

ENVIRONMENT/INFECTION/GENE INTERACTIONS IN AUTOIMMUNE DISEASE

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P.T.

National Institute of Environmental Health Sciences
National Institute of Allergy and Infectious Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Arthritis, Musculoskeletal, and Skin Diseases
National Institute of Child Health and Human Development
National Institute on Deafness and other Communication Disorders
National Eye Institute
National Heart, Lung and Blood Institute
National Institute of Neurological Disorders and Stroke
National Institute of Mental Health
National Institute of Dental and Craniofacial Research
Office of Research on Women's Health

Letter of Intent Receipt Date: March 12, 1999

Application Receipt Date: May 7, 1999

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Arthritis, Musculoskeletal, and Skin Diseases (NIAMS), National Institute of Child Health and Human Development (NICHD), National Institute on Deafness and other Communication Disorders (NIDCD), National Eye Institute (NEI), National Heart, Lung and Blood Institute (NHLBI), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Mental Health (NIMH), National Institute of Dental and Craniofacial Research (NIDCR), and the Office of Research on Women's Health (ORWH) invite applications for innovative investigator-initiated basic or population based research to determine the role of environmental and infectious agents in the initiation and/or exacerbation of autoimmune diseases. Three specific areas of interest are: 1) the role of exposure to environmental and/or infectious

agents in the development of autoimmune diseases, including timing of exposure; 2) the role of genetic factors in modulating the induction or perpetuation of autoimmune diseases by environmental or infectious agents and 3) the interaction of hormones and gender differences with environmental or infectious agents in development of autoimmune diseases. It is anticipated that research fostered by this RFA will lead to the development of more extensive hypothesis-driven mechanistically-oriented research projects.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Environment/Infection/Gene Interactions in Autoimmune Diseases, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2000" at: <http://www.crisny.org/health/us/health7.html>.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions may not submit applications in response to this RFA. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

This Request for Applications (RFA) will use the National Institutes of Health (NIH) Exploratory Research Grant (R21) mechanism. Specific R21 application instructions have been modified to reflect 'MODULAR GRANT' and 'JUST IN TIME' concepts. The R21 grants provide support to develop new research activities in categorical program areas. These pilot/feasibility grants provide support for high risk/high payoff activities that lack a traditional historical basis or sufficient preliminary data. Indeed areas of science in which there is a sufficient historical base or sufficient preliminary data to support the submission of a regular research project (R01) do not qualify under this RFA. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Applications in response to this RFA may request from one to three years of support. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed

according to the customary peer review procedures. The anticipated award date is September 1999.

For this RFA, funds must be requested in modules of \$25,000 (direct cost), with a minimum of two modules and no more than four modules requested in total. A feature of the modular grant concept is that no escalation is provided for future years, and all anticipated expenses for all years of the project must be included within the modules being requested. Only limited budgetary information will be required and any budget adjustments made by the initial review group will be in modules of \$25,000. Instructions for completing the biographical sketch have also been modified. These modifications are described below in the application procedure section.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for all awards made under this RFA will be \$2.5M. In Fiscal year 1999, the participating Institutes plan to fund approximately 15 to 18 new grants. An applicant may request a project period of one to three years and a budget for direct costs of \$50,000, \$75,000, or \$100,000 per year. Although this program is provided for in the financial plans of the IC(s), awards pursuant to this RFA are contingent upon the receipt of a sufficient number of applications of outstanding scientific and technical merit.

RESEARCH OBJECTIVES

Background

Approximately 80 separate autoimmune diseases, including Graves' disease, Hashimoto's thyroiditis, rheumatoid arthritis, type 1 diabetes mellitus, multiple sclerosis, systemic lupus erythematosus, inflammatory bowel disease, psoriasis, uveitis, Sjogren's syndrome, autoimmune inner ear disease and scleroderma, affect over 9 million Americans (1 in 31). Autoimmune mechanisms may also underlie rapidly progressive sensorineural hearing loss with or without vertigo and certain childhood neuropsychiatric disorders such as obsessive compulsive disorder and Tourette's disorder. Women and some minorities are disproportionately affected by many autoimmune disease. All of these diseases result from an attack of the immune system on the body's own tissues.

Environmental and infectious agents and/or their products have been implicated in the pathogenesis of autoimmune diseases. Several environmental chemicals have been associated

with autoimmune diseases, including silica dust and lupus, vinyl chloride and organic solvents in scleroderma, mercury, gold or perchloroethylene in autoimmune kidney disease, and polybrominated biphenyls in autoimmune thyroid disease. Environmental chemicals may also contribute to autoimmune liver disease (e.g. non-alcoholic steatohepatitis or NASH). Infection with *Campylobacter jejuni* is a common antecedent of the Guillain-Barre syndrome, an autoimmune neurologic disease. An association of rheumatoid arthritis with various organisms, including mycoplasma, Epstein-Barr virus, parvovirus, and rubella, has been suggested, but not convincingly proven. Type 1 diabetes, a metabolic disease caused by immune destruction of the pancreatic beta cells, has also been associated epidemiologically with various infectious agents, including rubella, rotovirus, and Coxsackie virus, although causality has not been established. In addition, various viral and bacterial peptides are able to activate myelin basic protein specific T-cell clones, which were isolated from patients with multiple sclerosis.

Interaction of the immune and endocrine systems is now well recognized. However, the mechanism of the increased incidence of autoimmune diseases in women is not clear. Prolactin and androgen levels appear to modulate the lacrimal secretory cell response in Sjogren's syndrome thus providing an explanation for its gender bias. An interesting exception to the gender preference in autoimmune disease is type 1 diabetes, which has an equal prevalence in males and females. Interestingly, however, there is a higher incidence of type 1 diabetes in offspring when there is paternal, rather than maternal, diabetes. There is also the possibility that environmental agents that disrupt the endocrine system, for example endocrine disrupting chemicals, play a role in autoimmune diseases although the data are mostly hypothetical at this time.

Most autoimmune diseases also have a genetic component, which may play a role in the development of pathologic autoimmune responses to environmental agents and microorganisms. For example, the cross reactivity of T-cell clones to Coxsackie protein and GAD65 was only evident in mice with a diabetes susceptible MHC background. Equally, the maintenance of HLA-B27 transgenic mice in germ-free conditions prevents the development of the inflammatory disease. However, the NOD mouse develops diabetes at an increased frequency when kept in a "clean" facility.

Various mechanisms by which infectious agents and environmental agents could induce autoimmune diseases have been suggested. The pathogen or environmental toxicant, chemical or metal, may directly generate an immune response by its continued presence. Alternately, the chemical or organism may induce an immune response, possibly by revealing self antigens that

are normally sequestered from the immune system, and this autoreactive response then becomes self-sustaining.

This has been shown to occur by molecular mimicry in a mouse model of autoimmune herpes keratitis. Whereas in an animal model of type 1 diabetes, by-stander activation has been implicated. A role for superantigens, which can be of viral or bacterial origin, has also been postulated.

Recently NIEHS, NIAID, NIDDK, NIAMS, and NIDR cosponsored two meetings, which brought together microbiologists, virologists, toxicologists, immunologists and developmental biologists. These groups highlighted opportunities for further research in this area, in particular the effect of genetic factors on the ability of environmental and infectious agents to initiate, perpetuate, or prevent autoimmune disease. They concluded that in most cases a definitive role for environmental agents, chemical, physical or infectious, in the initiation or exacerbation of autoimmune diseases is not strong and mechanism are not well developed and that hypotheses generating pilot/feasibility studies are needed to move the field forward.

Investigation of the role of environmental agents and pathogens in the development and regulation of the immune response in autoimmune diseases may lead not only to understanding of the pathogenesis of these diseases, but also to new preventive or therapeutic strategies for these diseases.

Research Objectives and Scope

This RFA is designed to support innovative basic, epidemiological, and preclinical research to understand the role of and mechanisms by which environmental and infectious agents influence the development and/or the exacerbation of autoimmune diseases and to understand the role of genes and hormones in modulating the immune response to environmental and infectious agents. Relevant topics of research include, but are not limited to, the following:

- o Identification and characterization of environmental exposures (chemical, physical or infectious), singly or in combination, that initiate autoimmune diseases or that exacerbate existing autoimmune diseases.

- o Identification and characterization of periods of exposure to specific environmental and infectious agents such as during development, perinatal, prepubertal, adult and aged and sensitivity to the development of autoimmune disease.

- o Exploration of the possible role of environmental endocrine disrupting chemicals on the development of autoimmune disease, including interaction with genes and the hormonal environment.

- o Identification of mechanisms by which environmental agents and pathogens initiate, potentiate, or perpetuate an autoimmune response.

- o Characterization of molecular, cellular, immunologic, and biological mechanisms of a host autoimmune associated response to environmental chemicals, such as solvents, pesticides and metals, and pathogens or pathogen products.

- o Exploitation of the known animal models of microbially- and chemically-induced autoimmune disease and of the known animal models of autoimmunity for information on the role of environmental and infectious agents in their pathogenesis.

- o Examination of whether persistence of the pathogen or environmental agent in the host is necessary to cause disease, or if the agent can initiate a cascade of irreversible or reversible immunologic consequences. What factors determine the mechanism: the host, the inciting agent, or both?

- o Development of hypothesis-driven investigations to establish the role of environmental and infectious agents in the etiology of various human autoimmune diseases and to determine the fraction of cases attributable to environmental or infectious agents.

The above examples of research approaches are not meant to be all-inclusive or restrictive. Investigators are encouraged to develop their own innovative approaches to achieve the goals of this RFA. Research in response to this RFA must have relevance to human autoimmune disease, or idiopathic diseases where autoimmunity may play a role, however, animal models, in vitro systems, or epidemiologic studies (pilot or add-on) are appropriate. A multidisciplinary approach is encouraged as the areas of interest cross disciplines of immunology, genetics, infectious diseases and environmental health sciences.

For the purposes of this solicitation, environmental agents include chemical agents found in the environment, dietary agents, infectious agents, and physical agents or combinations of the above. Pharmaceuticals are not part of this RFA. Applications examining the role of drugs in autoimmune disease will not be accepted as part of this RFA. In addition, applications which do not address

the role of environmental or infectious agents in autoimmune disease will not be accepted in response to this RFA.

SPECIAL REQUIREMENTS

Applicants should include funds for a two-day grantee meeting at the NIEHS in Research Triangle Park, North Carolina.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which was published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994, available on the web at:

<http://grants.nih.gov/grants/guide/notice-files/not94-100.html>.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows the program staff of the participating ICs to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Ethel Jackson, at the address listed under INQUIRIES, by the letter of intent receipt date listed in the heading of this RFA.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: GrantsInfo@nih.gov. They may also be downloaded from the Internet at <http://grants.nih.gov/grants/forms.htm>

In preparing Modular Grant Applications, standard instructions for specific award mechanisms should be followed: (PHS 398 and R21), with these specific modifications reflecting modular budget and just-in-time concepts:

- o Face Page - Items 7a and 7b should be completed, indicating Direct Costs (in \$25,000 increments up to a maximum of \$100,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.
- o Detailed Budget for the Initial Budget Period - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o Budget for the Entire Proposed Period of Support - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o Narrative Budget Justification - Use a Modular Grant Budget Narrative page. (See <http://grants.nih.gov/grants/funding/modular/modular.htm> for sample pages.) At the top of the page, enter the total direct costs requested for each year.

o Under Personnel, List key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o Biographical Sketch - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at:

<http://grants.nih.gov/grants/funding/modular/modular.htm>

- Complete the educational block at the top of the form page;
- List current position(s) and then previous positions;
- List selected peer-reviewed publications, with full citations;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.

o Other Support - Do not submit the 'other support' pages. Selected other support relevant to the proposed research may be included in the Biographical Sketch as indicated above. Complete

other support information will be requested by the staff of NIEHS or collaborating Institutes if there is a possibility for an award.

- o Checklist - This page should be completed and submitted with the application.

- o Page Limitation - In keeping with the pilot/feasibility nature of the requested studies the application (aims, background and significance, preliminary data and experimental design and methods) is limited to 20 pages. Tables and figures are included in the 20-page limitation.

- o Appendix - An appendix or additional supporting materials will not be accepted with the exception of originals of photos used in the application.

The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

Comments and inquiries concerning this notice are encouraged. Nevertheless, the instructions and procedures described in this notice must be observed.

Additional information, including sample budget narratives and biographical sketch, may be found at this site: <http://grants.nih.gov/grants/funding/modular/modular.htm>.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Ethel Jackson, D.D.S.

Division of Extramural Research and Training

P.O. Box 12233, MD EC-24

111 T. W. Alexander Drive, East Campus, Rm. 3413 (Courier Service Only) Research

Triangle Park, NC 27709

Telephone: (919) 541-7846

FAX: (919) 541-2503

Email: jackson4@niehs.nih.gov

Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIH. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

An appropriate peer review group convened by the NIEHS in accordance with the review criteria stated below will evaluate applications that are complete and responsive to the RFA for scientific and technical merit. As part of the initial merit review, a process may be used by the initial review group in which applications receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score. The scored applications will receive a second level review by the Institutes National Advisory Council if the direct cost recommended exceeds \$50,000.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) Significance: Does this study address an important problem in an area covered by the RFA. If the aims of the application are achieved, how will scientific knowledge concerning the role of environmental agents, gender, or genetics in the initiation or exacerbation of autoimmune diseases be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? In the context of the R21 mechanism, a strong rationale and conceptual framework are normally sufficient for establishing the feasibility of the project, in lieu of preliminary data.

(3) Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? If the project is not innovative but is essential to move the field forward, the applicant should mention and discuss this aspect in the proposal.

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of this scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The initial review group will also examine the provisions for the protection of human subjects and the safety of the research environment.

SCHEDULE

Letter of Intent Receipt Date: March 12, 1999
Application Receipt Date: May 7, 1999
Peer Review Date: June 1999
Council Review: September 1999
Earliest Anticipated Start Date: September 1999

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o scientific merit (as determined by peer review)
- o programmatic priorities
- o availability of funds.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues of this RFA to:

Jerrold J. Heindel, Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-23

111 T. W. Alexander Drive, East Campus, Rm. 3413 (Courier Service Only)

Research Triangle Park, NC 27709

Telephone: (919) 541-0781

FAX: (919) 541-5064

Email: Heindelj@niehs.nih.gov

Elaine Collier, M.D.

Division of Allergy, Immunology, and Infectious Diseases

National Institute of Allergy and Infectious Diseases

6003 Executive Boulevard, Room 4A20

Bethesda, MD 20892-7640

Telephone: (301) 496-7104

FAX: (301) 402-2571

Email: ec5x@nih.gov

Barbara Linder, Ph.D.

National Institute of Diabetes and Digestive and Kidney Diseases

45 Center Drive, MSC 6600

Bethesda, MD 20892-6600

Telephone: (301) 594-0021

FAX: (301) 480-3503

Email: Linderb@extra.niddk.nih.gov

Susana Serrate-Sztejn, M.D.

Arthritis Program Director

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building, Room 5AS-25E

Bethesda, MD 20892-6500

Telephone: (301) 594-5032

FAX: (301) 480-4543

Email: ss86e@nih.gov

Karen Winer M.D.

National Institute of Child Health and Human Development

6100 Executive Boulevard, Room 4B11

Rockville, MD 20892

Telephone: (301) 435-6877

FAX: (301) 480-9791

Email: winerk@mail.nih.gov

A. Julianna Gulya, M.D.

Clinical Trials Branch

National Institute of Deafness and Other Communication Disorders

6120 Executive Boulevard, Room 400D-7

Rockville, MD 20892

Telephone: (301) 435-4085

FAX: (301) 402-6251

Email: julie_gulya@nih.gov

Ellen Liberman, Ph.D.

National Eye Institute

6210 Executive Boulevard, Suite 350, MSC 7164

Bethesda, MD 20892-7164

Telephone: (301) 496-0484

FAX: (301) 402-0528

Email: ellenliberman@nei.nih.gov

Robert Musson, Ph.D.

National Heart, Lung and Blood Institute

6401 Rockledge Drive, Room 10108

Bethesda, MD 20892-7952

Telephone: (301) 435-0222

FAX: (301) 480-3557

Email: mussonr@gwgate.nhlbi.nih.gov

A.P. Kerza-Dwiatecki, Ph.D.

National Institute of Neurological Disorders and Stroke

7550 Wisconsin Avenue, Room 504

Bethesda, MD 20892

Telephone: (301) 496-1431

FAX: (301) 402-2060

Email: ak45w@nih.gov

Dianne Rausch, Ph.D.

National Institute of Mental Health
6100 Executive Boulevard, Room 6209 MSC-9619
Bethesda, MD 20892-6100
Telephone: (301) 443-6100
FAX: (301) 443-9719
Email: drausch@mail.nih.gov

Kenneth A. Gruber, Ph.D.
Chronic and Disabling Diseases Program
National Institute of Dental and Craniofacial Research
Building 45, Room 4AN-18C
Bethesda, MD 20892
Telephone: (301) 594-4836
FAX: (301) 480-8318
Email: kenneth_gruber@nih.gov

Vivian Pinn, Ph.D.
Office of Research on Women's Health
National Institutes of Health
Building 1, Room 201
Bethesda, MD 20892
Telephone: (301) 402-1770
FAX: (301) 402-1798
Email: pinnv@od.nih.gov

Direct inquiries regarding fiscal matters to:

Mr. David Mineo
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O Box 12233 (EC-22)
Research Triangle Park NC, 27709
Telephone: (919) 541-1373
FAX: (919) 541-2860
Email: mineo@niehs.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.113 - Biological Responses to Environmental Health Hazards, and No. 93.856 'Microbiological and Infectious Disease Research, and No, 93.855 ' Immunology, Allergy, and Transplantation Research.

Awards are made 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 grants 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.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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