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For Grants and Contracts

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The NIH Guide announces scientific
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mural programs administered by the
National Institutes of Health.

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NOTICES

NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN IN STUDY POPULATIONS

P.T. 34, II; K.W. 1014002, 1014006

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

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) recognize that most researchers adequately and appropriately consider gender representation in clinical research design. Nevertheless, the following statement is published as a reiteration and further interpretation of the existing NIH/ADAMHA policy concerning inclusion of women in study populations. Clinical research findings should be of benefit to all persons at risk of the disease, regardless of gender. This policy was previously published in the NIH Guide for Grants and Contracts on October 24, 1986; January 23, 1987; March 27, 1987; January 15, 1988; and June 16, 1989. For the purpose of this policy, clinical research includes human studies of etiology, treatment, diagnosis, prevention, and epidemiology of disease, including but not limited to clinical trials. While this policy statement refers to inclusion of women, applicants are strongly reminded that a similar policy exists regarding the inclusion of minorities (NIH Guide for Grants and Contracts - September 25, 1987; January 15, 1988; and June 16, 1989). Both policies must be considered when preparing clinical research applications/proposals for submission to the NIH/ADAMHA.

Public concern requires that clinical studies include both genders in such a way that results are applicable to the general population; exceptions would be those diseases or conditions that occur only in one gender. Therefore, applications/proposals for NIH/ADAMHA support of clinical research should employ a study design with gender representation appropriate to the known incidence/prevalence of the disease or condition being studied. If inclusion of women 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, these reasons for excluding women or men must be well explained and justified by the applicant. Similar justification is required if women will not be included in numbers appropriate to the incidence/prevalence of the disease.

In conducting peer review for scientific and technical merit, members of Initial Review Groups (IRGs)/Technical Evaluation Groups (TEGs) will be

instructed to evaluate the proposed gender composition of the study population.

- 1) If there is an inadequate number of women in a study design AND this affects the potential to answer the scientific question(s) addressed, that will be considered a weakness or deficiency in the study design and should be reflected in the assigned score given to the application/proposal, and in the summary statement of the review.
- 2) If an applicant proposes that there is justification for conducting a study in men only, or in a study population in which the proportion of women does not reflect the gender prevalence of the disease or condition under study, a strong scientific rationale, an explanation of the need to protect the health of the subjects, or other well-supported justification must be provided. The IRG/TEG will be instructed to evaluate the merit of such justifications. Appropriate justification will not adversely affect the assigned score. The NIH/ADAMHA will not fund such applications/proposals unless the justification provided is compelling.
- 3) If the gender composition of the study population is not described, BUT the study otherwise has the potential to answer the scientific question(s) posed and translate the findings to all persons at risk of the disease, the omission will be documented by the Executive Secretary of the IRG/TEG in an administrative note, and will not adversely affect the scientific assessment and the assigned score. If there is inadequate information on the study population to allow evaluation of the scientific question(s), the review may be deferred. The NIH/ADAMHA funding components will not fund/award grants or contracts until the applicant provides sufficient information on the study population to assure compliance with the NIH/ADAMHA policy on inclusion of women in study populations.

Since the need to modify sample design could delay award and affect the costs of the study, applicants are strongly advised to address this issue in the initial submission. If costs or study designs are significantly affected by such modification, submission of an amended application/proposal for IRG/TEG review and/or reconsideration by the appropriate National Advisory Council or Board may be necessary.

Whenever there are scientific reasons to anticipate differences between men and women with regard to the hypothesis under investigation, applicants should consider the inclusion of an evaluation of gender differences in the proposed study. However, if men and women are enrolled in numbers that reflect the gender proportion of the disease under study, it is not an automatic requirement for the study design to include statistical power for men and women separately.

It is important to note that regardless of the program relevance of the proposed research, the NIH/ADAMHA funding components will not fund/award grants or contracts that do not comply with this policy.

ADAMHA/NIH POLICY CONCERNING INCLUSION OF MINORITIES IN STUDY POPULATIONS

P.T. 34, FF; K.W. 1014002, 1014006

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

There are clear scientific and public health reasons for specifically including members of minority groups in study populations. Accordingly, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and the National Institutes of Health (NIH) require that applications/proposals for clinical research must give appropriate attention to inclusion of minorities in study populations, unless compelling scientific or other justification for not including minorities is provided. For the purpose of this policy, minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics), and clinical research includes human studies of etiology, treatment, diagnosis, prevention, and epidemiology of diseases, disorders and conditions, including but not limited to clinical trials and research on health service and its impact on disease. Grants, cooperative agreements, and contracts are covered by this policy.

This statement is published as a reiteration and further interpretation of the existing ADAMHA/NIH policy concerning inclusion of minorities in study populations. This policy was previously published in the NIH Guide for Grants and Contracts on September 25, 1987, Vol. 16, No. 32; January 15, 1988, Vol. 17, No. 2; and June 16, 1989, Vol. 18, No. 21. While the focus of this policy is on inclusion of minorities in general population studies, ADAMHA and NIH also encourage attention to gaps in knowledge about specific U.S. racial/ethnic minorities and health problems that significantly affect them. Examples of these problems include but are not limited to: cancer, substance abuse, heart disease and stroke, homicide and accidents, diabetes, infant mortality, and acquired immunodeficiency syndrome (AIDS). Addressing these gaps may be appropriate justification for focusing a particular study on a single racial/ethnic group.

While this policy statement refers to inclusion of minorities, applicants are strongly reminded that a similar policy exists regarding women (NIH Guide for Grants and Contracts - October 24, 1986, Vol. 15, No. 22; January 23, 1987, Vol. 16, No. 3; January 15, 1988, Vol. 17, No. 2; June 16, 1989, Vol. 18, No. 21; and August 24, 1990, Vol. 19, No. 31). Both policies must be considered when preparing research applicants/proposals for submission to ADAMHA/NIH.

Applicants for grants/cooperative agreements and offerors for contracts should be aware that in attempting to include minority groups in a particular study, attention must be paid to research design and sample size issues. ADAMHA and NIH recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

In all applications or proposals for clinical research, applicants must describe the anticipated race/ethnic composition of the study population. In conducting peer review for scientific and technical merit, members of Initial Review Groups (IRGs)/Technical Review Groups (TEGs) will be instructed to evaluate the appropriateness of the proposed minority composition:

- 1) If there is insufficient attention to inclusion of minorities in a study design AND this affects the potential to answer the scientific question(s) addressed, that will be considered a weakness or deficiency and must be reflected in the assigned score given to the application/proposal, and in the summary statement of the review.
- 2) However, if an applicant proposes that there is justification for conducting a study where there will be limited minority participation or inclusion of only one racial/ethnic group, a strong scientific rationale or other well-supported justification must be provided. The IRG/TEG will be instructed to evaluate the merit of such justifications. Appropriate justification will not adversely affect the assigned score. The ADAMHA/NIH will not fund/award such applications unless the justification is compelling.
- 3) For grant and cooperative agreement applications, if there is inadequate information on the study population to allow evaluation of the scientific question(s), the review will be deferred or the application returned.

It is important to note that the ADAMHA/NIH funding components will not fund/award grants, cooperative agreement, or contracts that do not comply with this policy.

REMINDER: 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

As stated in the NIH Guide for Grants and Contracts, Vol. 18, No. 45, December 22, 1989, administrative guidelines for the National Research Service Award (NRSA) institutional training grant applications submitted to the National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) have been revised "to require that a program in the principles of scientific integrity be an integral part of the proposed research training effort". This requirement applies to all competing training

grant applications received after July 1, 1990. The principal goal of the NRSA grant mechanisms is to train scientists for future careers in biomedical and behavioral research. An important factor in biomedical and behavioral research is the need to maintain the highest levels of integrity in the conduct of research. The research training environment in the university setting provides a powerful context in which to promote responsible research practices.

NIH and ADAMHA recognize that the scientific community is at an early stage of developing information and methods that pertain specifically to training in research ethics for trainees. Not all methods will work in all training situations given the heterogeneity among disciplines and professions. There are many models and paradigms. Appreciation of the heterogeneity among the biomedical and behavioral research components within the institutions calls for flexibility in approaches to effective education and training models.

Institutions must accept primary responsibility and be allowed to develop their own ways of promoting responsible conduct of research in conjunction with their training programs. Scientific and administrative leaders of the university or from outside (as consultants or speakers) could be a visible part of this effort. Applicants are urged to discuss the development of methods on this important topic with their colleagues and also look to the professional associations for guidance as well as discussions with NIH and ADAMHA staff.

An array of methods might be used at various training levels. It was stated in the NIH Guide for Grants and Contracts, December 22, 1989 notice:

"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."

For the first 18 months of implementation of this requirement, it is expected that institutions will be given considerable flexibility in order to encourage innovation in the development of methods for providing training in scientific integrity. However, descriptions of formal or informal activities related to incorporation of efforts relevant to the responsible conduct of research (i.e., "the plan") should be explicit as possible (e.g., topics to be covered; faculty that may be involved; format; schedule, etc.). No application will be awarded until a description of the institution's plan to provide instruction on ethics in research and research training is furnished.

NATIONAL WORKSHOPS ON THE 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 sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings may 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 all other Public Health Service agencies. The current schedule includes the following:

NORTH MIDWESTERN WORKSHOP

DATES: October 17 and 18, 1991

WORKSHOP SITE: Detroit, MI

SPONSORS:

Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

Wayne State University
4237 Scott Hall
Detroit, MI 48201

REGISTRATION CONTACT:
Mr. Jerome Wilczynski
Vice President for Operations
Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201
Telephone: (313) 745-5450

TOPIC: The Vulnerable Patient As A Research Subject

WEST COAST WORKSHOP

DATES: December 5 and 6, 1991

WORKSHOP SITE: Los Angeles, CA

SPONSORS:
University of Southern California
Los Angeles, CA 90089-4014

California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202

REGISTRATION CONTACT:
Ms. Lily Patterson
Assistant to the Director
Research and Sponsored Programs
California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202
Telephone: (213) 343-3820

TOPIC: Protection of Human Subjects

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:
Ms. Angie Khan
Institutional Coordinator of Research Review
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Protection of Human Subjects

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:
University of Pennsylvania
133 South 36th Street
Suite 300
Philadelphia, PA 19104-3246

Lincoln University
Lincoln University, PA 19352

REGISTRATION CONTACT:
Ms. Lynn Bevan
Assistant Director
Office of Research Administration
University of Pennsylvania
133 South 36th Street
Suite 300
Philadelphia, PA 19104-3246
Telephone: (215) 898-2614

TOPIC: Protection of Human Subjects

For further information regarding these workshops or future NIH/FDA National Workshops on the Protection of Human Subjects, please contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

DEVELOPMENT AND PRODUCTION OF PARENTERAL DOSAGE FORMS FOR CLINICAL STUDIES

RFP AVAILABLE: NCI-CM-27724-71

P.T. 34; K.W. 0740021, 0715008, 0715035

National Cancer Institute

The primary objective of this project is to develop and produce pharmaceutically acceptable parenteral dosage forms of promising new agents with activity against cancer or the HIV virus. Certain agents selected by the National Cancer Institute (NCI), Division of Cancer Treatment, Cancer and AIDS operating committees will be assigned for development and production as parenteral products (primarily sterile freeze dried products). Batch sizes will range from small developmental batches (less than 100) to intermediate size batches to be used in Phase I and II trials; however, escalation to large batch size (10-30,000 or more) for Phase III/IV trials and Group C distribution is possible. It is estimated that the successful offerors must be prepared to supply more than five-hundred thousand parenteral dosage units each year. The capability to develop and manufacture other pharmaceutical dosage form (e.g., large volume parenterals, sterile emulsions, sterile micro-dispersions) is desirable but not essential. Data obtained from the contract will: (1) be used to support IND applications submitted by the NCI to the U.S. Food and Drug Administration; (2) be provided to other NCI contractors engaged in manufacture and analytical evaluation of these dosage forms; and (3) be provided to physicians, pharmacists, nurses, and other medical personnel handling these products in a clinical setting. It is anticipated that an incrementally funded, cost-plus-fixed-fee type contract will be awarded for a period of five years beginning on or about March 15, 1992.

RFP NCI-CM27724-71 will be available upon request on or about September 3, 1991. Proposals will be due approximately 45 days thereafter.

To obtain a copy of this RFP, send a stamped, self-addressed envelope to:

Mr. Joseph E. Bowe
Contract Specialist
National Cancer Institute
6120 Executive Boulevard
Room 603
Rockville, MD 20904

DEVELOPMENT AND IMPLEMENTATION OF A PLAN TO ASSESS THE NEURODEVELOPMENT OF INFANTS AND CHILDREN EXPOSED TO DRUGS IN UTERO

RFP AVAILABLE: NICHD-CRMC-92-01

P.T. 34; K.W. 0715006, 0740025, 0775000

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) is seeking a contractor to select and implement a battery of assessment techniques to describe the neurodevelopmental outcome of children at risk for abnormal outcome as a result of exposure to substances of abuse in utero. These instruments will be selected on the basis of their ability to describe anticipated developmental deficits. The specific objectives of this project will be: (1) select a battery of neurodevelopmental assessment techniques appropriate for administration between birth and five years of age that will identify and characterize the social/emotional, cognitive, language, learning, and neurologic and physiologic functions associated with prenatal drug exposure; (2) Provide techniques that will be equally appropriate, regardless of gestational age at birth (i.e., term or preterm) or birth weight; (3) develop and implement a plan to examine the reliability and validity of the assessment techniques for the study population, controlling for confounding variables; (4) train infant follow-up clinic personnel in selected NICHD Neonatal Research Network clinical centers in the administration, scoring, and interpretation of these instruments; and (5) provide collaboration in the statistical analysis and interpretation of the resulting data.

The Request for Proposals (RFP) NICHD-CRMC-92-01 will be issued on or about August 26, 1991, and the responses are due by 4:00 p.m. on October 20, 1991. Those organizations desiring a copy of this RFP may send their written requests to Ms. Mya Hlaing at the address listed below. All requests must cite the RFP number and include two self-addressed mailing labels. Send requests to:

Mrs. Mya Nwe Hlaing
Contracting Officer
Contracts Management Branch, OGC
National Institute of Child Health and Human Development
EPN Bldg., Room 515
9000 Rockville Pike
Bethesda, MD 20892

This announcement does not commit the Government to award a contract.

FAMILY AND GENETIC STUDIES OF CARDIOVASCULAR DISEASE - COORDINATING CENTER

RFP AVAILABLE: NHLBI-HC-91-07

P.T. 34; K.W. 0715040, 1002019, 0755018

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires a coordinating center for a family and genetic study of cardiovascular disease (CVD) on 6,000 participants. The primary objective of the coordinating center is to provide research and development capabilities for the design and coordination of this long-term, multicenter study to identify and evaluate genetic and non-genetic determinants of familial aggregation of CVD and risk factors. The period of performance is anticipated for four years beginning January 1992.

This is a notice of the availability of a Request for Proposals (RFP). RFP NHLBI-HC-91-07 will be available on or about August 27, 1991, and proposals are due September 27, 1991. One award is anticipated by the Government. Offerors other than U.S. organizations will not be considered. Written requests for the RFP must include three mailing labels, self addressed, and must cite RFP NHLBI-HC-91-07.

Send requests for copies of the RFP to:

Ms. Lisa O'Neill
Contract Specialist
ECA Contract Section
National Heart, Lung, and Blood Institute
Federal Building, Room 200
Bethesda, MD 20892

GROUP B STREPTOCOCCAL VACCINE DEVELOPMENT

SOURCES SOUGHT

P.T. 34; K.W. 0740075, 0715125

National Institutes of Allergy and Infectious Diseases

The Respiratory Diseases Branch of the Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), is interested in the prevention of neonatal and obstetrical Group B streptococcal (GBS) sepsis by maternal immunization. Studies have shown that vaccination of pregnant women with Type III GBS polysaccharide results in placental transfer of antibody to the infants of women who respond to the immunogenicity of the polysaccharide vaccine. For other polysaccharides (e.g., Haemophilus influenzae), conjugation to a protein carrier has greatly enhanced immunogenicity. The NIAID is seeking a contractor with the ability to: (1) develop and prepare a GBS polysaccharide-protein conjugate vaccine containing four clinically relevant serotypes (Ia, Ib, II, and III); (2) demonstrate the safety and immunogenicity of this vaccine in an animal model; and (3) prepare, package, and safety-test lots of the candidate vaccine for delivery to the NIAID for future Phase I and II clinical trials. The contractor is expected to provide all data necessary for filing an Investigational New Drug Application (IND) for the Phase I and II clinical trials to be conducted under NIAID auspices.

It is desirable for the contractor's facility to be maintained in accordance with the Food and Drug Administration prescribed Current Good Manufacturing and Laboratory Practices. It is anticipated that NIAID may award a contract for these services in the 1992 fiscal year. A three- to five-year period of performance is anticipated.

Interested parties may submit a capability statement that describes their technical expertise and facilities to provide the above services. Capability statements should be sent to the below address (original plus three copies). No additional information is available at this time. If the NIAID proceeds with this requirement, a competitive solicitation will be issued.

Capability statements that are clearly identified as such are due by 4:30 p.m. on September 13, 1991, to:

Thomas C. Porter
Contracting Officer
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 326P
6003 Executive Blvd.
Bethesda, MD 20892

HYPERIMMUNE GLOBULIN ADJUNCTIVE THERAPY

SOURCES SOUGHT

P.T. 34; K.W. 0745045

National Institute of Allergy and Infectious Diseases

The Respiratory Diseases Branch of the Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), is interested in hyperimmune globulin adjunctive therapy for the prevention or treatment of neonatal group B streptococcal (GBS) disease. Despite antibiotic therapy, morbidity and mortality rates due to GBS disease in newborns remain high, and passive immunization with GBS-directed IgG warrants investigation. The NIAID is seeking one or two contractors capable of performing the following:

(A) Preparing immune globulin directed against serotypes Ia, Ib, II, and III GBS with high functional antibody activity against multiple strains of each type. Strategies that would produce single or multiple lots of hyperimmune globulin demonstrating high anti-GBS functional activity and the potential for limited volume administration are desirable. The contractor must prepare the hyperimmune globulin in sufficient quantity to undertake antibody measurements, opsonophagocytic assays, and neonatal animal model studies to demonstrate protection. The contractor is expected to provide all data necessary for filing an Investigational New Drug Application (IND) for Phase I/II clinical trials to be conducted under NIAID auspices. The ultimate goal of this contract is a source and supply of GBS hyperimmune globulin with high

functional activity and minimal lot-to-lot variability. It shall be necessary for the contractor's facility to be maintained in accordance with the Food and Drug Administration prescribed Current Good Manufacturing and Labor Practices. It is anticipated that NIAID may award a contract for these services in the 1992 fiscal year. A two-year period of performance is anticipated.

(B) Undertaking Phase I/II clinical trials in neonates. The contractor must have the above capability and expertise must provide capacity, capability, and expertise to undertake such a clinical trial, and have access to sufficient numbers of neonates with GBS infection or potential for infection.

It is anticipated that the NIAID may award a contract for these services in the 1992 fiscal year. A three- to four-year period of performance is anticipated.

Interested parties may submit a capability statement that describes: (A) the expertise and facilities to prepare the described hyperimmune globulin; AND/OR (B) the capacity and capability of undertaking the Phase I/II clinical trials. Capability statements must be sent to the below address (original plus three copies). No additional information is available at this time. If the NIAID proceeds with this requirement, a competitive solicitation will be issued.

Capability statements that are clearly identified as such are due by 4:30 p.m. on September 13, 1991, to:

Thomas C. Porter
Contracting Officer
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 326P
6003 Executive Blvd.
Bethesda, MD 20892

CANCER CENTER OUTREACH EDUCATION PROGRAMS

RFA AVAILABLE: CA-91-23

P.T. 34; K.W. 0715035, 0403004

National Cancer Institute

Letter of Intent Receipt Date: November 1, 1991
Application Receipt Date: December 6, 1991

PURPOSE

The purpose of this Request for Applications (RFA) is to invite grant applications for the support of community outreach education programs from recipients of National Cancer Institute (NCI) Center Core Grants (P30). It is anticipated that these education programs will result in increased community efforts related to cancer prevention, to expansion of programs for screening, to earlier detection of cancer, and to the systematic application of the best available methods for the treatment and care of cancer patients. The underserved, elderly, and minority populations must receive high priority in carrying out these objectives.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cancer Center Outreach Education Programs, is related to the priority area of health promotion: educational and community-based programs. 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).

ELIGIBILITY REQUIREMENTS

Only organizations that have a currently active Cancer Center Support Grant (P30) are eligible to apply for this grant since its primary purpose is to encourage Cancer Centers to expand their role in technology transfer by providing state-of-the-art information about cancer prevention, detection, diagnosis, and treatment to community professionals and relevant community organizations.

MECHANISM OF SUPPORT

Support of this program will be through the National Cancer Institute Cancer Education Grant mechanism (R25). Applicants will be responsible for the planning, direction, and execution of the proposed project. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

This RFA is a one-time solicitation. Generally, future unsolicited competitive continuation applications will compete with all investigator-initiated applications. Should the NCI, however, determine that there is a sufficient continuing program need, a request for competitive continuation and/or new applications will be announced.

FUNDS AVAILABLE

For FY 1992, \$1.0 million in total costs per year for three years will be committed to fund applications submitted in response to this RFA. Awards will be limited to a maximum of \$100,000 in direct costs plus eight percent indirect costs, and only one award will be made to a given Cancer Center. It is anticipated that ten to 15 awards will be made. This funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA may not exceed three years. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose. The earliest award date will be July 1, 1992.

PROJECT DESCRIPTION

This RFA is to provide funding, on a competitive basis, for the development and implementation of cancer education outreach programs by Cancer Centers that have been awarded a P30 grant by the NCI. A number of reports have indicated that if state-of-the-art approaches to the prevention, detection, diagnosis, treatment, and care of cancer patients used at major cancer centers were widely implemented at the local community level, there would be a significant reduction in cancer incidence, morbidity, and mortality. A key step in the dissemination of this knowledge is the establishment of educational programs that will transmit state-of-the-art cancer information to community health professionals who are primarily responsible for providing the majority of cancer care. These educational programs must also include community leaders (e.g., those affiliated with civic, religious, and occupational organizations) who are concerned about improving the prevention, detection, diagnosis, and treatment of cancer. These individuals can access and influence the behavior of large segments of the population.

The NCI-designated Cancer Centers are a logical location for these outreach education programs since an essential programmatic element of the Cancer Centers is their role as a focal point for clinical and research training and for continuing education programs designed for local and regional health care professionals.

These education programs must provide state-of-the-art knowledge related to the prevention, screening, detection, diagnosis, and treatment of cancer to local and regional health care professionals, community leaders, and staff of relevant community organizations. Topics must be selected on the basis of their relevance to the day-to-day activities and problems of the community health care professionals and to the welfare of cancer patients and their families.

These outreach programs are intended to be of particular benefit to underserved communities and to groups with disproportionate cancer incidence and death rates (e.g., minorities, people over age 65). High priority local and regional needs for specific types of cancer education programs must be addressed by the proposed programs and described in the application.

The type of programs, their subject content and duration will depend upon local priorities, the availability of appropriate resources, and the nature of the target professional and lay populations to be addressed.

SPECIAL REQUIREMENTS

The application must describe examples of specific topics and approaches that might be included in the cancer education programs if an award were to be made. Emphasis must be given to outreach education topics that would have the greatest impact on reducing cancer incidence and mortality and on improving the quality of life for cancer patients in general.

An area of special interest to NCI, for example, would be educational programs designed to improve the quality of mammography and the accuracy of its interpretation. Other high priority topics include: improved procedures for prevention, detection, diagnosis, and treatment of cancer among elderly, ethnic, minority, low socioeconomic, and other underserved populations that have an elevated incidence of cancer.

The application must include a detailed budget describing and justifying each category of costs requested, and it must indicate the nature and extent of any institutional contribution to the activities supported by a grant awarded as a result of this RFA.

APPLICATION PROCEDURES

The most recent revision of the research grant application form PHS 398 (rev. 10/88) must be used in applying for these Cancer Education (R25) awards. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441.

Applications must be received by December 6. The full RFA contains the complete procedures that must be used by applicants and may be obtained from Dr. Adams (see INQUIRIES below).

LETTER OF INTENT

Although not required, a letter of intent is requested by November 1, 1991. It may only include a descriptive title of the proposed educational program, the name and address of the Principal Investigator, names of other key personnel, participating institutions, and number and title of the RFA. The letter of intent is to be sent to Dr. Adams (see INQUIRIES below).

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged and are to be directed to Dr. Robert Adams at the above address. The opportunity to clarify any issues or questions from potential applicants is welcome. The program official will be pleased to mail the complete RFA to all who request it.

Direct inquiries regarding programmatic issues to:

Dr. Robert C. Adams
Cancer Training Branch
National Cancer Institute
Executive Plaza North, Room 232
Bethesda, MD 20892
Telephone: (301)-496-8580
FAX: (301)-402-0181

Direct inquiries regarding grants management issues to:

Mr. Robert Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301)-496-7800, extension 13

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.398, Cancer Research Manpower. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

IMMUNOLOGIC RECOGNITION AND CONTROL OF TUMORS: A BASIS FOR CANCER VACCINES

RFA AVAILABLE: CA-91-26

P.T. 34; K.W. 0715035, 0710070, 0740075

National Cancer Institute

Letter of Intent Receipt Date: November 1, 1991

Application Receipt Date: December 6, 1991

INTRODUCTION

The Cancer Immunology Branch of the Division of Cancer Biology, Diagnosis, and Centers (DCBDC) of the National Cancer Institute (NCI) invites applications for grants to improve the understanding of the immunologic recognition and control of tumors. The intent of this initiative is to accelerate the application of emerging immunologic concepts of antigen recognition and cellular effector mechanisms to the special problems of cancer, with the long-range goal of developing a sufficient understanding of cancer immunology to permit rational development of effective vaccine strategies for the primary or secondary prevention of cancer.

The present Request for Applications (RFA) announcement is for a single solicita specified deadline for receipt of applications (see above). A maximum of eleven awards will be made if meritorious applications are received and funds are available.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Immunologic Recognition and Control of Tumors: A Basis for Cancer Vaccines, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (full report: Stock No. 017-001-00474-0; 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)

RESEARCH GOALS AND SCOPE

The goal of this initiative is to encourage basic immunologic studies that can serve as a basis for the rational design of vaccine approaches to cancer prevention and treatment. There are many unanswered questions regarding the immune response to tumors. They may be summarized as: (1) What antigens on tumors can be recognized by T lymphocytes in a manner that can lead to an effective antitumor response; (2) How can tumor recognition by cells of the immune system be improved; (3) When recognition occurs, how can the consequences of recognition be amplified and channeled into a pathway that will lead to eradication of the tumor; (4) How can immunoregulatory deterrents to a successful antitumor response (e.g., tolerance, suppression, inadequate local supply of regulatory cytokines) be overcome. An approach that has the potential to shed light on one or more of these questions will be considered responsive to this initiative. The focus of this initiative is on cell-mediated immunity and not on antibody responses. Applications that are limited the definition of new tumor-associated antigens by monoclonal antibodies or for the development of antitumor responses measured only by antibody production will be excluded from review and will be returned to the applicant.

Because the ultimate goal is to improve the immune response in human cancer, applicants are strongly encouraged to consider the relevance to human cancer of the tumor system proposed in the experimental plan. Long-established, highly immunogenic, transplantable murine tumor cell lines may not be appropriate models for certain kinds of studies because such cell lines have many features that distinguish them from primary human tumor cells. However their use will not be considered a sign of nonresponsiveness, per se, if applicants using these systems justify their use and include plans to test their conclusions in more relevant systems. Any combination of in vivo and in vitro experiments is acceptable, but applicants pursuing in vitro observations are encouraged to proceed, whenever possible, to in vivo application of principles under study at some point during the term of the project. Studies may be proposed using either human or animal tumors. Although the development of new knowledge that will permit better approaches to vaccine development is the ultimate goal of this initiative, immediate clinical applicability is not required and large-scale clinical trials of approaches developed are beyond the scope of the RFA.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) grant-in-aid (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

This RFA is a one-time solicitation. Generally, future unsolicited competitive continuation applications will compete with all investigator-initiated applications and be reviewed by the Division of Research Grants (DRG). However, should the NCI determine that there is a sufficient continuing program need, a request for competitive continuation applications will be announced. In that event, only recipients of awards under this RFA will be eligible to apply.

Approximately \$2,000,000 in total costs per year for five years will be committed to fund applications submitted in response to this RFA. It is anticipated that nine to 11 awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest feasible start date for the initial award will be July 1, 1992. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

ELIGIBILITY REQUIREMENTS

Non-profit and for-profit, domestic and foreign, organizations and institutions are eligible to apply. Application from minority individuals and women are encouraged.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA and inquiries about whether or not specific proposed research would be responsive are encouraged and are to be directed to Dr. John A. Sogn at the following address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants. To request the full RFA, contact:

Dr. John A. Sogn
Acting Chief
Cancer Immunology Branch
National Cancer Institute
National Institutes of Health
Executive Plaza South, Room 634
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-7815
FAX: (301) 402-1037

Inquiries concerning fiscal matters are to be directed to:

Robert E. Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
Rockville, MD 20892
Telephone: (301) 496-7800, ext. 13

This program is described in the Catalog of Federal Domestic Assistance No.93.396. Awards are made under authorization of the Public Health Service Act Title, IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the

intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

LEADERSHIP AND EXCELLENCE IN ALZHEIMER'S DISEASE AWARD

RFA AVAILABLE: AG-91-12

P.T. 34; K.W. 0715180

National Institute on Aging

Application Receipt Date: January 15, 1992

PURPOSE

The U.S. Congress, through section 445B of the Public Health Service (PHS) Act as amended (42 U.S.C. 285e-3), authorized the National Institute on Aging (NIA) to make one or more awards to senior researchers who have made distinguished achievements in Alzheimer's disease (AD) and related dementias. The objectives of this program are to help strengthen the capabilities of established senior investigators who have distinguished records in biomedical research on AD by providing up to seven years of support to allow the recipients the time to devote to research and to the development of outstanding but less established biomedical investigators who are interested in working on AD and related dementias.

The senior scientist is to be the focal point of this award. That individual is to provide leadership on research in AD and related dementias of aging.

Relevant activities are provision of encouragement and assistance to other faculty members so that they may integrate issues of aging and AD and other related dementias into their research and teaching, organization and conduct of research, development of courses on these issues, recruitment and development of junior investigators, and integration of AD-related activities among and within the various units of his or her institution. This individual must have the active and continuing support of the applicant institution, and the institution must be strongly committed to the objectives of this program. Prospective awardees must demonstrate a strong commitment to and history of research on AD and related dementias of the aged.

It is hoped that this award will stimulate the recipient institution(s) to develop substantial continued support such as endowed chair(s) for AD and related dementias of aging when this award is terminated. Applications must include the following three components:

A. Salary support for the applicant. The primary intention of this component is to provide continued and stable salary support for the duration of the award thus permitting the senior investigator time to devote to the goals of this award while being relieved of other responsibilities.

B. Salary support for at least one, but not more than three, junior researchers who demonstrate exceptional promise to conduct research in the area of aging and AD and related dementias. The primary intention of this component is to provide continued and stable salary support for the duration of the award to outstanding and promising junior investigators who would have the opportunity to develop as researchers under the close tutelage of the senior awardee.

C. Research Support. The primary intention of this component is to support the research program(s) of the senior investigator in the following ways:

- o Expansion of the scope of currently funded research into new lines of inquiry through novel techniques or approaches and by the addition of personnel.
- o Support or expansion of the research of the junior investigator(s) for up to three years.
- o Support of innovative or opportunistic research on aging and AD and related dementias as pilot studies of no more than two years duration.

ELIGIBILITY REQUIREMENTS

The award recognizes the distinguished accomplishments of a senior researcher in biomedical research in areas related to AD and related dementias. Although the award will be made to the applicant institution in the name of the senior

investigator, it may not be transferred to another investigator. Eligibility is restricted to U.S. institutions. Only one application per institution will be accepted. Applications will not be accepted from institutions that have received a Leadership and Excellence in Alzheimer's Disease (LEAD) award.

MECHANISM OF SUPPORT

This Request for Applications (RFA) will use the National Institutes of Health in-aid mechanism (R35). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Except as stated in this RFA, awards will be administered under PHS Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

REVIEW PROCEDURES

Applications must be submitted to the NIH Division of Research Grants and will be assigned to the NIA. Applications will be assigned to a special review committee for review. Because a site visit is not a prerequisite, each application must be thorough and complete enough to stand on its own. The second level review will be by the National Advisory Council on Aging.

FUNDS AVAILABLE

No more than \$1,000,000 total cost per year for seven years will be committed to specifically fund each award made in response to this RFA. Up to three awards may be granted. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIA, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose. The earliest start date will be July 1, 1992.

STUDY POPULATIONS: SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applications must be received by January 15, 1992, for earliest starting date of July 1, 1992. The application must be submitted on the 10/88 revision of form PHS 398. Supplemental information regarding the RFA and application procedures must be obtained from Dr. Banner of NIA program staff.

INQUIRIES

Written and telephone inquiries concerning this Notice of Availability of an RFA encouraged. The opportunity to clarify any issues and to provide the RFA to potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Carl Banner, Ph.D.
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
National Institutes of Health
Building 31, Room 5C35
Bethesda, MD 20892
Telephone: (301) 496-9350

Direct inquiries regarding fiscal matters to:

Joseph Ellis
Grants Management Officer
Office of Extramural Affairs
National Institute on Aging
National Institutes of Health
Building 31, Room 5C07
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ANIMAL/CELLULAR MODELS FOR STUDIES OF CYSTIC FIBROSIS

RFA AVAILABLE: HL-91-09-L

P.T. 34; K.W. 0715165, 0755020

National Heart, Lung, and Blood Institute
National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: October 14, 1991
Application Receipt Date: December 30, 1991

The National Heart, Lung, and Blood Institute (NHLBI) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announce the availability of a Request for Applications (RFA) on Animal/Cellular Models for Studies of Cystic Fibrosis. This initiative is to develop and utilize models of cystic fibrosis (CF), including intact animal and/or somatic cellular models, for investigation of the molecular basis of the disease and the development and testing of new modes of treatment, including strategies for somatic gene therapy. The major goal of this program is the development of animal models of CF that exhibit disease analogous to the human counterpart. A second goal is to generate somatic cellular models of CF, utilizing individual epithelial cell types, to explore relationships between the CF gene product, called the cystic fibrosis transmembrane conductance regulator (CFTR), and specific epithelial cell activities. These studies can best be performed in cell lines with defined CFTR genotypes. Proposed studies, in either case, may focus exclusively on pulmonary, pancreatic, or intestinal dysfunction, or any combination of these.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Animal/Cellular Models for Studies of Cystic Fibrosis, is related to the priority area of chronic disabling conditions. 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).

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual research project grant (R01). Although the financial plans for fiscal year 1992 include \$1,800,000 for the total costs of this program, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that up to six grants will be awarded under this program. It is expected that four of these awards will be made to grants focused on the development of CF animal models. The specific number to be funded, however, will depend on the merit and scope of the applications received and the availability of funds.

ELIGIBILITY

All domestic, public and private, for-profit and nonprofit, institutions or organizations are eligible to apply in response to this RFA. Awards in connection with this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with PHS policy governing such awards.

Letter of Intent

Prospective applicants are asked to submit a letter of intent and include a descriptive title, the name of the Principal Investigator, and the names of any other participating institutions or investigators. A letter of intent is not binding, and it will not enter into the review of any application

subsequently submitted, nor is it a necessary requirement for application. Such letters are requested for the purpose of obtaining an indication of the number of applications to be received. The Institute staff will not provide a response to a letter of intent. This letter is to be received no later than October 14, 1991, and sent to:

Dr. Charles L. Turbyfill
Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institute of Health
Westwood Building, Room 553
Bethesda, MD 20892

Upon receipt, applications will be reviewed for their responsiveness to the objectives of this RFA. Applications that address only the development of animal and cellular models of CF, exclusive of studies directed at their characterization and utilization for studies of CF pathophysiology and treatment, will not be acceptable. This RFA will not support research programs exclusively directed at the development of new or improved technologies without specific plans to apply them to the development of cellular and animal models of CF.

If an application is judged unresponsive, the applicant will be contacted and given an opportunity to withdraw the application or to have it considered for the investigator-initiated grant program of the NIH. Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group that will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications.

Inquiries regarding this program and requests for the complete RFA document may be addressed to the appropriate program administrator:

Susan P. Banks-Schlegel, Ph.D.
Program Director, Asthma and Cystic Fibrosis
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A15
Bethesda, MD 20892
Telephone: (301) 496-7332
FAX: (301) 496-9886

Nancy Lamontagne, Ph.D.
Cystic Fibrosis Program
Division of Diabetes, Endocrinology and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 607
Bethesda, MD 20892
Telephone: (301) 496-4980
FAX: (301) 496-9721

For fiscal and administrative matters, contact:

Tanya McCoy
Grants Management Specialist
Grants Operations Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A17
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-4970

Sharon Tempchin
Grants Management Specialist
Grants Management Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-7467

This program is described in the Catalog of Federal Domestic Assistance, No. 93.838. Grants will be awarded 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 Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the

intergovernmental review requirements of Executive Order 12372 or to review by a Health Systems Agency.

MAPPING THE DROSOPHILA GENOME

RFA AVAILABLE: HG-91-05

P.T. 34; K.S. 1002058, 0755045, 0760015

National Center For Human Genome Research

Letter of Intent Receipt Date: October 18, 1991

Application Receipt Date: November 15, 1991

The National Center for Human Genome Research (NCHGR) invites applications for assistance awards to support research projects that develop high-resolution physical maps of the *Drosophila melanogaster* genome and feasibility studies for large-scale DNA sequencing projects using biologically interesting regions of the *Drosophila* genome for such pilot projects.

RESEARCH SCOPE

Research projects responsive to this Request for Applications (RFA) to support characterization of the *D. melanogaster* genome must focus on the following areas:

- o Development of high-resolution physical maps: the objective of these projects will be to achieve map continuity across the genome and to develop a resource that will serve as a basis for DNA sequencing and detailed functional studies;
- o Feasibility studies for large-scale DNA sequencing using regions of high biological interest for the pilot studies;
- o New technologies to detect all the coding regions or expressed genes in genomic DNA.

Applications submitted in response to this RFA must approach the characterization of the *Drosophila* genome from the point of view of the whole genome rather than one or a few genes, must use the most appropriate, state-of-the-art technology, and must be cost- and labor-efficient. Moreover, the resources and technology developed must be easily transferrable among laboratories. Projects must focus on the development of new resources rather than on the maintenance of existing resources.

MECHANISM OF SUPPORT

Support for this program will be through individual research grants (R01s), pilot projects/feasibility studies (R21), program project grants (P01s), developmental grants (P20s), and center grants (P30s and P50s). The total amount of support available for grants under this RFA will be \$2.5 million (direct and indirect costs) for the first year of the project and is contingent upon appropriation of funds for this purpose and the quality of the applications received. It is anticipated that three to five awards will be made representing a mix of research topics and grant mechanisms. This number may be increased if a large number of highly meritorious applications are received and if funds are available. The number of awards made will be contingent upon the quality of applications received for each funding mechanism and the available funds.

ELIGIBILITY

Domestic universities, medical colleges, hospitals, and other public, private, and for-profit and non-profit research institutions, including state and local government units, are eligible. Applications from minority investigators and women are encouraged.

LETTER OF INTENT

A letter of intent that includes a descriptive title of the proposed research, names of the Principal Investigator, and other key investigators and their institutions is requested by October 18, 1991. Letters of intent are to be sent to:

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
National Center for Human Genome Research
National Institutes of Health
Building 38A, Room 610
9000 Rockville Pike
Bethesda, MD 20892

APPLICATION AND REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in accordance with the customary NIH peer review procedures. Applications will first be screened for responsiveness to this RFA by NIH staff. Those deemed non-responsive will be returned to the applicant. If a large number of responsive applications is received, they will undergo a preliminary peer review by the Genome Research Review Committee (GRRC), NCHGR, to identify the most meritorious ones. Applications that are deemed non-competitive by this process will be returned to the investigator.

The remaining applications will be reviewed for scientific and technical merit by the GRRC, NCHGR. Review criteria will include the following: (1) originality and innovativeness of the approach; (2) feasibility of the research and adequacy of the experimental design; (3) overall scientific and technical merit of the research; (4) the potential of the proposed work to attain the research objectives outlined in this RFA; (5) training, experience, research competence, and dedication of the investigator(s); (6) adequacy of available facilities; (7) provision for the protection of human subjects and the humane care of animals; and (8) appropriateness of the requested budget for the work proposed. The second level of review will be conducted by the National Advisory Council for Human Genome Research.

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 office at most academic or research institutions, and from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892,

Applications will be reviewed by the GRRC in March 1992 and by the National Advisory Council for Human Genome Research in May 1992. The earliest date that an award will be made is July 1, 1992.

It is essential that applicants type "Mapping the Drosophila Genome" and the RFA number, HG-91-05, 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
Bethesda, MD 20892**

To expedite the review process, it is also important to submit by November 15, 1991, 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

INQUIRIES

Prospective applicants are encouraged to request a copy of the RFA and to contact early in the planning phase of the application. For the complete RFA and for more information regarding specific research areas or mechanisms, please contact:

Physical Mapping Grant Applications (R01, R21, P01):
Bettie J. Graham, Ph.D.

Sequencing and Technology Development Grant Applications (R01, R43, R44):
Robert L. Strausberg, Ph.D.

Center Grant Applications (P20, P30, P50):
Jane L. Peterson, Ph.D.

PHS Grants Policy:
Ms. Alice Thomas

All can be reached at:

National Center for Human Genome Research
National Institutes of Health
Building 38A, Room 613
Bethesda, MD 20892

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

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards will be made under the authority of the Public Health Service Act, Sections 301 (Public Law 78-410, as amended 42 U.S.C. 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or to Health Systems Agency review.

ERRATUM

NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS

RFA: CA-91-19

P.T. 34; K.W. 0715035, 0740020, 0755025, 0755020

National Cancer Institute

Letter of Intent Receipt Date: October 11, 1991
Application Receipt Date: November 13, 1991

This Request for Applications was published in the NIH Guide for Grants and Contracts on August 16, 1991, Vol. 20, No. 31. The receipt date for letters of intent has been changed to October 11, 1991. The application receipt date remains the same.

For further information, contact:

George S. Johnson, Ph.D.
Grants and Contracts Operations Branch
Developmental Therapeutics Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 832
Bethesda, MD 20892
Telephone: (301) 496-8783