

The Division of Research Resources (DRR), National Institutes of Health (NIH) currently plans to continue the Minority High School Student Research Apprenticeship Program in 1988.

The purpose of the program is to provide minority high school students with a meaningful experience in various aspects of health-related research in order to stimulate their interest in careers in science.

#### ELIGIBILITY

Eligible institutions are those that were awarded grants during the latest complete Federal fiscal year 1987 from either the Biomedical Research Support Grant (BRSG) Program or the Minority Biomedical Research Support (MBRS) Program, both of which are administered by DRR, NIH. Only one application for the Apprenticeship Program can be submitted by a component of an institution that is the recipient of both the BRSG and MBRS awards.

Students eligible for support under this program are those who (1) identify themselves as minority (i.e., Black, Hispanic, American Indian, Alaskan Native, Pacific Islander, or Asian); (2) are U.S. citizens or have a permanent visa; and (3) are enrolled in high school during the 1987-88 academic year. (Students who will graduate from high school in 1988 are eligible, as is a student who participated in a previous year--provided he/she is still enrolled at the high school level.)

## MECHANISM OF SUPPORT

The mechanism of support for this program will be the NIH grant-in-aid. Support will be provided at a level of \$1,500 for each apprentice position allocated. No indirect costs will be paid. Direct support to the apprentice must be as salary; stipends are not allowed. Within the \$1,500 per student allocation, funds may also be utilized for supplies, extending the research experience, or if adequate funds exist, for the addition of an apprentice. However, funds from these grants may only be used for the costs of the apprentice program. The Program Director is responsible for recruitment and selection of the apprentices and assignment of each to an investigator. Recruitment and selection of students should emphasize factors of the students' motivation, ability and scholastic aptitude and accomplishments. In addition, consideration should be given to science teachers' recommendations and where possible the degree of parental commitment. Assignments should be made to investigators involved in health-related research who are committed to developing in the high school students both understanding of the research in which they participate and the technical skills needed.

## APPLICATION

Eligible institutions should submit an application consisting of no more than:

- 1 A one-page letter stating the number of student positions requested, plus
- 2 An original and two signed and completed copies of the Grant Application Form, PHS 398 (Rev. 09/86) face page only.

Mark the "YES" box in item 2 and indicate the announcement title as "Minority High School Student Research Apprentice Program."

Mark items numbered 4, 5, 7, 8b, 10 and 14 Not applicable (N.A.). Complete item 8a with the total dollar amount of your request, which is the sum of the number of student positions requested times \$1,500 per student.

A one-page Program Director's report, and a one-page report for each student may be submitted at any time but these reports and a Financial Status Report will be required by May 31, 1989.

Please Note: Limited funds and increased requests for such student positions may restrict the final allocations by DRR to three or four students per eligible applicant institution. Upon recommendation of the National Advisory Research Resources Council, the Division will give preference in making awards to those institutions that can support a summer program having a "critical mass" of at least five or six students using institutional as well as DRR funds.

The applications should be submitted to:

Biomedical Research Support Program  
Division of Research Resources  
National Institutes of Health  
Building 31, Room 5B-23  
9000 Rockville Pike  
Bethesda, Maryland 20892

Inquiries can be made of Dr. Marjorie A. Tingle at the above indicated address or by calling (301) 496-6743.

The firm deadline for receipt of applications is December 1, 1987. Awards will be effective March 1, 1988, contingent upon availability of appropriated funds.