

NIH GUIDE

For Grants and Contracts

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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.

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April 19, 1991

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NOTICES

THE NATIONAL CELL CULTURE CENTER

P.T. 34; K.W. 0780015, 0780000, 0760045

National Center for Research Resources

The National Cell Culture Center is a resource facility that provides large scale mammalian cell culture services. The Center, available to researchers throughout the United States, has been established to alleviate the current shortage of facilities and expertise required to meet the cell culture needs of the biomedical research community.

Specifically, the Cell Culture Center supports basic research and provides investigators with the following customized services:

- o Large quantity production of mammalian cells in suspension or monolayer cultures. Quantities range from 10 to 150 liters.
- o Large quantity production of monoclonal antibodies. Quantities range from 0.5 to 100 grams.
- o Large quantity production of non-hybridoma cell secreted proteins. Quantities vary depending on individual cell lines.

An application form, obtained from the Cell Culture Center, should contain a description of the relevant research project. Following approval of the application by the Cell Culture Center's Scientific Advisory Board, the applicant's cell line is sent to the Center, and grown to the requested amount. Researchers are charged only for the consumable materials and a portion of the labor costs required for each project. Application forms and inquiries should be directed to:

Mark Hirschel, Ph.D.
Director
National Cell Culture Center
Endotronics, Inc.
Minneapolis, MN 55433
Telephone: 1-800-325-1112

The Cell Culture Center is supported by a cooperative agreement award from the National Center for Research Resources, NIH.

NOTICE FOR APPLICANTS USING PHS FORM 416-1

P.T. 34; K.W. 1014006

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

INSERT FLYER FOR APPLICANTS USING PHS FORM 416-1 REGARDING IMPLEMENTATION OF THE NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

The purpose of this notice is to provide special instructions to research grant and cooperative agreement applicants using Form PHS 416-1, regarding NIH and ADAMHA policies concerning the inclusion of women and minorities in clinical research study populations. These policies were published in the NIH Guide for Grants and Contracts on February 8, 1991, Vol. 20, No. 6.

PRIORITY ANNOUNCEMENT

SPECIAL INSTRUCTIONS TO APPLICANTS USING FORM PHS 416-1 REGARDING IMPLEMENTATION OF THE NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NOTE: THESE INSTRUCTIONS APPLY ONLY TO THE LIMITED NUMBER OF GRANT AND COOPERATIVE AGREEMENT APPLICANTS WHO PROPOSE CLINICAL RESEARCH STUDIES, WHICH INCLUDE 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.

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants, cooperative agreements and contracts 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. If women or minorities are not included or are inadequately represented in clinical research, particularly in proposed populations-based studies, a clear, compelling rationale should be provided.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH and ADAMHA recognize 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 (American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

Beginning immediately, all applications submitted to NIH/ADAMHA will be required to address this policy.

INSTRUCTIONS TO APPLICANTS

Applications must include a description of the composition of the proposed study population in terms of gender and racial/ethnic group, together with a rationale for its choice. 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 416-1 in Part I (Applicant), Item 29.b. (1) - (3) of the Research Proposal AND summarized in 29.b. (5) Human Subjects/Vertebrate Animals, and in Part II (Sponsor), Item 36. Human Subjects.

Applications must employ a study design with gender and/or minority representation (by age distribution, risk factors, incidence/prevalence, etc.) appropriate to the scientific objectives of the disease, disorder or condition being studied.

It is not an automatic requirement for the study design to provide statistical power to answer the questions posed for men and women and racial/ethnic groups separately; however, whenever there are scientific reasons to anticipate differences between men and women with regard to the hypothesis under investigation, applicants should include an evaluation of gender and minority group differences in the proposed study.

If adequate inclusion of women or minorities is impossible or inappropriate with respect to the purpose of the research, the health of the subjects, or other reasons, or if in the only study population available there is a disproportionate representation of one gender or minority/majority group, the rationale for the study population must be well explained and justified in the application.

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 in the application.

PEER REVIEW

Scientific Review Administrators (formerly Executive Secretaries) of the Initial Review Groups (IRGs) will request written clarification from the applicant when the application does not describe and justify the gender or minority composition of the study population. If such information is not contained within the application, and is not provided upon request, the application will be deferred without IRG review until it is complete, or be returned to the applicant. In the case of responses to RFAs with single receipt dates, applications that are not brought into compliance will be returned without review, rather than deferred.

Scientific Review Administrators of all scientific IRGs will instruct the IRG members that the assessment of scientific and technical merit of applications must include an evaluation of the proposed gender and minority composition of the study population and its appropriateness to the scientific objectives of the study and to this policy. 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 the assigned score given to the application. When preparing the summary statement, the Scientific Review Administrator will summarize the

findings and recommendations of the reviewers on this policy in a special section at the end of the Critique sub-headed: Women and Minority Subjects.

Regardless of the priority score, percentile ranking or program relevance of the proposed research, the NIH and ADAMHA funding components will not fund/award grants that do not comply with this policy.

APPLICANTS SHOULD CONTACT NIH/ADAMHA PROGRAM STAFF FOR ADDITIONAL GUIDANCE IN INTERPRETING THIS POLICY IN THE CONTEXT OF ANY SPECIFIC INSTITUTE, CENTER OR DIVISION RESEARCH PROGRAM OF NIH/ADAMHA.

For further information or for questions concerning this notice, contact:

Dr. Samuel Joseloff
Chief, Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
Bethesda, MD 20892
Telephone: (301) 496-7441

NOTICES OF AVAILABILITY (RFPs AND RFAs)

NEW TECHNOLOGIES FOR DETECTING ALL GENES AND CODING REGIONS IN GENOMIC DNA

RFA AVAILABLE: HG-91-02

P.T. 34; K.W. 1215018, 0755045, 1002008, 1002058

National Center For Human Genome Research

Letter of Intent Receipt Date: June 17, 1991

Application Receipt Date: July 15, 1991

The National Center for Human Genome Research (NCHGR) invites applications for assistance awards to support the development of new technologies capable of (1) detecting all coding sequences and/or genes in genomic DNA or (2) preparing complementary DNA (cDNA) libraries that are representative of all expressed genes.

BACKGROUND

There are several approaches to detecting coding information in the genome: (1) identification of cDNAs representing expressed genes; (2) identification of sequences conserved across species; and (3) identification of sequences capable of being expressed, using techniques such as exon trapping. Problems in using these approaches for thorough screening of the genome include the low abundance of many mRNAs and the differential tissue or developmental expression of many genes. Given the magnitude of the effort necessary to identify all genes and/or coding sequences and to differentiate non-coding sequences from coding sequences, new or significantly improved strategies need to be developed to insure that all coding sequences located within a region of genomic DNA can be identified and characterized in an expeditious and cost-effective manner.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDIES

NIH policies concerning research on human subjects apply to this program. For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded from this requirement. 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 must be addressed by applicants.

RESEARCH SCOPE

Projects responsive to this Request for Applications (RFA) should seek to develop new technologies or research strategies to identify genes and/or coding sequences in genomic DNA or to isolate cDNAs in a rapid, thorough and cost-effective manner. Applications in the following areas are encouraged:

- o Methods of identifying all the genes or complete coding regions directly from genomic DNA;

- o New methods of generating high quality, full-length cDNAs;
- o New methods of generating and ordering cDNA libraries that are representative of the complete coding information content of genomic DNA or of all coding regions expressed in various tissues.

Emphasis will be on projects that are based on experimental rather than computational approaches.

MECHANISM OF SUPPORT

Support for this program will be through research grants (R01s). The total amount of support available for grants under this RFA is approximately \$1.5 million for the first year of the project and is contingent upon the appropriation of funds for this purpose. Approximately six awards will be made and will be contingent upon the quality of the applications received.

ELIGIBILITY

Domestic universities, medical colleges, hospitals, and other public or private research institutions, including State and local government units, are eligible. Applications from minority investigators and women are encouraged.

LETTER OF INTENT

Potential applicants are asked to submit a letter of intent by June 17, 1991. This letter should include a descriptive title of the proposed research, name of the Principal Investigator and other key investigators and their institutions. The letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application. Letters of intent should be sent to the program person listed at the end of this RFA.

APPLICATION AND REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in accordance with the usual NIH peer review procedures. Applications will be screened first by NIH staff for responsiveness to this RFA. Those deemed non-responsive will be returned to applicants or referred to the Division of Research Grants for processing by the regular procedure. If a large number of responsive applications is received, they will undergo a preliminary peer review by the Genome Research Review Committee, NCHGR, to identify the most meritorious ones. Applications that are deemed non-competitive by this process will receive only a brief critique and will not be reviewed further. The remaining applications will be reviewed for scientific and technical merit by the Genome Research Review Group, NCHGR. The second level of review will be conducted by an appropriate national advisory council. Review criteria include the following:

- o Originality and innovativeness of the approach;
- o Overall scientific and technical merit of the research;
- o The potential of the proposed work to attain the research objectives outlined in this RFA;
- o Training, experience, research competence, and dedication of the investigator(s);
- o Adequacy of available facilities;
- o Provision for the protection of human subjects and the humane care of animals; and
- o Appropriateness of the requested budget for the work proposed.

Applications must be submitted using the form PHS 398 (rev. 10/88). The RFA label available in the revised application kit MUST be affixed to the bottom of the face page. 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. Application kits are available in the business or grants offices at most academic or research institutions and from the Division of Research Grants, National Institutes of Health.

TIMETABLE:

Receipt Date: July 15, 1991
IRG Review: November 1991
Council Review: February 1992
Earliest Funding Date: April 1992

It is essential that applicants type "New Technologies for Detecting Genes in Genomic DNA" and the RFA number, HG-91-02, on line 2 on the face page of the application form. The original and four copies of the application must be submitted to:

Grant Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
5333 Westbard Avenue
Bethesda, MD 20892**

To expedite the review process, it is also important to submit two copies of the application directly to:

Office of Scientific Review
National Center for Human Genome Research
National Institutes of Health
Building 38A, Room 604
9000 Rockville Pike
Bethesda, MD 20892

Funding decisions will be based on recommendations of the initial review group and the advisory council regarding scientific merit and program relevance, and on the availability of funds.

Prospective applicants are encouraged to contact staff very early in the planning phase of the application. For more information regarding the program or a complete copy of the RFA, please contact:

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
National Center for Human Genome Research
National Institutes of Health
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
E-mail: B2G@NIHCU.BITNET; B2G@CU.NIH.GOV

For information about PHS Grant Policy, applicants may contact:

Ms. Alice Thomas
Chief, Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
National Institutes of Health
Bethesda, MD 20892

The program and grants management officials welcome the opportunity to clarify any issues or questions related to this RFA and encourage written or telephone inquiries.

ONGOING PROGRAM ANNOUNCEMENTS

SPECIALIZED MENTAL HEALTH CLINICAL RESEARCH CENTERS
GENERAL MENTAL HEALTH CLINICAL RESEARCH CENTERS

PA: PA-91-43

P.T. 04; K.W. 0715095, 0715129

National Institute of Mental Health

The National Institute of Mental Health seeks applications for the support of Specialized Mental Health Clinical Research Centers (SMH-CRC) and General Mental Health Clinical Research Centers (GMH-CRC). An SMH-CRC provides research resources that are to be used by a cooperating group of researchers as the foundation for a research program focused around a single major theme, typically a mental disorder or a group of closely related disorders. A

GMH-CRC has no single thematic focus but provides the enabling research infrastructure to support a broad range of mental health clinical investigations; it may have multiple research foci that are not necessarily related in nature. Both types of centers provide infrastructure support, rather than support for specific research studies.

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, "Specialized Mental Health Clinical Research Centers; General Mental Health Clinical Research Centers," is related to the priority area of mental health. 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).

This announcement supersedes the prior announcements for Mental Health Clinical Research Centers (MH-CRC) and Clinical Research Centers for the Study of the Psychopathology of the Elderly (CRC/PE) and will govern future competitive renewals for existing Centers, as well as applications for new Centers.

These grants are available to any public or private, nonprofit institution, such as a university, college, hospital, or community agency, units of State and local government, authorized units of the Federal Government, and for-profit institutions and entities. Each of the Centers should involve a clinical facility with research laboratory capability and be affiliated with a major university or research center. No organization may have both an SMH-CRC and a GMH-CRC, and it may not have more than one GMH-CRC.

Applications for NIMH grants are required to include both women and minorities in study populations for clinical research. Research projects that use Center resources should incorporate into their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or is not appropriate, the reasons for this must be explained and justified.

There are two categories of grant applications under each of these two different programs: applications for Developing Centers (P20) and applications for Mature Centers (P30). The intent is to encourage the broadened use of the clinical research center approach across a wide range of institutions at various stages of research capacity development. The funding cap for grants for Developing Centers is \$300,000, plus negotiated institutional indirect costs. The funding cap for Mature Centers is \$1,000,000, plus negotiated institutional indirect costs.

All of the following characteristics must be apparent in each application: Each Center should provide an environment of scientific excellence that will assure the highest quality research and leadership in its particular area(s) of investigation. Each SMH-CRC and GMH-CRC must include a research apprentice or career development component that is an integral aspect of training programs in psychiatry, nursing, social work, clinical psychology, and/or graduate training programs in basic science departments in medical and graduate schools. Each Center must have a scientifically and administratively well-qualified Center Director with primary responsibility for administration. He or she is responsible for the overall coordination and development of the Center as a valuable integral resource for the parent institution and for the quality of the ongoing research.

The Center must have an administrative structure that will assure maximum effectiveness and efficiency of operation and sound financial practices. The Center should have access to sufficient inpatient and/or outpatient facilities to ensure availability of patients for the specific clinical research programs. The Center accomplishes its research goals through the provision of core facilities and research laboratories that provide an infrastructure for the independently funded research associated with the Center. The provision of these facilities is designed to enhance the overall research effort.

One of the most important roles of a Developing Center is that of a magnet to draw other high quality scientists, laboratories, and project grants into the Center. Application for a Developing Center should not be made if the resources for a full operating Center are present. Each Developing CRC should be capable of providing research experience for at least two research apprentices annually. Such apprenticeships shall be made available to junior faculty and postdoctoral staff, as well as senior residents. Criteria for Developing Centers include the quality and extent of institutional support available to facilitate the development of the Center; the likelihood that the

Center will develop into a fully mature Center during the five years of support; the quality of the plans to recruit excellent, new research faculty; and the likelihood that the establishment of a Developing Center will facilitate the existing research activities.

For a Mature Center, the research program must be focused on an organizing theme which should be a clearly defined mental disorder or related group of disorders or a specific mental health problem or issue of major scientific and/or public health importance. The following criteria apply specifically to MH-CRCs: the quality, appropriateness, and originality of the integrating theme, including its logic and linear development; the appropriateness and novelty of the research questions being asked; and the kind and degree of synergistic potential of the individually supported research projects.

Applications will be accepted and reviewed according to the regular Center review schedule. Funding for Developmental Centers is for a five-year period only. Funding for Mature Centers can be for a maximum project period of five years, and additional project periods may be funded following competitive renewal. Actual amounts and years of support that may be approved and awarded will depend on the appropriate level of support necessary for the scientifically meritorious work proposed.

Potential applicants may seek information and consultation from the Division of Clinical Research, NIMH, by contacting:

Leonard Lash, Ph.D., Chief
Parklawn Building, Room 10-99
Telephone: (301) 443-3264

For Aging Clinical Research Centers:

Barry D. Lebowitz, Ph.D., Chief
Parklawn Building, Room 7-103
Telephone: (301) 443-1185

For grants management information:

Stephen J. Hudak
Parklawn Building, Room 7C-26
Telephone: (301) 443-4456

The address for all of the above is:

National Institute of Mental Health
5600 Fishers Lane
Rockville, MD 20857

This program is described in the Catalog of Federal Domestic Assistance No. 93.242. Under authority of Section 301 of the Public Health Service Act, as amended PL 78-410, 42 U.S.C. 241, the National Institute of Mental Health provides support for Clinical Research Centers.

RESEARCH GRANTS ON THE NEUROLOGICAL BASIS OF COGNITION

PA: PA-91-44

P.T. 34; K.W. 1002030, 0414005, 0705010

National Institute of Neurological Disorders and Stroke

This program announcement, reissued by the Division of Fundamental Neurosciences of the National Institute of Neurological Disorders and Stroke (NINDS), is designed to encourage the submission of research grant applications dealing with the neurological basis of cognitive processes.

I. BACKGROUND

The 1990s have been designated as the Decade of the Brain. The 1980s saw a burgeoning of research into how the two hemispheres of the mammalian brain differ in anatomy and in their contributions to cognitive functions, and it can now be expected that sophisticated physiological investigations will provide a more thorough understanding of mechanisms that underlie asymmetrical brain functions. Recent studies have demonstrated a system of structures in the human brain supporting mechanisms of attention; different components of attention will likely be found to be associated with different neural systems. Sex differences also have been reported in brain functions underlying cognitive processes, but possible reasons for these differences are not yet

well understood. Lately, research on cognitive processes has intensified because of advances in understanding the neurobiology of cognitive function. This announcement encourages continued research in this field and development of new investigative techniques.

II. SCOPE

The Division presently supports research on the nature of the neurological basis of cognition, some of which resulted from an announcement on the "Neurophysiology of Cognitive Processes" issued a decade ago. The present announcement supersedes the earlier one and is meant to expand this area of research.

Examples of research areas:

Investigations envisioned by this announcement could include the following:

- o Localization of function with brain scanning devices, using reliable methods of assessing such functions as imagery, closure, autobiographical memory, different facets of attention and problem solving.
- o Neurophysiological and noninvasive neuropsychological research on nonhuman primates engaged in language-relevant communication, including the use of numbers. If, as in the human being and certain birds, there is asymmetrical function, tracking the localization as it develops can provide further insight into the nature of the mechanisms.
- o Comprehensive analysis of gender differences on the effects of circumscribed static neurological lesions upon well-standardized cognitive measures, with attention to comparing patients with either anterior or posterior locations of lesions, subcortical or cortical locations, right or nonright handedness, etc.
- o Neurophysiological measures obtained from nonhuman primates engaged in repetitive event-related activities. Certain theories about brain function during event-related potentials might profitably be tested in primates or other nonlissencephalic animals. Noninvasive methods could be used with the more rare and endangered species.
- o Investigations of episodic and semantic memory which could lead to biologically based distinctions.

III. MECHANISM OF SUPPORT

The support mechanisms for grants in this area are individual research grants (R01), program projects (P01), and First Independent Research Support and Transition (FIRST) awards (R29).

APPLICATION AND REVIEW PROCEDURES

Applications are to be prepared on form PHS 398 (rev. 10/88) using the instructions included in the application kit available from the Office of Sponsored Research at most institutions, from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, or from the NINDS address given below. Additional application guidelines for NINDS P01 applications should be obtained from NINDS (see below).

Receipt dates for new research project grant and FIRST award applications are February 1, June 1, and October 1.

To identify responses to this announcement, indicate "Research Grants on the Neurological Basis of Cognition, PA-91-44" under item 2 of page 1. A mailing label is provided in the application kit. Send the signed original and six exact copies to:

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

Applications for research project grants and FIRST awards will be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Secondary review will be provided by an appropriate national advisory council. Applications judged to be within the purview of

other Institutes of NIH will be assigned accordingly, e.g., applications dealing with cognition and aging would be sent to NIA.

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 research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator may be included in the application.

For further information, and for program project guidelines (P01s), potential applicants are encouraged to call or write to:

Herbert C. Lansdell, Ph.D.
Division of Fundamental Neurosciences
National Institute of Neurological Disorders and Stroke
Federal Building, Room 916
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-5745

For fiscal and administrative matters, contact:

Patricia Driscoll
Grants Management Specialist
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1004
7500 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-9231

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, together with a rationale for its choice. 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 review will be deferred until the information is provided. (For RFAs, change to read: 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.

ELIGIBILITY REQUIREMENTS

Applications for research grants may be made by public or private for-profit or non-profit organizations, such as universities, colleges, hospitals or laboratories, units of State or local government, or authorized units of the Federal Government. Women and minority investigators, in particular, are encouraged to apply.

This program is described in the Catalog of Federal Domestic Assistance No. 93.854, Biological Basic Research in the Neurosciences. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

ERRATA

CLINICAL MENTAL HEALTH ACADEMIC AWARD

PA: PA-91-38

P.T. 34; K.W. 0715095, 0715129

National Institute of Mental Health

The National Institute of Mental Health announces that incorrect information pertaining to funding was contained in the third paragraph of the Clinical Mental Health Academic Award announcement in the NIH Guide for Grants and Contracts, Vol. 20, No. 13, March 29, 1991.

The funding information is as follows: NIMH will provide 75 percent of the base institutional salary, up to a maximum stipend of \$75,000 plus fringe for each year of the award. An additional \$25,000 may be requested each year for research and/or career development support.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, Maryland 20816