

NIH GUIDE

For Grants and Contracts

NOTICE OF MAILING CHANGE

Check here if you wish to
discontinue receiving this
publication

Check here if your address has
changed and you wish to con-
tinue receiving this publication.
Make corrections below and
mail this page to:

NIH Guide
Printing & Reproduction Branch
National Institutes of Health
Room B4BN08, Building 31
Bethesda, Maryland 20892

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICIAL BUSINESS
Penalty for Private Use, \$300

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

Vol. 20, No. 34 (Part II of II)
September 13, 1991

First Class Mail Postages & Fees Paid PHS/NIH/OD Permit No. G-291
--

ONGOING PROGRAM ANNOUNCEMENTS

GENETICS AND FUNDAMENTAL MECHANISMS OF CHEMICAL SENSES (PA-91-91) 1
National Institute on Deafness and Other Communication Disorders
Index: DEAFNESS, COMMUNICATION DISORDERS

LITERACY IN DEAF INDIVIDUALS (PA-91-92) 3
National Institute on Deafness and Other Communication Disorders
Index: DEAFNESS, COMMUNICATION DISORDERS

MECHANISMS OF VOICE DISORDERS (PA-91-93) 6
National Institute on Deafness and Other Communication Disorders
Index: DEAFNESS, COMMUNICATION DISORDERS

CAREER DEVELOPMENT AWARDS IN ALLERGY, IMMUNOLOGY, TRANSPLANTATION, INFECTIOUS DISEASES AND AIDS (PA-91-94) .. 8
National Institute of Allergy and Infectious Diseases
Index: ALLERGY, INFECTIOUS DISEASES

ONGOING PROGRAM ANNOUNCEMENTS

GENETICS AND FUNDAMENTAL MECHANISMS OF CHEMICAL SENSES

PA: PA-91-91

P.T. 34; K.W. 0705070, 1002019, 1002058

National Institute on Deafness and Other Communication Disorders

PURPOSE

The National Institute on Deafness and Other Communication Disorders (NIDCD) invites grant applications that apply the methodology of various areas of genetics, such as molecular, classical, developmental, and behavioral genetics, to analyze the functional properties of the senses of smell and taste. Of particular interest are multi-level studies that combine various approaches of genetics with those of molecular biology or that integrate structure-function relations from the molecular to the behavioral levels.

BACKGROUND

Genetic approaches offer the potential to provide fundamental insights into normal and abnormal chemosensory function. For example, investigators may study genetic variants using molecular biologic techniques, such as gene cloning, restriction mapping, in-situ hybridization, and the development of transgenic mutants.

RESEARCH GOALS AND SCOPE

The research must be planned to characterize the molecular basis of the function of the chemical senses with the ultimate goal of effective diagnosis, treatment, and prevention of chemosensory disorders and medical conditions associated with chemosensory disorders. The NIDCD wishes to foster a broad range of basic and clinical research related to this announcement, to support basic and clinical scientists at all stages of their careers, and to encourage collaboration among investigators with diverse biomedical and behavioral research skills, including investigators from outside the traditional fields of chemosensory research. The research opportunities described below are not intended to limit the range of topics that are encouraged by this announcement but to illustrate the broad range of topics that are relevant to this announcement:

- o Describe the taste or olfactory performance of genetically defined inbred and recombinant inbred strains of animals.
- o Apply classical Mendelian techniques to identify major allelic influences on chemosensory phenotypes and isolate the relevant alleles in congenic or coisogenic lines.
- o Use traditional and molecular genetic approaches to map major gene loci and quantitative trait loci affecting the chemical senses.
- o Isolate chemosensory-relevant genes and investigate their properties in vitro.
- o Establish transgenic animals to study the expression and regulation of chemosensory-relevant genes.
- o Apply in-situ hybridization histochemistry to investigate sites of expression of chemosensory-relevant genes.
- o Develop psychophysical procedures for precise characterization of chemosensory phenotypes in various genetic models.

- o Identify the mechanisms of gene action on chemosensory systems.
- o Investigate similarities between animal models and human phenotypes.

ELIGIBILITY

Any of the following organizations are eligible to apply: non-profit institutions of higher education; other non-profit and for-profit organizations; State and local governments and their agencies; and authorized Federal agencies.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders, or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women and minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

MECHANISMS OF SUPPORT

Support mechanisms for the announcement include the individual research project grant (R01), Small Grants (R03), First Independent Research Support and Transition Award (R29), Research Career Development Award (K04), and Clinical Investigator Development Award (K08). The NIH policies that govern the programs will prevail.

REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed for scientific and technical merit by an appropriate initial review group. A second level of review will be made by an appropriate national advisory council. Institutes other than NIDCD may have interests related to the content of this Program Announcement; in all cases, existing guidelines for the assignment of applications will be followed.

METHOD OF APPLYING

Applications must be submitted on form PHS 398 (rev. 10/88) using the instructions included in the application kit. These kits are available from most institutional offices of sponsored research, the NIDCD Program Administrator cited below, and the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

On page 1 of form PHS 398, check "yes" in item 2 and type: PA-91-91, Genetics and Fundamental Mechanisms of Chemical Senses.

Send the original and six copies of the application to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

INQUIRIES

Investigators are encouraged to call or write:

Jack Pearl, Ph.D.
Program Administrator
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400B
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-5061
FAX: (301) 402-6251

For questions concerning budget and fiscal matters, contact:

Sharon Hunt
Grants Management Officer
Division of Extramural Activities
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-B
6120 Executive Blvd.
Rockville, MD 20892
Telephone: (301) 402-0909
FAX: (301) 402-6251

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.173, Research Related to Deafness and Communication Disorders. Awards will be made under the authority of the Public Health Service Act, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. The program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

REFERENCE

Chemical Senses Volume 3, Genetics of Perception and Communication, C. J. Wysocki and M. R. Kare (Ed.), Marcel Dekker, Inc., New York, 1991.

LITERACY IN DEAF INDIVIDUALS

PA: PA-91-92

P.T. 34; K.W. 0715050, 0502000

National Institute on Deafness and Other Communication Disorders

PURPOSE

Problems associated with the acquisition of reading and writing skills are the most pervasive academic and vocational consequences of deafness. The purpose of this program announcement is to encourage research in the reading and writing abilities and deficits of children and adults with severe to profound deafness. The Division of Communication Sciences and Disorders (DCSD) of the National Institute on Deafness and Other Communication Disorders requests submission of investigator-initiated (R01) and First Independent Research Support and Transition (FIRST) Award (R29) research grant applications focused on literacy in deaf individuals. Studies of reading and/or writing acquisition and remediation in children and adults are encouraged.

BACKGROUND

Severe to profound deafness in early childhood has been found to have a significant negative impact on later reading and writing achievement. Lags in reading achievement, difficulties in comprehending and writing English syntax, and limited English vocabularies characterize these individuals. Research has consistently shown that deaf students age 16 or over have significantly lower reading scores than hearing students of similar ages. Despite a wealth of new instructional tools and communication strategies, the average reading comprehension of hearing-impaired students in their last grade of secondary school remains at a third-to-fourth grade equivalent, essentially the same as for their hearing-impaired peers whose test results were reported almost eighty years ago.

The deaf child must learn to read an orthography designed to represent the phonological structure of English. In the absence of significant auditory input, awareness of this phonological structure is limited for many deaf children. The role of phonological awareness and processing needs further examination in this population. In addition, the role of cognitive processes such as memory in the acquisition of literacy should be investigated. Finally, the early age at which reading comprehension ability tends to plateau in this population and the severity of the problem suggest that this issue needs careful investigation.

RESEARCH GOALS AND SCOPE

The NIDCD encourages investigations into the reading and writing abilities and deficits of deaf children and adults. Examples of possible investigations include but are not limited to the following:

- o the relation between deaf children's reading achievement and the method of communication used by their hearing parents;
- o the relationship between reading and writing abilities in deaf children or deaf adults;
- o factors that are predictive or differentiate deaf readers/writers who are proficient in reading or writing English from those with less fluency;
- o the impact of closed captioning, telecommunication devices, personal computers, and other technological influences on literacy skills of the deaf;
- o cognitive factors associated with good reading/writing skills;
- o innovative strategies for teaching of literacy to deaf individuals learning English as a second language as well as to those learning English through an auditory-oral approach;
- o the relationship between speech processing and literacy in deaf children who use spoken language primarily;
- o the relationship among speech processing, sign processing and literacy in deaf children and adults who use sign language;
- o examination of the interaction of acquisition of signed languages with spoken and written language and characterization of the resulting bilingualism;
- o examination of the order of acquisition of speech and signed language as they affect children's eventual acquisition of English language and literacy; and,
- o examination of language acquisition through printed media, with implications for how to teach English to a deaf population that only has access to the language through print.

ELIGIBILITY

Any of the following organizations may apply: non-profit institutions of higher education; other non-profit and for-profit organizations; State and local governments and their agencies; and authorized Federal agencies.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders, or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women and minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

MECHANISM OF SUPPORT

The support mechanisms for grants in this area will be the individual investigator-initiated research grant (R01) and the FIRST award (R29). Potential applicants also must be aware of the Clinical Investigator Development Award and the Small Grant Program, if appropriate. Under any of these mechanisms, the Principal Investigator and any participating investigators will plan, direct, and perform the research.

REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed for scientific and technical merit by an appropriate study section of the Division of Research Grants. Secondary review will be by an appropriate national advisory council.

METHOD OF APPLYING

Applications must be submitted on form PHS 398 (rev. 10/88) using the instructions included in the application kit. These kits are available from most institutional offices of sponsored research, the NIDCD Program Administrator cited below, and the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

Receipt dates are February 1, June 1, and October 1.

On page 1 of form PHS 398, check "yes" in item 2 and type: PA-91-92, Literacy in Deaf Individuals.

Send the original and six copies of the application to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

INQUIRIES

Investigators are encouraged to call or write:

Judith A. Cooper, Ph.D.
Deputy Director,
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-B
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-5061
FAX: (301) 402-6251

For budget and fiscal matters, contact:

Sharon Hunt
Grants Management Officer
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-B
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 402-0909

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93-854. Awards will be made under the authority of the Public Health Service Act, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. The program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISMS OF VOICE DISORDERS

PA: PA-91-93

P.T. 34; K.W. 0715055, 0710120, 0765035

National Institute on Deafness and Other Communication Disorders

PURPOSE

Voice disorders cause significant impairment to individuals in today's society, where much demand is placed on oral communication. Careers may be altered with the inability to function in the work situation. The ability to communicate verbally may be severely limited; many individuals with voice disorders must rely on writing in order to communicate effectively. However, the basis for many voice disorders remains unclear. Knowledge about the mechanisms underlying the bases and development of voice disorders is vitally needed. The purpose of the program announcement is to encourage research in this area. The Division of Communication Sciences and Disorders (DCSD) of the National Institute on Deafness and Other Communication Disorders (NIDCD) requests submission of investigator-initiated (R01) and First Independent Research Support and Transition (FIRST) Award (R29) research applications focused on mechanisms of voice disorders. Studies of disorders and pathologies of voice in the general population as well as in professional voice users (e.g., opera singers, actors, orators, teachers, and other public speakers) are encouraged.

BACKGROUND

If vocal fold vibration is impaired, sound generation for speech is affected and voice disorders often result. The basis for many common voice problems in children and adults remains unclear. There is a need for research on structural alterations that result in voice disorders. For example, investigations of factors underlying development of vocal fold nodules and polyps are critical. In addition, understanding is limited regarding how lesions and inflammatory disorders alter vocal fold vibration and lead to voice disorders.

Laryngeal movement disorders include spasmodic dysphonia, vocal tremor and vocal fold paralysis. Control of laryngeal function may also be impaired in many neurological diseases such as Parkinson's disease and amyotrophic lateral sclerosis. Studies of the neural control of the larynx are needed to determine why laryngeal functions are particularly vulnerable to neurological disorders causing selective neuronal loss either in the brain stem or in the basal ganglia. A better understanding of the pathophysiology of these laryngeal motor control disorders would lead to more effective management.

Increased daily usage of vocal communication and increased environmental noise have resulted in increased demands on the vocal system. Complaints of vocal fatigue by teachers, public speakers, coaches, salespersons, and many other professional users of voice are common. It is important to know the degree to which central and peripheral mechanisms are involved in vocal fatigue. Research into peripheral and central mechanisms involved in fatigue is needed. In addition, the gifted or trained vocalist offers a very important model for vocal evaluation of all voice, establishing the limits of capability in such areas as pitch control. Such information can be used in average voice evaluation as both a criterion and a role model. Research is needed into determination of vocal control in this population.

RESEARCH GOALS AND SCOPE

The NIDCD encourages investigations into disorders and pathologies of voice in the general population as well as in professional voice users. Examples of possible investigations include, but are not limited to, the following:

- o anatomical bases of specific vocal pathologies;
- o the effects of hormonal and pharmacologic substances on voice;
- o clarification of the relationships between neuropathology and laryngeal disorders;
- o problems associated with laryngeal injury and surgery;
- o mechanisms underlying idiopathic dysphonia, including environmental noise, air pollution, and systemic disease;
- o pathophysiology of inflammatory diseases of the upper airway and larynx, including rhinitis, sinusitis, and laryngitis;
- o pathophysiology of specific vocal pathologies, such as spasmodic dysphonia;
- o mechanisms of voice abuse and breakdowns of voice in the professional voice user;
- o mechanisms of pitch, loudness and vocal quality and usage in the professional voice user, including attention to vocal limits and efficiency; and,
- o effective therapies for the voice disorders associated with the professional voice user.

ELIGIBILITY

Any of the following organizations may apply: non-profit institutions of higher education; other non-profit and for-profit organizations; State and local governments and their agencies; and authorized Federal agencies.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions which disproportionately

o Immunologic Skin Diseases. Autoimmune mechanisms and immuno-inflammatory components appear to play central roles in the development of numerous skin disorders including atopic dermatitis, allergic contact dermatitis and angioedema. The mechanisms underlying the basic immunologic processes and immunopathology of these diseases are incompletely understood, although some advances have been made such as the results that have been recently reported on the striking effects of immuno-suppression in the treatment of psoriasis. Basic training in immunology would allow dermatologists and dermatopathologists to better understand the pathogenesis of many skin diseases, and would facilitate the development of new, improved immuno-modulatory therapies.

o Immunologic Eye Diseases. The eye and its surrounding tissues comprise a complicated organ system in which immunologically mediated diseases that are intrinsic to the eye or are ocular manifestations of systemic disease often occur. Autoimmunity is the main cause of uveoretinitis in this country. Knowledge of the chemistry and sources of ocular autoantigens is just now emerging. Training of ophthalmologists and other individuals with suitable backgrounds in clinical and basic science in the immunopathology of eye diseases such as uveitis, various forms of keratitis, and conjunctivitis would enable them to develop new approaches to eye disease research, including applications of emerging immunomodulatory therapies to prevent or halt the progress of these diseases.
Division of Microbiology and Infectious Diseases (DMID)

o Sexually transmitted diseases (STDs). In order to meet evolving demands for high quality STD research, there is an urgent need to increase STD research opportunities. Areas of emphasis in STD research include sequelae of STDs in women (e.g., infertility and adverse outcomes of pregnancy); genital ulcer disease (particularly chancroid and syphilis); human papillomavirus infection; and the inter-relationships between HIV infection and other STDs. Because of the interdisciplinary character of these research issues, there is a need to encourage research training to include not only specialists in infectious diseases, but also other clinical investigators (e.g., obstetricians, gynecologists, and pediatricians), behavioral scientists, and basic researchers.

o Tropical medicine and parasitology. This emphasis is to support the training of physicians in clinical research on parasitic diseases in endemic areas where other collaborative research and field programs are already in place. It is intended to allow the participant to gain relevant research expertise in such disciplines as biochemistry, cell biology, molecular biology, pharmacology, immunology and epidemiology as well as experience in diagnosis and management of tropical parasitic diseases.

o Tuberculosis. The Department of Health and Human Services (DHHS) Advisory Council for the Elimination of Tuberculosis has listed the training of tuberculosis researchers as a high priority item necessary to achieve tuberculosis control. Additional individuals trained as physician-investigators and basic scientists to initiate high quality research programs on tuberculosis would be highly desirable. Therefore, there is a great need to promote clinical and basic research training in all aspects of tuberculosis control but particularly training in epidemiology, treatment, immunology and molecular biology.

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 program announcement, Individual National Research Service Awards in Allergy, Immunology, Transplantation, Infectious Diseases and AIDS, is related to the priority areas of HIV Infection, Sexually Transmitted Diseases, and Immunization and Infectious Diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made

to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

MECHANISMS OF SUPPORT

Each of the career development mechanisms is tailored to a particular stage of the investigator's career. Existing mechanisms supported by the NIAID include the: Physician Scientist Award (PSA-K11); Clinical Investigator Award (CIA-K08); and Research Career Development Award (RCDA-K04). Physician investigators are encouraged to use the PSA and CIA to develop expertise in basic and clinical research.

The support mechanisms for career development are summarized below. This announcement is particularly intended to encourage applications for CIA and PSA Awards in the emphasis areas cited above. Detailed instructions and application forms for each of the mechanisms may be obtained from the office of sponsored programs at most research institutions and from the Division of Research Grants, NIH, (301) 496-7441.

C. PHYSICIAN SCIENTIST AWARD - PSA (K11)

The PSA is designed to encourage the newly trained clinician to develop independent research skills and experience in a fundamental science. The award is divided into two phases. During Phase I, which may last two to three years, the candidate is expected to develop independent research skills and experience in a fundamental science and may elect to work toward a Ph.D. degree. The primary sponsor must be an accomplished basic science investigator. Phase II entails intensive research activity, applying the skills learned during Phase I.

Applicants for the PSA must:

- o Hold an M.D. or other health professional degree. Ordinarily, candidates holding the Ph.D. are ineligible;
- o Have completed at least one postgraduate year of clinical training by the time the award is made;
- o Not have previous independent research support;
- o Commit at least 75 percent time to PSA activities.

Provisions of the PSA include:

- o Three to five years of support, nonrenewable;
- o Salary up to \$50,000 per year plus fringe benefits;
- o Up to \$10,000 (Phase I) and \$20,000 (Phase II) per year for research supplies, equipment, technical assistance, and travel.

D. CLINICAL INVESTIGATOR AWARD - CIA (K08)

The CIA is offered to provide the opportunity for promising clinically trained individuals with demonstrated aptitude in research to develop into independent investigators.

Applicants for the CIA must:

- o Hold an M.D. or other health professional degree;
- o Have had approximately three to seven years of postdoctoral experience, both clinical and research by the projected start of the award;
- o Not have been a Principal Investigator on a Public Health Service-supported research project.

Provisions of the CIA include:

- o Three years of support, nonrenewable;
- o Salary up to \$50,000 per year plus fringe benefits;
- o Up to \$20,000 per year for research supplies, equipment, technical assistance, travel;
- o Commitment of at least 75 percent time to the project.

E. RESEARCH CAREER DEVELOPMENT AWARD - RCDA (K04)

The RCDA is a special salary grant to enhance the research capabilities of individuals in the formative stages of their careers. Candidates who have demonstrated outstanding potential as independent investigators in health-related research, but need to be released from some of the teaching, clinical, and administrative duties

assigned to junior faculty, are eligible. The award is not intended for untried investigators or for those already established as independent investigators.

Applicants for the RCDA must:

- o Hold a doctoral degree or equivalent and have at least five years postdoctoral research experience, including two years as the Principal Investigator of a peer-reviewed research grant, prior to the requested beginning date of the award;
- o Describe in the application how the award will enhance development as independent investigators;
- o Have independent research support sufficient for the research proposed in the RCDA application;
- o Hold a faculty appointment.

Provisions of the RCDA include:

- o Five years of support, nonrenewable;
- o Salary up to \$50,000 per year plus fringe benefits. No funds are available under this award for research expenses. These expenses are expected to be included in the independent research support described above.
- o Commitment of at least 80 percent time to research. The remaining time (up to 20 percent) must be spent on research-related activities that will enhance research career development.

RCDA applications may be submitted concurrently with a research grant application but may not be submitted concurrently with other development awards such as the PSA, the CIA, or the FIRST Award.

APPLICATION SUBMISSION AND REVIEW

Application receipt dates for all competing career development awards (K series) are February 1, June 1, and October 1. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. RCDA applications will be reviewed through the NIH peer review system in the Division of Research Grants. Earliest possible funding dates are approximately nine months after the receipt dates. Use application form PHS 398, Rev. 10/88, with special instructions for the PSA, CIA, and RCDA found in the publication entitled "The K Awards," revised October 1990, available from the sources cited previously in this section.

Applications submitted in response to the seven emphasis areas described above must be identified by typing "PA-91-94, CAREER DEVELOPMENT AWARDS" on line 2 of the face page, below the title of the project. Applications for training in areas other than those emphasized above must leave line 2 blank.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed activity. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator may be included with the application.

For further information about NIAID career development awards, contact the representative from the appropriate NIAID Division:

Nancy R. Brown
Health Specialist
Basic Research and Development Program
Division of AIDS
Control Data Building, Room 208N
Bethesda, MD 20892
Telephone: (301) 402-0755

Leslye D. Johnson, Ph.D.
Chief, Enteric Diseases Branch
Division of Microbiology and Infectious Diseases
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 496-7051

Eugene M. Zimmerman, Ph.D.
Special Assistant to the Director
Division of Allergy, Immunology and Transplantation
Westwood Building, Room 752
Bethesda, MD 20892
Telephone: (301) 496-8973

For inquiries regarding fiscal and business matters, contact:

Ms. Barbara Huffman
Special Assistant for Operations
Office of the Chief, GMB, DEA, NIAID
Westwood Building, Room 718
Bethesda, MD 20892
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.855, Immunology, Allergic and Immunologic Diseases Research, and No. 93.856, Microbiology and Infectious Diseases 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 grants policies and Federal Regulation 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.