NIH GUIDE

For Grants and Contracts

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

Vol. 18, No. 45
December 22, 1989

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NOTICES

DATED ANNOUNCEMENTS (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NOTICES

REQUIREMENT FOR PROGRAMS ON THE RESPONSIBLE CONDUCT OF RESEARCH IN NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING PROGRAMS

P.T. 44; K.W. 1014004, 1014006

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

A fundamental aspect of research is that it be conducted in an ethical and scientifically responsible manner. National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) supported research training programs are notable for producing high quality researchers in the various fields of biomedical and behavioral science. Within this framework of excellence and relevance, it is important that attention be directed towards scientific integrity in the conduct of research.

Most universities and academic institutions have practices and procedures to ensure the responsible conduct of research. These may include informal seminars and presentations on conflict of interest, data recording and retention, professional standards and codes of conduct, responsible authorship, institutional policies and procedures for handling allegations of misconduct, policies regarding the use of human and animal subjects, etc. or formal courses on bioethics, research conduct, the ideals of science, etc.

To address this aspect of research training, the NIH and ADAMHA are revising the administrative guidelines for all National Research Service Award institutional training grants to require that a program in the principles of scientific integrity be an integral part of the proposed research training effort.

Effective July 1, 1990, all competing National Research Service Award institutional training grant applications must include a description of the formal or informal activities related to the instruction about the responsible conduct of research that will be incorporated into the proposed research training program.

NIH/FDA REGIONAL WORKSHOPS - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to the Alcohol, Drug Abuse, and Mental Health Administration as well as other Public Health Service agencies. The current schedule includes:

Dates: January 11-12, 1990

Location: Houston, Texas

Title of Workshop: "1990 IRB Challenges"

Contact: Ms. Laurie Flowers
Conference Coordinator
Affiliated Systems Corporation
1200 Post Oak Blvd., Suite 540
Houston, Texas 77056-3104
Telephone: (713) 439-0210

Dates: March 8-9, 1990

Title: "IRB Issues"

Contact: Ms. Mary Jane Peratt
Secretary, IRB
University of Colorado Health Sciences Center
4200 East 9th Avenue, Box C290
Denver, Colorado 80262
Telephone: (303) 270-7960

Dates: June 22-23, 1990 (originally scheduled for May 14-15, 1990)

Title: "NIH/FDA Regional Human Subjects Protections Workshop"

Contact: University of Washington
Continuing Medical Education
Washington Building, Suite 2000
1325 4th Avenue
Seattle, Washington 98101
Telephone: (206) 543-1050

Dates: July 19-20, 1990

Title: "NIH/FDA Regional Human Subjects Protections Workshop"

Contact: Ms. Leigh Tenkku
Assistant Director of Research Administration
Jewish Hospital of St. Louis
216 South Kings Highway
St. Louis, Missouri 63110
Telephone: (314) 454-8322

NIH/FDA have planned human subjects regional workshops in other parts of the United States. For further information regarding these workshops contact:

Darlene Marie Ross
Education Program Coordinator
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B62
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-8101

DATED ANNOUNCEMENTS (RFPs AND RFAs)

EXPLORATORY CENTER GRANT ON THE HEALTH AND EFFECTIVE FUNCTIONING OF OLDER RURAL POPULATIONS

RFA AVAILABLE: AG-90-01

P.T. 04; K.W. 0710010, 0404000, 0414000, 0730000

National Institute on Aging

Application Receipt Date: March 20, 1990

The National Institute on Aging (NIA) invites Exploratory Center Grant applications (P20) to establish a coordinated, multidisciplinary research environment on social, economic, psychological, environmental, and biomedical factors affecting the health, effective functioning, and related aging processes of older people in rural areas. Recent governmental and non-governmental reports highlight the special health-care and other service needs of rural people and especially the needs of those who are old. People in rural areas are more likely than their urban counterparts to be in fair or poor health, to suffer from chronic or serious illness, and to be without a regular source of health care and health insurance. Moreover, a higher proportion of deaths occur among the nonmetropolitan than the metropolitan population over 65 years of age. The U.S. Congress has called for a center in order to improve the knowledge base necessary for the promotion of health and the prevention of disease among rural older people and to develop and implement effective, acceptable, and accessible health care and other services.

Although many research topics are worthy of consideration, NIA consultants and staff have identified five as requiring special attention: A) The changing sociodemographic and epidemiologic characteristics of the older rural population, B) the occupational and physiochemical environment, C) the population aging of rural communities (including the infrastructure of families, churches and other social organizations), D) the availability, utilization, and quality of health-care and other services, and E) aging rural people as resources. Applications should propose activities relevant to at least two of these broad topics.

This Request for Applications (RFA) follows the Bureau of the Census' definitions of "rural vs. urban", "metropolitan vs. nonmetropolitan", and "farm vs. nonfarm". It recognizes that "rural" and "nonmetropolitan" are not synonymous with "agriculture" and that appropriate research populations include people living in small towns engaged in nonagricultural occupations. Proposed investigations should include minorities and women in the study populations for research.

The support mechanism for this RFA is the Exploratory Center Grant (P20). This grant mechanism consists of: (A) an administrative and planning component providing administrative, coordinating, research planning, logistical, and/or methodological support; and (B) small scale studies. NIA intends that the majority of funds under this RFA be devoted to the small scale studies. Consequently the Administrative and Planning Core should not exceed 45 percent of the amount requested.

The initial award period is for three years and may not be extended. Institutions are eligible to apply if they have at least (A) two principal investigators with any PHS agency or comparable peer-reviewed research project (R01) grants and/or (B) one program project (P01) grant that are currently active or that were awarded during the 2 years prior to submitting an application under this RFA. These grants must be on aging and/or rural research topics related or similar to those described above.

Subject to the availability of funds, the NIA anticipates making 2 awards under this RFA. The maximum amount per award will be $250,000 (direct and indirect costs) per year. In order to obtain a copy of the complete RFA and the NIA Guidelines for Exploratory Center Grants as well as to discuss the suitability of the grant application, contact:

Ronald P. Abeles, Ph.D.
Behavioral and Social Research
National Institute on Aging
Building 31C, Room 5C32
Bethesda, Maryland 20892
Telephone: (301) 496-3136

NATIONAL MULTI-PURPOSE RESEARCH AND TRAINING CENTER

RFA AVAILABLE: DC-90-01

P.T. 04, 44; K.W. 0710030, 0720005, 0715050, 0715055, 0785035

National Institute on Deafness and Other Communication Disorders

Application Receipt Date: March 22, 1990

PURPOSE

The National Institute on Deafness and Other Communication Disorders (NIDCD) announces its intent to designate and support a limited number of National Multi-purpose Research and Training Centers (RTC) for the multi-disciplinary study of communication sciences and disorders. The goal of the RTC is the support of basic and clinical research; research training; continuing education for health professionals; and dissemination of information to the general public, in one of the program areas of the institute.

A National Research and Training Center is a national resource and is dedicated to working with the NIDCD in furthering the goals of the Institute, through a multi-disciplinary, coordinated approach involving laboratory and clinical research, research training and an outreach program of education for health care professionals and the public. An RTC may focus on one or more of the major program areas of the Institute (hearing and balance; speech, voice and language; or taste and smell; and other disciplines related to these areas) but each of the components must relate to the central theme including the research training and education components. All of the components must be of high quality and meet the standards of excellence of biomedical research.

BACKGROUND

In 1988, Congress established the National Institute on Deafness and Other Communication Disorders, Public Law 100-553, which mandated that "the Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing Centers for studies of disorders of hearing and other communication processes...."

The law further specified that each Center shall conduct--

"(1) basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;

"(2) training programs for physicians, scientists, and other health and allied health professionals;

"(3) information and continuing education programs for physicians and other allied health professionals who will provide care for patients with disorders of hearing and or other communication processes; and

"(4) programs for the dissemination to the general public of information--

"(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of following an appropriate regimen; and

"(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes...."

In January 1989, over 100 U.S. scientists representing various specialties in the communication sciences, met to develop a research plan for the NIDCD. These scientists addressed the issue of the National Multi-purpose Research and Training Centers. With the Congressional mandate providing guidance, the Task Force identified and expanded on the critical features of such Centers, that is, research, training, continuing education, and information dissemination.

Plans for inclusion of underrepresented minorities, women, and individuals with disabilities must be included within this component of the application.

The Purpose of this Request for Applications (RFA) is to implement the Congressional mandate and the recommendations of the Task Force regarding the establishment of these National Multi-purpose Research and Training Centers.

MECHANISM, NUMBER OF YEARS, AND BUDGET

National Multi-purpose Research and Training Centers will be funded through the Center grant mechanism (P60). Up to seven (7) years of support may be requested at an annual direct cost not to exceed 1.5 million dollars per annum. Budget increments in subsequent years will be limited to necessary cost-of-living increases.

METHOD OF APPLYING

Potential applicants may request additional information, copies of the complete RFA, and guidelines for preparing an application from:

Dr. Ralph F. Naunton
Director, Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
National Institutes of Health
Federal Building, Room 1C-11
7550 Wisconsin Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-1804

Letters of Intent will be due (optional):	February 15, 1990
Application Due:	March 22, 1990
Awards:	September 1990

OBESITY RESEARCH CENTER (CORE CENTER) GRANT

RFA AVAILABLE: 90-DK-03

P.T. 04; K.W. 0715145, 0710095, 0710030

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: January 15, 1990
Application Receipt Date: March 30, 1990

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for an obesity research center (core center) to be awarded in Fiscal Year 1991. The award of one obesity research core center is anticipated in Fiscal Year 1991.

An obesity research center provides for an integrated array of research, educational and service activities that is oriented towards obesity and related eating disorders. The research core center grant is awarded to facilitate the planning and coordination of these research activities primarily by providing funding for core facilities and associated staff that serve the various projects of the obesity research center on a shared basis.

The Core Center mechanism builds upon an established base of already funded research excellence which emphasizes common themes or foci. The Core Center grant may provide funds for: (1) core units such as body composition analyses, lipid analyses or cell culture; (2) pilot/feasibility projects which encourage new investigators to pursue new innovative ideas to a point where they can compete for independent support; (3) temporary salary support to one new named investigator, usually for 24 months, in specified areas of research complementary to ongoing activities; (4) program enrichment funds.

The objectives of the Core Center are to encourage a multidisciplinary approach to research in obesity and to bring together, on a cooperative basis, clinical and basic science investigators in a manner which will enhance and extend the effectiveness of research being conducted in the field of obesity.

An average Center may include about 5 to 7 pilot/feasibility projects and 4-6 core units with a direct cost of approximately $500,000. However, the actual cost of the Center will vary depending on the needs of the Center. In no case shall direct costs requested exceed $700,000. The anticipated award(s) will be for 5 years and is contingent upon the availability of appropriated funds. Currently, funds totalling approximately 1.0 million dollars are available for support of applications responsive to this announcement.

Potential applicants are urged to submit a letter of intent that provides a descriptive title, names of key investigators involved and other institutions participating in their application. The letter of intent, which is non-binding and is not a precondition for an award, should be submitted by January 15, 1990, to Dr. Hubbard at the address below. In addition, the general description of a Core Center, copies of Core Center Guidelines, a more detailed Request for Applications (RFA) and consultation may be obtained from:

Van S. Hubbard, M.D., Ph.D.
Director, Clinical Nutrition Research Units Program
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A18B
5333 Westbard Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-7823

Applications for the Obesity Research Core Center grant will be evaluated in a national competition by the NIH grant peer review process. The receipt of one competing continuation application is anticipated. Applications will be reviewed initially by a special review committee convened by the NIDDK and subsequently by the National Diabetes and Digestive and Kidney Diseases Advisory Council. The special single receipt date for submissions in response to this announcement is March 30, 1990 with earliest funding December 1990. Applications are unlikely to be reviewed by a site visit team; therefore, the written application should be complete so as to facilitate review without a site visit. Extensive additional material submitted subsequent to the stated receipt date will not be accepted.

When human subjects are to be included within investigations responsive to this announcement, inclusion of women and minorities is encouraged. If they are excluded, reasons for this exclusion must be explained in the application.

Complete line 2 of the application face page of the PHS 398 (rev. 10/88) by typing in "OBESITY RESEARCH CENTER, RFA 90-DK-03." The RFA label (found in the 10/88 revision of application form PHS 398) must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review.

Two copies of the application are to be sent to:

Review Branch
NIDDK
5333 Westbard Avenue
Westwood Building, Room 406
Bethesda, Maryland 20892

Four copies of the application are to be sent to the address on the mailing label in the application kit.

CORE GRANTS FOR CLINICAL NUTRITION RESEARCH UNITS

RFA AVAILABLE: 90-DK-02

P.T. 04; K.W. 0710095, 0720005, 0710030, 0785035

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Aging

Letter of Intent Receipt Date: January 15, 1990
Application Receipt Date: March 30, 1990

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute on Aging (NIA) invite applications for Clinical Nutrition Research Unit (CNRU) grants to be awarded in Fiscal Year 1991. The award of two CNRU grants is anticipated in Fiscal Year 1991.

A CNRU is an integrated array of research, educational, and service activities that is oriented toward human nutrition in health and disease. A research core center grant is awarded to facilitate the planning and coordination of the activities of the CNRU primarily by providing funding for core facilities and associated staff that serve the various projects of the CNRU on a shared basis.

ESSENTIAL COMPONENTS OF A CNRU

A CNRU, at a minimum, must comprise the following seven components which also should have other sources of support such as a regular NIH research grant (R01), NIH FIRST Award (R29), NIH Program Project (P01), NIH Individual Fellowship (F32), and the NIH Institutional National Research Service Award (T32) or other Federal and non-federal sources:

1. Research with human subjects and populations;

2. Laboratory investigations;

3. Research training (funds to be derived from other sources*);

4. Shared facilities and research services;

5. Education programs for medical students, house staff, practicing physicians, and allied health personnel (funds to be derived from other sources*);

6. Research components of nutritional support services; and

7. Public information activities (funds to be derived from other sources*).

* Funds to support these components may not be requested as part of an application in response to this announcement.

An average Center may include about 5 to 7 pilot/feasibility projects and 4-6 core units with a direct cost of approximately $500,000. However, the actual cost of the Center will vary depending on the needs of the Center. In no case shall direct costs requested exceed $700,000. The anticipated award(s) will be for 5 years and is contingent upon the availability of appropriated funds. Currently, funds totalling approximately $1.1 million are available for

support of applications responsive to this announcement. It is expected that two awards of comparable size will be made.

When human subjects are to be included within investigations responsive to this announcement, inclusion of women and minorities is encouraged. If they are excluded, reasons for this exclusion must be explained in the application.

Potential applicants are urged to submit a letter of intent that provides a descriptive title, names of key investigators involved and other participating institutions regarding their application. The letter of intent, which is non-binding and is not a precondition for an award, should be submitted by January 15, 1990 to Dr. Hubbard at the address below. In addition, the general description of a Core Center, copies of Core Center Guidelines, the full Request for Applications (RFA) and consultation may be obtained from:

Van S. Hubbard, M.D., Ph.D.
Director, Clinical Nutrition
Research Units
Westwood Building, Room 3A18B
5333 Westbard Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-7823

For information concerning NIA research research interests in nutrition contact:

Ann Sorenson, Ph.D.
Program Director for the
NIA Nutrition Program
Building 31, Room 5C-21
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-1033

Applications for the CNRU Core Center grant will be evaluated in a national competition by the NIH grant peer review process. The receipt of two competing continuation applications is anticipated. Applications will be reviewed initially by a special review committee convened by the NIDDK and subsequently by the National Diabetes and Digestive and Kidney Diseases Advisory Council and/or the National Advisory Council on Aging. The special single receipt date for submissions in response to this announcement is March 30, 1990 with earliest funding December 1990. Applications are unlikely to be reviewed by a site visit team; therefore, the written application should be complete so as to facilitate review without a site visit. Extensive additional material submitted subsequent to the stated receipt date will not be accepted.

Complete line 2 of the application face page (PHS 398, rev. 10/88) by typing in "CORE GRANTS FOR CLINICAL NUTRITION RESEARCH UNITS, RFA 90-DK-02." The RFA label available in the 10/88 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review.

Two copies of the application are to be sent to:

Review Branch
NIDDK
5333 Westbard Avenue
Westwood Building, Room 406
Bethesda, Maryland 20892

Four copies of the application are to be sent to the address on the mailing label in the application kit.

AVAILABILITY OF INDIVIDUAL POSTDOCTORAL FELLOWSHIPS IN GENOMIC ANALYSIS AND TECHNOLOGY

P.T. 22; K.W. 1215018, 1002058, 0755045, 0755018

National Center for Human Genome Research

Application Receipt Dates: January 10, May 10, September 10

The mission of the National Center for Human Genome Research (NCHGR) is to characterize the human genome and the genomes of selected model organisms. The research program has the following interrelated goals: the construction of high resolution genetic linkage maps; the development of a variety of physical maps; the determination of the complete nucleotide sequence of the DNA of human and other selected model organisms; the development of the capability for collecting, storing, distributing, and analyzing the data produced; and the development of appropriate new technologies to achieve these goals.

To accomplish the goals of the research program and to use, for further research, the resources that the program will develop, scientists who are well trained in one or more of a variety of disciplines will be needed. Therefore, the NCHGR is offering individual postdoctoral fellowships to highly qualified scientists who are seeking training that will enable them to engage in research relevant to the genome project. Candidates for these fellowships include biologists who wish to obtain training in genomic research. The NCHGR also is interested in offering fellowships to scientists who wish to obtain interdisciplinary training, such as those who wish to integrate mathematical, physical, chemical, engineering, and/or computer scientific approaches with those of molecular biology and genetics. The goal of the fellowship program is to train highly skilled scientists who will use their skills to develop research programs in the mapping and sequencing of the human genome and the genomes of other organisms, in the analysis of the resulting data, and in the development of biological, medical or biotechnological applications based on the data.

Support for fellowships will be provided through the National Research Service Award (NRSA). The stipend levels for the individual postdoctoral fellowships range from $17,000 to $31,000, depending on the number of years of relevant experience subsequent to the award of the doctoral degree. In addition, the training institution may request an institutional allowance of up to $3,000 per year for supplies, equipment, travel, tuition, fees, insurance, and other training-related expenses. Individual postdoctoral fellowships are made for project periods of up to 3 years. The Center plans to support about 50 individual postdoctoral fellowships in fiscal year 1990, which runs from October 1, 1989 to September 30, 1990.

Recipients of National Research Service Awards are subject to payback provisions. Details about this requirement and the policies governing this program can be found in the National Research Service Awards Guidelines, which were published in the NIH Guide to Grants and Contracts, Vol. 13, No.1, January 6, 1984. Single copies are also available from this office.

Application kits are available from the university business office or from the Office of Grants Inquiries; Division of Research Grants; Westwood Building, Room 449; National Institutes of Health, Bethesda, Maryland 20892.

Receipt dates for applications are January 10, May 10, and September 10 annually. The earliest dates that awards can be made are July, December, and March, respectively.

For additional information about individual postdoctoral fellowship opportunities available through the NCHGR, please contact:

Bettie J. Graham, Ph.D.
Building 38A, Room 613
National Center for Human Genome Research
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7531

NOTE: This is an expanded version of an announcement that appeared in the NIH Guide to Grants and Contracts, Vol. 18, No. 25, July 21, 1989.

THE NCI OUTSTANDING INVESTIGATOR AWARD

P.T. 34; K.W. 0715035, 0710030, 1014006

National Cancer Institute

Application Receipt Date: April 2

SUMMARY AND PURPOSE

The National Cancer Institute (NCI) will continue to accept new applications for the Outstanding Investigator Grant (OIG), as well as competing continuation applications from currently funded OIG recipients in the fifth year of the initial award period. The purpose of the OIG is to encourage investigators to continue or embark on projects of unusual potential in cancer research. Emphasis will be placed on evidence of recent substantive contributions (i.e., seminal ideas and innovative approaches to resistent problems) and the potential for continued work of high caliber.

Special features of the OIG include: (1) seven-year project periods for new and competing continuation awards and (2) alleviation of the need to manage more than one grant instrument through consolidation of the OIG principal investigator's (PI's) current cancer-related peer reviewed support.

ELIGIBILITY

Applications may be submitted only by domestic institutions on behalf of investigators who have recently demonstrated outstanding research productivity for at least five years. There are no age restrictions. Only United States citizens, nationals or permanent residents are eligible for this grant.

Applications will be accepted by the NCI only when they are cancer-related as defined by the Division of Research Grants (DRG) grant referral guidelines. Investigators whose current research support is derived predominantly from sources other than the NCI may not be eligible and are encouraged to discuss their research objectives with appropriate NCI officials before applying.

The OIG PI is required to commit 75 percent of his/her time/effort to the OIG project, and the institution sponsoring the OIG application is required to commit itself to providing 25 percent of the investigator's salary support.

Applications which do not meet all of the above eligibility criteria or which have not had approval from the NCI for exceptions to the above criteria will be returned to the applicant.

HOW TO APPLY

o The receipt date for all OIG applications, including competing continuation applications, will be April 2 instead of June 15 of each year. They will be processed for review at the earliest possible meeting of the NCAB.

o Application for this award should be made on form PHS 398 (revised 10/88) in accordance with instructions in this Announcement. These application forms are available in the business or contracts offices at most academic or research institutions, or from:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, Maryland 20892

o The title "NCI OUTSTANDING INVESTIGATOR GRANTS" should be typed in section 2 on the first page of the application.

o A letter indicating clear and continuing institutional commitment to the applicant must either accompany the application or be received separately before the NCI will begin the initial review process.

INQUIRES

All potential applicants for this award are advised that the full text of this Program Announcement, containing currently applicable guidelines, will be available after January 1, 1990 and should be requested prior to submitting an application for the April 2, 1990 receipt date.

Please direct inquiries for further information and for copies of the full announcement to:

Mrs. Barbara S. Bynum
Director, Division of Extramural Activities
National Cancer Institute
Building 31, Room 10A03
Bethesda, Maryland 20892
Telephone: (301) 496-5147

NEONATAL NURSING CARE OF LOW BIRTHWEIGHT INFANTS

P.T. 34; K.W. 0730005, 0403020, 0775015, 0715165

National Center for Nursing Research
National Institute of Child Health and Human Development

PURPOSE

This program announcement (PA) invites applications for research grants to study optimal physical care practices of hospitalized low birthweight (LBW) infants (<2500 grams). Of particular importance are basic science and clinical studies related to issues of infant feeding, respiratory support, physical positioning, and skin care and the underlying explanatory mechanisms. Studies need to show evidence of interdisciplinary research teams.

SCIENTIFIC BACKGROUND

LBW is a major cause of infant mortality and morbidity in the United States. Although the U.S. neonatal mortality rate has decreased in the past 15 years, currently 6.8 percent of all live births are LBW. LBW infants contribute disproportionately to the morbidity rates; infants <1500 grams comprise less than 1 percent of all singleton live births but account for almost 40 percent of all infant deaths. Neonatal intensive care units (NICUs) are an important factor in the survival of these infants. A major problem in neonatal clinical practice is the balance between prompt implementation of new technologies, procedures, and treatments and the demonstration of their safety and efficacy. Because of the urgent care needs of the NICU, many neonatal care modalities have not been evaluated scientifically. The purpose of this PA is to promote research which will increase the theoretical and empirical data base for the management of LBW infants.

Issues Related to Feeding

Nutrition represents a critical requirement for LBW infant survival. Clinical research on sucking and the management of enteral feeding and the infant's response to enteral feeding will provide opportunities to improve the physiological and behavioral outcome of LBW infants.

Enteral Feeding:

Enteral feeding is physiologically stressful for infants, particularly the LBW infant who has not mastered coordination of suck and swallow. Among the significant risks of enteral feeding in the LBW infant are apnea and bradycardia, hypoxia, gastroesophageal reflux, aspiration, and necrotizing enterocolitis. Optimal methods do not exist for monitoring these risks. There is also wide variability in clinical practice in the introduction and advancement of enteral feeds, procedures for administration of tube feedings, and methods of monitoring infant responses to feeding. Major basic and clinical research areas in the area of enteral feedings include the following:

(1) methods for determining feeding readiness
(2) advantages and disadvantages of gavage vs jejunal tube feeding
(3) advantages and disadvantages of continuous infusion vs intermittent bolus feeding
(4) optimal advancement schedules for enteral feeding
(5) interventions to decrease harmful physiological alterations induced by enteral feeding.

Nutritive Sucking:

Although sucking can be demonstrated as early as 11 weeks, the development of coordination of suck/swallow and respiration (which allows oral feeding) is thought to occur after 34 weeks postconception. Although the sucking reflex is present in extremely immature infants and the pressure/volume feeding curves of some large premature infants seem to be quite efficient, little is known about the effect of oral feeding experience on the development of mature

coordination of suck/swallow and respiration. The reflex can be extinguished by the lack of oral feeding experience, i.e. prolonged deprivation secondary to intubation. Sweetness of the feeding and volume delivered are also known to influence sucking; however, little is known about the effect of nipple shape, size, and rigidity. Interdisciplinary collaboration with nurses, neonatologists, biomedical engineers, nutritionists, and child development specialists are encouraged. Research areas of interest include but are not limited to the following:

(1) Methods of assessing feeding readiness
(2) Desirability of feeding on schedule vs "on cue"
(3) Methods and oral feeding devices to facilitate oral feeding in LBW infants
(4) Assessment of the effects of maturity vs experience on the development of feeding-respiratory coordination.

Non-nutritive Sucking:

Non-nutritive sucking, or the use of a pacifier, can be provided to LBW infants before the introduction of oral feeding. It has been associated with improved gastrointestinal motility and weight gain. Research in progress is designed to test the effect of non-nutritive sucking on behavioral organization, oxygenation, and fat absorption of LBW infants. Further studies are needed to evaluate the optimal design of pacifiers and the effect of non-nutritive sucking on physiologic function.

Issues Related to Respiratory Care

Many LBW infants require respiratory support, including ventilation, constant positive airway pressure, and oxygen administration. Research is needed to design respiratory equipment and techniques that will assure infant safety and minimize complications. Areas of interest include the following:

(1) development of a system to secure endotracheal tubes and nasal prongs that will minimize skin trauma and restraint of the infant

(2) demonstration of a system of endotracheal suctioning that minimizes hypoxia, decreased ventilation, tracheal trauma, and bacterial colonization

(3) demonstration of the risks and benefits of chest physical therapy (chest wall percussion and vibration and postural drainage)

Issues Related to Skin Care

LBW infants have poorly keratinized skin that is prone to significant injury with relatively minor trauma (alcohol and electrode burns, epidermal stripping with tape removal, and skin breakdown at flexion sites). Consequences include increased vulnerability to infection and pressure necrosis, the absorption of substances applied to the skin surface, and high insensible water losses. Methods used to minimize these problems have included covering of the infant with plastic sheeting and application of various types of protective surfaces to the skin. Additional studies are needed to identify basic science concepts and clinical treatment methods for the protection and care of the skin of LBW infants.

Issues Related to Physical Positioning

Positioning and restraint of an infant can affect the shape of the head and face, intracranial pressure, body alignment, and muscle tone. Oxygenation, energy expenditure, and state regulation are also influenced by position. For example, studies to investigate ways to appropriately conserve energy expenditure during body positioning are needed. A systematic description of the effects of minimal-restraint positioning on LBW development is needed.

PROGRAMMATIC BACKGROUND

This initiative was developed to study nursing practices in the neonatal nursery that impact on the care of LBW infants. Meetings of priority expert panels have defined gaps in existing knowledge related to care of LBW infants and identified several research opportunities. These opportunities exist in three major areas: prenatal care to prevent LBW, neonatal care to support the LBW infant and prevent further complications, and follow-up care to the infant and family after discharge. Interdisciplinary studies with significant sample size are encouraged. While this initiative is focused on the physical care given to LBW infants in the NICU, subsequent initiatives will address related areas of research on LBW.

MECHANISM OF SUPPORT

All policies and requirements that normally govern the grant programs of the Public Health Service apply.

APPLICATION PROCEDURES AND REVIEW CRITERIA

Applications should be submitted on the standard PHS form 398 (rev. 10/88). Application forms are available at most institutional business offices or from the Division of Research Grants, NIH, telephone (301) 496-7441. In order to expedite the application routing within NIH, please (1) check the box #2 on the face page indicating that your application is in response to this announcement and (2) print (next to the checked box) "Neonatal Nursing Care of Low Birthweight (LBW) Infants." Mail the completed application and six copies to:

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

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

Applications will be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Secondary review will be by the corresponding National Advisory Council.

Applications compete on the basis of scientific merit with all other applications. Researchers considering an application in response to this announcement are encouraged to discuss their project, and the range of grant mechanisms available, with staff in advance of formal submission.

Investigators should be aware that NIH urges applicants for grants to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations. If minorities are not included in a given study, a clear rationale for their exclusion should be provided. Merely including an arbitrary number of minority group participants in a given study is insufficient to guarantee generalization of results.

Correspondence and inquiries should be directed to:

Dr. Moira Shannon
Health Promotion and Disease Prevention Branch
National Center for Nursing Research
Building 31, Room 5B09
Bethesda, Maryland 20892
Telephone: (301) 496-0523

or

Dr. Linda Wright
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North
6130/6120 Executive Boulevard
Rockville, Maryland 20892
Telephone: (301) 496-5575

**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:

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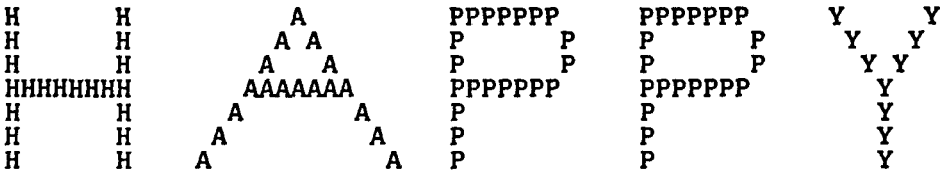
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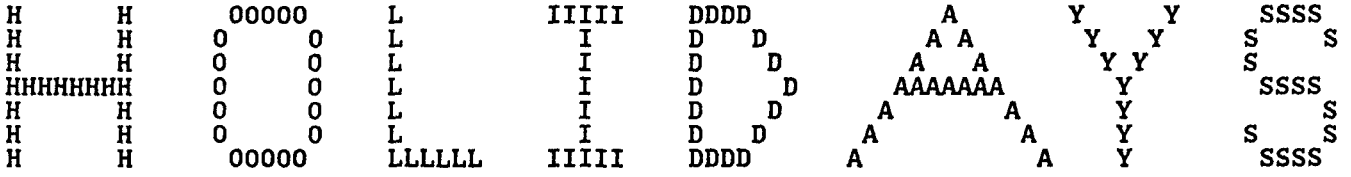
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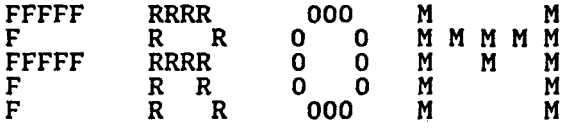
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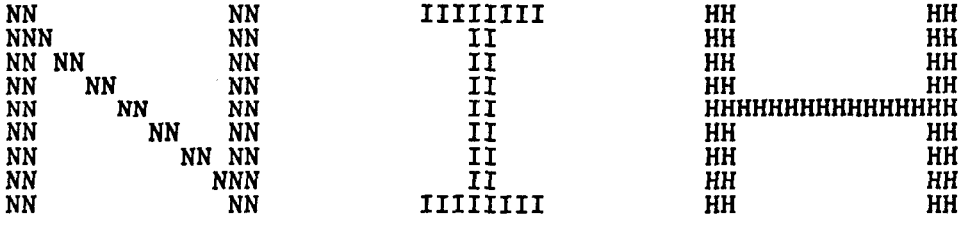
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