NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 19, No. 11
March 16, 1990

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

AVAILABILITY OF FISH OIL TEST MATERIALS

P.T. 34; K.W. 0780000, 0780017

National Institutes of Health

This notice supplements the previous announcement published in the NIH Guide for Grants and Contracts on August 25, 1989 (Vol. 18, No. 29).

SUMMARY AND PURPOSE

Additional Test Materials Currently Available

- o EPA ethyl ester, prepared from menhaden oil, packaged in 1-5 gm portions
- o DHA ethyl ester, prepared from menhaden oil, packaged in 1-5 gm portions

Processing and Specifications of Biomedical Test Materials

- o EPA Ethyl Ester

The ethyl ester of EPA is prepared from vacuum-deodorized menhaden oil using transesterification, urea adduction and short-path distillation to yield an n-3 ethyl ester concentrate. The purified ethyl ester of EPA is attained by supercritical fluid CO2 extraction from the n-3 ethyl ester concentrate followed by high performance liquid chromatography. The product contains >95% ethyl esters; of the ethyl esters EPA is 97%, other n-3's are <1%, n-6's are <1% and other fatty acids are <1%.

DHA Ethyl Ester

The ethyl ester of DHA is prepared from vacuum-deodorized menhaden oil using transesterfication, urea adduction and short-path distillation to yield an n-3 ethyl ester concentrate. The purified ethyl ester of DHA is attained by supercritical fluid CO2 extraction from the n-3 ethyl ester concentrate followed by high performance liquid chromatography. The product contains >95% ethyl esters; of the ethyl esters DHA is 96%, other n-3's are <2%, n-6's are <1% and other fatty acids are <1%.

FISH OIL TEST MATERIALS PROGRAM

The Fish Oil Test Materials Program is administered by the Division of Nutrition Research Coordination in the Office of Disease Prevention, NIH. The program was established in 1986 through the cooperation of the National Institutes of Health (NIH), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and the National Oceanic and Atmospheric Administration/Department of Commerce (NOAA/DOC). This program has been designed to provide a long-term, consistent supply of quality-assured/quality-controlled test materials to researchers in order to facilitate the evaluation of the role that omega-3 fatty acids play in health and disease.

Fish Oil Test Materials Advisory Committee

A Fish Oil Test Materials Advisory Committee (FOTMAC) is cochaired by scientific staff from ADAMHA and NIH and is composed of scientists representing the funding agencies (NIH, ADAMHA), the research community, Department of Commerce (DOC) and the Food and Drug Administration (FDA). The FOTMAC provides scientific advice to the DOC regarding the types of materials needed by research scientists, shipping procedures for the materials, and additional quality control and production issues. The committee is advisory to the Fish Oil Test Materials Program on general programmatic issues such as future directions and has produced a manual on Good Laboratory Practices for the handling of polyunsaturated materials. In addition, the committee provided guidance to DOC during the production of the Drug Master File submitted to the FDA by the FOTMAC. Manuals on Analytical Methods for the Quality Assurance of Fish Oil, Production Methods/Safety and Distribution were produced by the DOC.

Fish Oil Test Materials Distribution Committee

A Fish Oil Test Materials Distribution Committee (FOTMDC) is composed of NIH and other Federal scientists that do not use these products. The Distribution committee processes the applications received from investigators, advises the DOC of applicants that have fulfilled the application process, and makes recommendations regarding the distribution of requested materials.

APPLICATION PROCESS

To qualify to receive materials described in this announcement the applicant must: 1) have peer-reviewed research indicating the need for the requested materials, and 2) submit a correctly completed application form and a signed waiver of liability. The committee will not be responsible for assessing the scientific merit of the application. Regulations on human subjects and animal research apply. In accordance with federal regulations, an IND number will be required for the use of these materials in human studies. The FOTMAC has established a drug master file at the FDA which includes manufacturing, chemical composition and toxicological data relevant to these products. Investigators using NOAA/DOC materials may reference this file in order to expedite their IND requests. Availability of materials are contingent on DOC/NOAA production capabilities. When prioritization is necessary, the order will be: 1) NIH/ADAMHA funded, 2) other U.S. government funded, 3) peer-reviewed, other funded, 4) NIH/ADAMHA approved, not funded, and 5) other.

The awarded materials are provided to investigators free of charge. Requests for materials of amounts greater than 175 g/year of EPA ethyl ester and/or 100 g/year of DHA ethyl ester should not be submitted without prior discussion with the NMFS - Charleston Laboratory. For further information contact Ms. Patricia Fair at (803) 762-1200.

TEST MATERIALS AVAILABLE IN THE FUTURE

Test materials and their relevant application process will be announced in the NIH Guide as new materials become available.

OTHER INFORMATION

Additional information will be provided to the investigator in the form of complete quality assurance data for each lot of test material shipped, stability data and storage instructions.

INQUIRIES AND APPLICATIONS

Investigators may obtain further information and apply for available fish oil test materials for relevant studies by requesting an application form from:

Fish Oil Test Materials Program
Division of Nutrition Research Coordination
Building 31, Room 4B63
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-2323

PROMOTION OF INTEGRITY AND RESPONSIBLE PRACTICE IN BIOMEDICAL RESEARCH - AAMC/NIH REGIONAL WORKSHOPS

P.T. 42; K.W. 1014004

National Institutes of Health

On April 20-21, the George Washington University will host the first of four regional workshops sponsored by the Association of American Medical Colleges (AAMC), under contract with the National Institutes of Health (NIH), to address issues in the promotion of integrity and responsibility in biomedical research. The regional workshops will serve as a forum for discussing recent developments within the Public Health Service that include the establishment of the Office of Scientific Integrity and the new regulation requiring awardee institutions to assure that policies and procedures are in place for investigating possible misconduct in science. The workshop will address special topics such as training and mentoring, peer review and authorship practices, and data ownership as well as dissemination of the information developed by the Institute of Medicine study, "Promotion of Responsibility in Research in the Health Sciences" supported by the NIH. The workshop is expected to be of interest to program directors, investigators, and academic administrators involved in behavioral and biomedical research. CME credits will be available for the workshop through the George Washington University Office of Continuing Medical Education.

Location: Holiday Inn Crowne Plaza, Arlington Virginia

Contact:

Leah C. Valadez
The George Washington University Medical Center
Office of the Dean for Research
2300 Eye Street, N.W., Suite 514
Washington, DC 20037
Telephone: (202) 994-2801

Similar workshops are planned for Boston, Massachusetts; St. Louis, Missouri; and San Diego, California. Dates will be announced in future notices.

HEALTH AND SAFETY GUIDELINES FOR GRANTEES AND CONTRACTORS

P.T. 34; K.W. 1014002, 0725010, 0725020

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

This notice is a republication, with minor modifications, of an April 1989 issuance on this subject. It is being reissued to emphasize its continuing importance.

Organizations receiving grant or contract awards are responsible for protecting their personnel from hazardous conditions. The Government is not legally liable for accidents, illnesses, or claims arising out of research performed under its awards, but the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are nonetheless aware that a variety of hazards threaten the safety and health of both laboratory and clinical research personnel. Accordingly, the guidelines that follow are designed to (1) identify potential hazards, (2) advise awardee organizations and investigators of certain standards that should be considered in order to address particular health and/or safety concerns, and (3) emphasize that concerns about potentially hazardous conditions could result in grant or contract funding delays until those concerns have been resolved to the satisfaction of the awarding component.

1. Sources of potential danger to research personnel include the following classes of hazard:

   a. Biohazards (e.g., Human Immunodeficiency Virus, HIV; other infectious agents; oncogenic viruses).

   b. Chemical hazards (e.g., carcinogens; chemotherapeutic agents; other toxic chemicals; flammable or explosive materials).

   c. Radioactive materials.

2. The following guidelines and standards contain information designed to assist grantees and contractors in providing a safe work environment for research personnel. Therefore, depending upon the particular safety hazard at issue, grantees and contractors are expected to consult these guidelines. They may be obtained from:

Division of Safety
Office of Research Services
National Institutes of Health
Building, 31, Room 1C02
Bethesda, MD 20892

   a. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control and the National Institutes of Health. HHS Publication No. (CDC) 88-8395.

   b. Recommendations for Prevention of HIV Transmission in Health-Care Settings. Morbidity and Mortality Report, August 21, 1987, Vol. 35, No. 2S.

   c. Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.

   d. Recommendations for the Safe Handling of Parenteral Antineoplastic Drugs, NIH Publication No. 83-2621.

e. NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication No. 81-2385.

The following materials are also recommended and may be purchased from:

National Academy Press
2102 Constitution Avenue, N.W.
Washington, D.C. 20418

A. Prudent Practices for Handling Hazardous Chemicals in the Laboratory. Price $19.95

B. Prudent Practices for the Disposal of Chemicals from the Laboratory. Price $19.95

C. Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Materials. Price $29.95

3. Grant applications and contract proposals posing special hazards typically are identified during the initial review process, but such concerns can formally be expressed by agency staff or consultants at any time prior to award. Regardless of the timing of the described concern, grant or contract funding could be delayed until the matter has been resolved to the satisfaction of the awarding component.

Special hazards that are identified after an award is made may lead to suspension of work under the grant or contract pending corrective action by the awardee. (See 45 CFR 74, Subpart M, concerning grant suspension and 48 CFR 12.5 concerning contract "stop work" orders.)

Grantee and contractor organizations are not required to submit documented assurance of their specific attention to the guidelines and standards identified in section 2 of this notice. However, where dictated by the circumstances, grantees and contractors should be able to provide evidence that pertinent health and safety standards have been considered and, where necessary, have been put in practice. Such evidence may be requested by appropriate NIH and ADAMHA staff; for example, during a site visit.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

IN VITRO METHODS TO ASSESS HUMAN METABOLISM OF CHEMICAL XENOBIOTICS

RFP AVAILABLE: NIH-ES-90-06

P.T. 34; K.W. 0765020, 0755010

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), is soliciting proposals for a project to compare the in vitro metabolism of chemical xenobiotics in human tissue preparations to similar preparations from animal species commonly used in laboratory research and testing. Studies of hepatic metabolism shall be performed in liver tissue slices. Metabolism in other tissues, or other tissue preparations, if deemed necessary, shall be carried out using the best available techniques. It is estimated that 3-4 chemicals per year shall be studied. One contract is anticipated. The Request for Proposals (RFP) will be released on or about March 21, 1990, with responses due by May 9, 1990. All responsible sources may submit a proposal which shall be considered by the Agency.

Requests should reference RFP NIH-ES-90-06 and should be forwarded to:

National Institute of Environmental Health Sciences
Contracts and Procurement Management Branch, OM
ATTN: Mary B. Armstead, Contracting Officer
79 T. W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, NC 27709

NOTICE: DEVELOPMENT OF NONMAMMALIAN MODELS FOR BIOMEDICAL RESEARCH

RFA: RR-90-01

P.T. 34; K.W. 0755020, 0780015, 0780020

National Center for Research Resources

The Division of Research Resources, now a part of the National Center for Research Resources (NCRR), published a Request for Applications (RFA) RR-90-01, Development of Nonmammalian Models for Biomedical Research, in the NIH Guide for Grants and Contracts, Vol. 18, No. 44, December 15, 1989. A modification has been made to the RFA.

Because of the shortened time for the review process, limited staff resources, and the number of applications anticipated, applications may be subjected to a triage by a peer-review group to determine their scientific merit relative to the other applications received in response to this RFA. NIH will withdraw from competition those applications judged to be noncompetitive and notify the applicant and institutional business official. Those applications judged to be competitive will be further evaluated for scientific/technical merit by initial review groups which will be convened by the Office of Review, NCRR. Those applicants who sent a letter of intent will receive this notice. If further information is needed, please call:

Louise E. Ramm, Ph.D.
Biological Models and Materials Resources Program
National Center for Research Resources
Telephone: (301) 402-0630

ADDENDUM: KIDNEY DISEASES OF DIABETES MELLITUS: PATHOPHYSIOLOGY, CLINICAL FEATURES, AND EPIDEMIOLOGY

RFA: 90-DK-06

P.T. 34; K.W. 0715075, 0765035, 0785035, 0785055

National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Date: April 23, 1990

On January 19, 1990, the above mentioned Request for Applications (RFA) was announced in the NIH Guide for Grants and Contracts, Vol. 19, No. 3. Because the number of letters of intent received indicates that the number of applications will be large compared to the number of awards to be made, the NIH may conduct a preliminary scientific peer review to eliminate those applications which are clearly not competitive. The NIH will administratively withdraw from competition those applications judged to be noncompetitive and will notify the applicant and institutional business official.

Those applications judged to be both competitive and responsive will be further evaluated according to the review criteria stated in the RFA for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NIDDK.

All other aspects of the announcement remain the same.

MENTAL RETARDATION RESEARCH CENTERS

RFA AVAILABLE: HD-90-07

P.T. 04; K.W. 0715130, 0710030, 0745020, 0745027, 0745070

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: April 16, 1990
Application Receipt Date: July 12, 1990

The National Institute of Child Health and Human Development (NICHD), through the Mental Retardation and Developmental Disabilities (MRDD) Branch, Center for Research for Mothers and Children (CRMC), invites research center core grant applications (P30) to develop new knowledge in the field of prevention, treatment, and amelioration of mental retardation and developmental disabilities. Two centers may be supported in response to this announcement.

The primary objective of the NICHD Mental Retardation Research Centers (MRRCs) is to provide support and facilities for a cohesive, interdisciplinary program of research and research training in mental retardation and related aspects of human development.

NICHD has supported MRRCs through the provision of core grants (P30) which facilitate program coordination and support central research core units. Funds for the research projects using these core units come from independent sources including Federal, State and private organizations. This announcement seeks applications from existing MRRCs and from other comparable institutions that meet the qualifications for a program of mental retardation research.

BACKGROUND

A major goal of the MRDD Branch's research program is to prevent and/or ameliorate mental retardation. The degree of impairment associated with mental retardation varies in relation to the cause. Moderate and more severe mental retardation often results from problems that produce profound alterations in brain development and/or function. Diminished intellectual and adaptive capacity can often be traced to defective genes, teratogenic agents, infections, nutritional deficits, accidents, diseases and other disorders causing brain damage. A larger proportion of cases of mental retardation is related to environmental conditions and disorders of unknown etiology. These complex problems require integrated, multidisciplinary approaches involving biomedical and/or behavioral sciences in a variety of settings.

The purpose of an MRRC is to provide a research environment in which interdisciplinary collaboration among investigators who are working in areas of relevance to the prevention and/or amelioration of mental retardation is facilitated. Such research will cover a broad spectrum of scientific approaches ranging from laboratory research on fundamental processes of abnormal development to clinical and educational research in which persons with mental retardation are studied.

It is thought that major solutions to the problems of mental retardation may be found as a result of multidisciplinary collaboration involving a variety of approaches in the MRRCs. As a result of the administrative and scientific organization within a MRRC and across the network of MRRCs, opportunities for breakthroughs will be enhanced.

RESEARCH SCOPE

MRRC Core Grants are intended to bring together in a center a variety of disciplines to work on the common problems of mental retardation. Consequently, applications for Mental Retardation Center Core Grants (P30) should include investigators studying a range of topics in basic and clinical or applied research. Applicants are encouraged, but are not required, to include both biomedical and behavioral components from among the following topics:

1. Developmental neurobiological studies relevant to MRDD.
2. Inborn errors of metabolism relevant to MRDD.
3. Genetic/cytogenetic disorders associated with MRDD.
4. Molecular biology; development of animal models.
5. Toxicology and physical environmental factors in the etiology, treatment and prevention of MRDD.
6. Intellectual, behavioral, physical and the intergenerational effects of malnutrition.
7. Developmental pharmacology and psychopharmacology.
8. Infectious diseases in the etiology, prevention and treatment of MRDD.
9. Diagnosis.
10. Perinatal problems associated with MRDD.
11. Psychobiological processes in MRDD.
12. Psychological processes in MRDD.
13. Early intervention for infants born at risk.

14. Behavioral analysis of MRDD individuals.

15. Family and community studies.

16. Language and communication of MRDD populations.

17. Learning disabilities, dyslexia, and attention deficit disorder.

18. Behavior in residential and educational settings.

19. Socioecological processes.

20. Epidemiology of MRDD.

INCLUSION OF MINORITIES AND FEMALES IN STUDY POPULATION

PHS urges applicants to give added attention (where feasible and appropriate) to the inclusion of minorities and women in study populations for research. If minorities and women are not included, a clear rationale for their exclusion should be provided. Investigators are reminded that merely including arbitrary numbers of women and minority participants is a given study is insufficient to guarantee generalizability of results.

ELIGIBILITY

Any of the following organizations are eligible to apply: Non-profit organizations and institutions; State and local governments and their agencies; and authorized Federal institutions.

MECHANISM, SCOPE AND SCALE OF SUPPORT

MRRC grants will be supported through the center core grant (P30) mechanism. Review of applications and management of grants will be subject to applicable policies for NIH research center grants.

Awards will be made for a period of five years. To be eligible for award as an MRRC, the Center must provide core support for a minimum of 10 projects funded from non-university sources.

The total direct costs requested for the first year may not exceed $500,000 for new grants and not more than 104% of the level recommended for the previous budget period of a competing renewal grant. Budgets of applications for new and renewal support will be stringently reviewed within these guidelines. Applications with budget requests exceeding these guidelines will be administratively withdrawn by NICHD and returned to the applicant.

ESTIMATED NUMBER OF AWARDS

This is the fourth of a series of annual announcements. Plans are to make two awards in fiscal year 1991.

WHERE COMPLETE RFA MAY BE OBTAINED

A complete Request for Applications entitled "Mental Retardation Research Centers (P30)" and guidelines concerning "NICHD Research Centers Programs-Center Core Grants (P30)" may be obtained from:

Mental Retardation and Developmental Disabilities Branch
Center for Research for Mothers and Children, NICHD
Executive Plaza North, Rm. 631
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1383

This program is described in the Catalog of Federal Domestic Assistance No. 13.865 Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241) 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 intergovernmental review requirements of Executive Order 12372 or a Health Systems Agency Review.

HEALTH AND RETIREMENT STUDY

RFA AVAILABLE: 90-AG-02

P.T. 34; K.W. 0710010, 0730010, 0408006, 0404021, 0755018

National Institute on Aging

Letter of Intent Date: April 10, 1990
Application Receipt Date: May 23, 1990

The National Institute on Aging (NIA) invites applications for a cooperative agreement to design and conduct a national longitudinal study of men and women that focuses on the retirement process with emphasis on health issues. The general objective of the study is to increase understanding of the determinants and consequences of retirement in relation to health, economic and psychosocial processes and outcomes.

Research is needed to answer numerous questions about the determinants and dynamics of current retirement processes. For example, what objective health problems and subjective perceptions of health make continued work difficult, and what changes in the workplace could lessen these difficulties? What pension incentives and penalties (in conjunction with individual financial status and preferences) affect the timing of retirement, and what are the relevant effects of the different types of private pensions, employer-provided health benefits and the Social Security system? How has increased participation of women in the labor force affected retirement decisions, and to what extent are retirement decisions based on family rather than individual considerations?

The proposed study should have the following general characteristics: a focus on health and retirement; a longitudinal design with a national sample and a household focus; linkages to administrative records such as employer health and pension benefit records, Social Security earnings records, Medicare records, and the National Death Index; and an emphasis on data quality.

The NIH urges applicants to include women and minorities in study populations. If minorities and women are not included, a clear rationale for their exclusion should be provided. Applicants funded under this Request for Applications (RFA) will be supported through the Cooperative Agreement assistance mechanism (U01). An assistance relationship will exist between NIA and the awardee to accomplish this activity. The award recipients define the aims of the study and have the primary responsibility for the development and performance of the activity. However, there will be government involvement in a number of areas. These areas include the exploration of the use of alternative sampling frames, the development of record linkages with administrative files maintained by other federal agencies, and the coordination of the study with other surveys of the older population in order to enhance the capacity for comparative analyses.

Applications should include a suitable representation of women and minority populations of individuals. Any variances from this should include a reasonable explanation.

This RFA solicitation represents a single competition with a specified deadline of May 23, 1990, for receipt of applications. Responsive applications may be subjected to triage immediately preceding or concurrent with evaluation by a peer review group to determine their scientific merit relative to the other applications received in response to this RFA. NIH will remove from consideration those applications judged to be noncompetitive. Applications judged to be competitive will be fully reviewed for scientific and technical merit by the same review group convened for this purpose by the Scientific Review Office, NIA.

AVAILABILITY OF FUNDS

NIA has set aside $500,000 for the first year of the study. In the initial application, support should be requested for five years. A competitive continuation application may be submitted at a later date, but no funds have been specifically reserved for renewals at this time. It is anticipated that a single application will be funded.

Applications should be submitted on the Standard PHS Form 398 (10/88 revision). Separate instructions for completing Form 398 for this RFA are available from the NIA official named below. These instructions provide additional guidance in such areas as consortium arrangements, budget preparation, etc. Complete line 2 of the application face page by typing in "HEALTH AND RETIREMENT STUDY, RFA 90-AG-02." The RFA label (found in the

application kit) 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 might not reach the review committee in time for review.

For a copy of the complete RFA and special instructions for filling out PHS 398, please contact:

Dr. Richard Suzman
Chief, Demography and Population Epidemiology
Behavioral and Social Research Program
National Institute on Aging
Building 31, Room 5C32
Bethesda, MD 20892
Telephone: (301) 496-3136

COST-EFFECTIVE STRATEGIES OF CHOLESTEROL-LOWERING

RFA AVAILABLE: 90-HL-5-H

P.T. 34; K.W. 0715035, 0705015, 0745027, 0408006, 0710095, 0755020

National Heart, Lung, and Blood Institute

Application Receipt Date: June 19, 1990

The Lipid Metabolism-Atherogenesis Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI), announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will support the exploitation of existing data to develop quantitative models of the potential health effects of cholesterol-lowering and thereby to facilitate the evaluation of alternative strategies of cholesterol-lowering. Such models might evaluate a variety of health outcomes and compare the cost-effectiveness of cholesterol-lowering with other modalities of prevention and treatment of coronary heart disease. A multi-disciplinary approach, drawing on expertise in such areas as preventive medicine, lipid disorders, biostatistics and health economics, is encouraged. It is hoped that these models may be useful to the National Cholesterol Education Program in future deliberations on treatment of high blood cholesterol.

The support mechanism for this program will be the traditional, individual research grant (R01). Although approximately $300,000 for this program is included in the financial plans for fiscal year 1991, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that two to four grants will be awarded under this program. The specific amount to be funded, however, will depend on the merit and scope of the applications received and the availability of funds.

Requests for copies of this RFA should be addressed to:

David J. Gordon, M.D., Ph.D.
Project Officer
Lipid Metabolism-Atherogenesis Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 404
7550 Wisconsin Avenue
Bethesda, MD 20892

INVOLVEMENT OF GROWTH REGULATING FACTORS IN SEX STEROID HORMONE ACTION ON THE FEMALE GENITAL TRACT

RFA AVAILABLE: 90-HD-09

P.T. 34; K.W. 0760020, 0760025, 0413002

National Institute of Child Health and Human Development

Application Receipt Date: June 15, 1990

The Reproductive Sciences Branch (RSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), supports research on human reproduction which relies on a variety of approaches in biomedical sciences. Recently, scientific interest has surged with respect to the involvement of growth regulating factors (or growth factors, local

mediators) in gonadal function, and new information has been forthcoming concerning the modulating/mediating roles of a variety of growth regulating factors in gonadotropin actions on gonadal cells. In contrast to such gonadal studies, little attention has been paid to date to investigating the possible involvement of growth regulating factors in modulating sex steroid hormone actions on the female genital tract.

This Request for Applications (RFA) is specifically designed to provide small grants (R03) to stimulate research aimed at elucidating the involvement of growth regulating factors in the sex steroid hormone action on the female genital tract. Research may be proposed which seeks:

- To determine the kind of growth regulating factors involved in the sex steroid hormone action on the female genital tract, by identifying, quantitating and localizing growth regulating factors and/or their receptors in the female genital tract in various physiological conditions.

- To determine the manner of involvement of growth regulating factors in the sex steroid hormone action by investigating the cause-effect relationship between the involved growth regulating factors and/or their receptors and the specific functional event(s) in the female genital tract under the influence of the hormone.

- To fill the existing gap between our understanding of the physiological, endocrinological aspects of sex steroid hormone action and that of the molecular biological aspect, by investigating the relationship between the gene expression induced by sex steroid hormones and growth regulating factors and their receptors at the cellular level by cell biological approaches.

- To investigate how the synergistic and antagonistic actions (or up- and down-regulations) of one hormone on another are expressed in terms of growth regulating factors.

If clinical studies are proposed in response to this RFA, applicants are urged to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcome, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

This RFA aims at soliciting independent investigators to conduct pilot studies in order to develop the projects for preparation for R01 applications; thus, this award is not intended to be used to supplement ongoing funded projects.

Up to six small grant awards (R03) may be made as a result of this announcement.

For further information and a copy of the full RFA, contact:

Koji Yoshinaga, Ph.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health and Human Development
Executive Plaza North, Room 603
Bethesda, MD 20892
Telephone: (301) 496-6515

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act 301 (42 USC 241) and 441 (USC 289d) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 or Health Systems Agency review.

*U.S.GOVERNMENT PRINTING OFFICE:1990-261-138:00040