

# NIH GUIDE

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## For Grants and Contracts

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Vol. 18, No. 41  
November 17, 1989

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## NOTICES

### MORATORIUM ON CERTAIN FETAL TISSUE RESEARCH

P.T. 34; K.W. 0783005, 0745065

Public Health Service

The Secretary for Health and Human Services (HHS), has continued indefinitely the moratorium, instituted initially in March 1988 (NIH Guide for Grants and Contracts, May 9, 1988, Vol. 17, Special Notice), on research funded by the Public Health Service (PHS) utilizing human fetal tissue, obtained from induced abortions, for therapeutic transplantation research in human beings. No PHS funds (grant, cooperative agreement, or contract) may be expended on such research. Similar restrictions apply to research conducted by PHS scientists.

These restrictions do not apply to human therapeutic research using human fetal tissue from spontaneous abortions or stillbirths, nontherapeutic human research uses of any legally acquired human fetal tissue, or use of human fetal tissue in animal or in vitro research (HHS regulations require that applicable State and local laws be followed).

### REMINDER - ASSURANCES REGARDING PROCEDURES FOR DEALING WITH POSSIBLE MISCONDUCT IN SCIENCE

P.T. 34; K.W. 1014004, 1014006

Public Health Service

As soon as possible after November 8, 1989, but NO LATER THAN JANUARY 1, 1990, each institution that applies for or receives assistance under the Public Health Service (PHS) Act, for any project or program which involves the conduct of biomedical or behavioral research, research training, or related research activities, must complete and submit to the Office of Scientific Integrity (OSI) an assurance regarding procedures for dealing with and reporting possible misconduct in science.

The Office of Scientific Integrity (OSI) has mailed an Initial Assurance Form (Form PHS 6315) and Instructions to the President or Director of each institution that has received PHS research support in Fiscal Year 1988 or later, or had an application for support under consideration at the time the form was mailed. This form must be used to comply with the Final Rule published in the Federal Register on August 8, 1989. The Rule requires each institution to certify that it has (1) established policies and procedures for investigating and reporting instances of alleged or apparent scientific misconduct, and (2) will comply with its own administrative process and the requirements of the Rule.\*

Only one assurance is to be submitted for each organization or institution. Where major components (e.g., college of life sciences, school of medicine, department of pathology, research institute, etc.) have their own uniquely tailored scientific misconduct policies, the overall institutional or organizational assurance certifies that ALL the various policies are in compliance with the Final Rule.

If you have not received a form, but believe you should have, please check with the central administration of your institution to determine if your organization is covered under an already submitted assurance. If it is not, you may request a form.

FOR FORMS AND INSTRUCTIONS CONTACT:

ASSURANCE PROCESSING SECTION  
Office of Scientific Integrity, PHS  
National Institutes of Health  
Building 31, Mailroom  
Bethesda, Maryland 20892

QUESTIONS AND ASSISTANCE

Requests for assistance, copies of the Final Rule, or help with any questions on the assurance process should be directed to the address listed above. You may also contact the assurance section on (301) 496-7948.

\* Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 54 Federal Register 32446, August 8, 1989; amending Title 42, Subchapter D, of the Code of Federal Regulations, to add a new Subpart A to part 50 consisting of sections 50.101 through 50.105. [This rule was also published as a special issue of the NIH Guide for Grants and Contracts, Vol. 18, No. 30, September 1, 1989.]

REMINDER: LETTERS OF REFERENCE

P.T. 22, 34; K.W. 1014006

Division of Research Grants

We are reminding applicants for the Research Career Development Award (RCDA), the First Independent Research Support and Transition (FIRST) Award, and the individual and senior National Research Service Award (NRSA) Fellowship to submit three letters of reference WITH THEIR APPLICATION. Applicants submitting REVISED applications for RCDA, FIRST, and NRSA fellowships, must AGAIN submit letters of reference, or their applications will be returned without review.

For RCDA applications, both new and revised, reference letter guidelines to be sent to referees are included in the PHS 398 kit (revised 10/88). For NRSA fellowship applications, new and revised, the reference form (PHS 416-3) is included in the PHS 416-1 kit (revised 7/88 or 4/89). For FIRST Award applications, new and revised, there are no special reference forms to be sent to the referees, although printed guidelines are available from the Office of Grants Inquiries: (301) 496-7441.

Applicants should contact their referees well in advance of the application submission date, advising referees to use a typewriter with a black ribbon or a pen with black ink (to allow for better reproduction), and to return the letters of reference to the applicant in sealed envelopes as soon as possible. To protect the utility and confidentiality of reference letters, applicants are asked not to open the sealed envelopes. The sealed envelopes MUST be attached to the front page of the original copy of the application.

DATED ANNOUNCEMENTS (RFPs AND RFAs)

DCT SMALL GRANTS TO STIMULATE CORRELATIVE LABORATORY STUDIES AND INNOVATIVE CLINICAL TRIALS

RFA AVAILABLE: 90-CA-03

P.T. 34; K.W. 0755015, 0715035

National Cancer Institute

Application Receipt Date: February 9, 1990

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites grant applications from interested investigators for tightly focused innovative laboratory studies which are related to clinical trials or for innovative clinical trials which take advantage of new developments in the laboratory.

**BACKGROUND**

The NCI supports an extensive network of clinical and laboratory research studies related to cancer therapy through contracts, grants and cooperative agreements. It has been difficult for investigators to obtain complementary funding through either the traditional basic research grant (R01) mechanism or through the cooperative agreement (U10) mechanism for either: (1) innovative pilot clinical trials that take advantage of new developments in the laboratory or (2) correlative laboratory studies to existing clinical trials. The Cancer Therapy Evaluation Program, DCT, NCI, has targeted the use of the small grants mechanism (R03) to support single or multiple institutions (individual institutions, consortia, cancer centers, etc.) to perform innovative pilot clinical trials or correlative studies of relevance to clinical trials. Some examples of categorical areas for R03 studies include: (1) oncogenes and growth factors, (2) antigen expression on tumor cells, (3) biochemical modulation, (4) biological response modifiers, and (5) pharmacology and cell kinetic studies.

## RESEARCH GOALS AND SCOPE

The aims of this initiative are two-fold: (1) to provide a mechanism for accelerated review and funding of innovative correlative studies relevant to clinical trials, and (2) to stimulate pilot clinical studies with novel laboratory correlations so as to foster the development of interactions between basic science laboratories and clinicians performing clinical trials.

Studies should be proposed for a tightly focused, integrated research program at the interface of laboratory experimentation and concurrent clinical trials. The laboratory studies must have been demonstrated to be applicable to tissue samples and/or body fluids, etc. from patients entered onto clinical trials. Evidence of statistical support should be included to insure proper correlation of assay parameters with clinical outcome. Some examples of support that would qualify under this RFA would be: (1) salary for an additional technician; (2) funds for additional supplies or small equipment required for the project; (3) salary support for data management, data entry and coordination of sample procurement; (4) funds for the collection and shipment of specimens.

## MECHANISM OF SUPPORT

This Request for Applications (RFA) will use the NIH grant-in-aid. Small grants are designated as R03 grants. Approximately \$750,000 in first year total costs will be committed to specifically fund applications submitted in response to this RFA. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. NCI plans to make multiple awards for project periods up to two years. The total direct costs per year must not exceed \$48,000. The earliest feasible start date for the initial award will be June 1, 1990. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

## ELIGIBILITY

Domestic non-profit and for-profit institutions are eligible to apply. Foreign institutions are not eligible to apply. Although NCI funded Cooperative Groups are ineligible to be the principal investigator, individual institutions or consortia which may or may not be members of Cooperative Groups may apply. Awards will be made only to institutions with either a funded clinical or laboratory component of the proposed study. These awards are to complement a previously existing source of support. These pre-existing resources need not be at a single institution, but may exist within a consortium. The sources of funding must be documented in the application. Applications without this documentation will be returned to the applicants without further review.

## STUDY POPULATION

NCI encourages the applicant to recruit women and minorities into their study population. Applicants should address the study population issue in their application.

## INQUIRIES

A copy of the complete RFA describing the research goals and scope, the review criteria and the method of applying can be obtained by contacting:

Dr. Roy S. Wu  
Health Scientist Administrator  
Cancer Therapy Evaluation Program  
Division of Cancer Treatment  
National Cancer Institute  
Executive Plaza North, Room 734  
Bethesda, Maryland 20892  
Telephone: (301) 496-8866  
FAX: (301) 496-9384

Written or telephone inquiries concerning the objectives and scope of this RFA or inquiries about whether or not specific proposed research would be responsive are encouraged and should be directed to Dr. Roy S. Wu at the above address.

## LETTER OF INTENT

Prospective applicants are asked to submit by January 8, 1990 a letter of intent that includes a DESCRIPTIVE TITLE of the proposed research, the name and address of the principal investigator, the names of other key personnel,

the participating institutions, the number and title of this RFA. The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed. This letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, (Clinical Treatment Research). Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS Grant Policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

GENETICS AND BIOCHEMISTRY OF CELL FATE DETERMINATION IN DEVELOPMENT:  
CYTOPLASMIC DETERMINANTS, CELLULAR INDUCTION AND GENOMIC IMPRINTING

RFA AVAILABLE: 89-HD-08

P.T. 34; K.W. 1002019, 1003002, 1002004, 1002059

National Institute of Child Health and Human Development

Application Receipt Date: February 8, 1990

The Genetics and Teratology Branch (GTB) of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites research grant applications for studies on the genetics and biochemistry of cell fate determination in development. This initiative has important implications for both basic science and clinical studies. The information expected from these investigations will further our understanding of the specific molecules involved in establishing cell fate, how they are regulated, and how they function. In addition, underlying principles that direct normal patterns of growth differentiation and morphogenesis and against which aberrations of these processes can be understood will be further defined. In a clinical context these studies provide the basis for an improved understanding of the possible causes of birth defects and other developmental abnormalities that lead to early embryonic wastage and spontaneous abortion.

The primary goal of this Request for Applications (RFA) is to support a group of projects that are devoted to defining the underlying genetic basis, biochemical nature, and molecular mode of action of the processes that can influence cell fate, including cytoplasmic determinants, induction, and genetic imprinting. While our major interest rests in how such processes operate during mammalian development, other experimental model systems that can contribute to our understanding of the fundamental principles that apply to human development are strongly encouraged. The National Institute of General Medical Sciences (NIGMS) also supports research leading to an understanding of fundamental principles underlying genetics and cell biology, especially in model systems. Therefore, a secondary assignment to NIGMS for applications responsive to this RFA might be appropriate. It is expected that the latest molecular biological and molecular genetic technologies will be employed, including the generation of all appropriate and necessary reagents.

Applications should be submitted on Form PHS 398 (rev. 10/88), available in business or grants offices at most academic research institutions or from the Division of Research Grants, NIH. Insert the title and number of this RFA (GENETICS AND BIOCHEMISTRY: 89-HD-08) on line 2 of the face page of the application. The RFA label available in the October 1988 version of Form PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review.

This program will be funded through the traditional individual research award program of NICHD. Grant applications will be reviewed at a single competition by an initial review group convened by NICHD. It is anticipated that four (4) grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds.

Requests for copies of the full RFA should be addressed to:

Joel M. Schindler, Ph.D  
Genetics and Teratology Branch  
Center for Research for Mothers and Children  
National Institute of Child Health  
and Human Development  
Executive Plaza North, Room 643C  
Bethesda, Maryland 20892  
Telephone: (301) 496-5541

SPECIALIZED CENTERS OF RESEARCH IN ARTERIOSCLEROSIS

RFA AVAILABLE: 90-HL-4-H

P.T. 04; K.W. 0715040, 0710030, 0755030, 0745027

National Heart, Lung, and Blood Institute

Application Receipt Date: December 3, 1990

The Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health, announces the availability of a Request For Applications (RFA) for Specialized Centers of Research (SCOR) in Arteriosclerosis. This RFA solicits a variety of research areas relevant to interdisciplinary investigations focusing on arteriosclerosis. The goals of the program are to advance understanding of the causes and mechanisms of atherogenesis, to develop and exploit new technologies, and to foster new approaches to disease prevention, diagnosis and treatment.

Women and minority individuals should be included in the study population, otherwise a clear rationale for their exclusion must be provided in the application.

It is anticipated that approximately 10 SCORs will be funded under this RFA.

In keeping with the criteria for Centers, applicants must propose both basic and clinical research. New applications and applications for renewal of existing programs are invited. Copies of the RFA and Instructions for the Preparation of Applications are currently available from:

Montaz Wassef, Ph.D.  
Deputy Chief  
Lipid Metabolism-Atherogenesis Branch  
Division of Heart and Vascular Diseases  
National Institutes of Health  
Federal Building, Room 4A12  
7550 Wisconsin Avenue  
Bethesda, Maryland 20892  
Telephone: (301) 496-1978

ONGOING PROGRAM ANNOUNCEMENTS

SMALL GRANTS PROGRAM IN LABORATORY ANIMAL SCIENCES

P.T. 34; K.W. 0201058, 1002002, 0201011, 0755030, 0745027

Division of Research Resources

Application Receipt Date: February 1

BACKGROUND

The Animal Resources Program (ARP) of the Division of Research Resources (DRR), National Institutes of Health (NIH), assists institutions in developing and improving animal resources for biomedical research and research training through the award of research and resource grants. For the purpose of this program, animal resources are defined as all animals, their associated facilities, and the staff which support biomedical research activities. The ARP supports various activities which assist in meeting the animal resource needs of investigators, and the requirements for proper care and use of laboratory animals. To enhance this program, the ARP announces the initiation of a small grant award for support of pilot studies. Up to four awards per

year may be made, pending the receipt of meritorious applications and appropriated funds.

#### PURPOSE

This is a one-year, non-renewable award intended to provide support for pilot projects, testing of new techniques, or feasibility studies of innovative research in the area of laboratory animal medicine which would provide a basis for more extended research. Appropriate areas of study include but are not limited to the etiology, detection or prevention of laboratory animal disease; methods to decrease pain and distress associated with the use of animals in research; and optimal housing requirements.

#### ELIGIBILITY

Any domestic non-profit or for profit institution may apply for grant support through this program. The Principal Investigator must be a new or established investigator who is actively working in laboratory animal medicine at the time of the award. However, investigators receiving funds from grants for Laboratory Animal Diagnostic and Investigational Laboratories or Regional Primate Research Centers from the Division of Research Resources, NIH, may not act as Principal Investigators in this program.

#### APPLICATION AND REVIEW PROCEDURE

Applications should be submitted on Form PHS 398 (Rev. 10/88), available at most institutional business offices or from the Division of Research Grants, NIH. Because the format for preparing the Small Grant application is different from that used for regular research grants, the Supplementary Instructions attached to this announcement must be followed. Applicants must adhere to this format to be responsive. Unresponsive applications will be returned to the applicant without review. There will be a single annual receipt date of February 1. The initial scientific review will be conducted by the Office of Review, DRR, and final review by the DRR National Advisory Research Resources Council.

Receipt Date Annually	Institute Committee Review	Council Review	Earliest Date For Funding
February 1	February-March	May-June	July 1

Applications not funded by September 30 will be administratively inactivated.

#### REVIEW CRITERIA

Applications will be evaluated with respect to the following criteria: the significance and scientific merit of the proposed project as it relates to laboratory animal medicine, its characterization as an innovative pilot project, or the probability that the study will provide a basis for more extended research. The methodology and experimental design will be evaluated including the experimental groups, data to be collected, procedures of data analysis, and potential problems that may be encountered in the study and how they will be addressed. The investigator's background and training for carrying out the project, the adequacy of the facilities, and the adequacy of the justifications for the budget requested will also be considered.

#### TERMS OF THE AWARD

The award will be for one year and will provide a maximum of \$25,000 (direct costs) for technical assistance, supplies, small equipment, and travel. Support for professional salary should be obtained from another source. The award may not be used to supplement projects currently supported by Federal or non-Federal funds, or to provide interim support for projects under review by the Public Health Service.

#### INSTRUCTIONS FOR APPLICANT

Additional information on submitting a Small Grant application, supplementary to that given with PHS 398 (Rev. 10/88), can be obtained from the Laboratory Animal Sciences Program at the address given below.



STAFF CONTACT

Director  
Laboratory Animal Sciences Program  
Animal Resources Branch  
Division of Research Resources  
National Institutes of Health  
5333 Westbard Avenue, Rm. 853  
Bethesda, Maryland 20892  
Telephone: (301) 496-5175

This program is described in the Catalog of Federal Domestic Assistance No. 13.306, Laboratory Animal Sciences and Primate Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52, and 45 CFR Part 74. This program is not subject to the intergovernment review requirements of Executive Order 12372 or Health Systems Agency review.