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. 36
October 13, 1989

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NOTICES

DATED ANNOUNCEMENTS (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NIH REGIONAL WORKSHOPS ON IMPLEMENTATION OF THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health, Office for Protection from Research Risks, is continuing to sponsor a series of workshops in implementing the Public Health Service Policy on the Humane Care and Use of Laboratory Animals. The workshops are open to institutional administrators, members of animal care and use committees, laboratory animal veterinarians, investigators and other institutional staff who have responsibility for high-quality management of sound institutional animal care and use programs.

Date: October 24-25, 1989

Location: Columbus, Ohio

Contact: Dr. Margaret Duber Snyder
Ohio State University
6089 GoDown Road
Columbus, Ohio 43235
Telephone: (614) 292-9460

Date: December 7-8, 1989

Location: Honolulu, Hawaii

Contact: Ms. Liane Nakmura or
Ms. Becky Makizuru
University of Hawaii
Laboratory Animal Service
2538 The Mall - Snyder Hall, 5th Floor
Honolulu, Hawaii 96822
Telephone: (808) 948-8770

For additional information, contact:

Mrs. Roberta Sonneborn
Executive Assistant for Animal
Welfare Education
National Institutes of Health
Office for Protection from Research Risks
Building 31, Room 5B59
Bethesda, Maryland 20892

EXPANDED GRANT AUTHORITIES FOR RESEARCH ACTIVITIES AT GRANTEE ORGANIZATIONS

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

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

On July 3, 1989, the Office of the Assistant Secretary for Health issued Circular 89.02 of the PHS Grants Administration Manual, subject as above. As stated in Section F (Page 7) of the Public Health Service (PHS) Circular, the provisions of this policy, which became effective on October 1, 1988, "have previously been announced through other mechanisms." Specifically, the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) implemented the expanded grant authorities (as follows) in the NIH GUIDE FOR GRANTS AND CONTRACTS: The NIH announcement was issued on October 21, 1988 (Vol. 17, No. 34) and the ADAMHA announcement was issued on April 28, 1989 (Vol. 18, No. 15).

The purpose of this issuance is to make it explicit that NIH and ADAMHA will follow the policy provisions in the PHS Circular. Thus, the NIH and ADAMHA notices referenced above are superseded by PHS Circular 89.02, which is reprinted below in its entirety.

PHS Circular 89.02
Grants Administration Manual
Issue Date: July 3, 1989

SUBJECT: EXPANDED GRANT AUTHORITIES FOR RESEARCH ACTIVITIES AT GRANTEE ORGANIZATIONS

A. BACKGROUND

In March 1986, five Federal agencies, 10 universities in the State of Florida, and the Government/University/Industry Roundtable of the National Academy of Sciences/National Research Council undertook a demonstration project, called the Florida Demonstration Project, designed to address ways in which administrative burdens on sponsored research could be reduced. The Office of Management and Budget (OMB), through OMB Memorandum 88-20, has encouraged Federal agencies to make use of the expanded authority features of the project which will reduce overhead costs and increase research productivity.

OMB set forth criteria on how to determine who should have the expanded authority. PHS has taken the view that its research grant recipients are in compliance with those criteria unless and until actions or situations present themselves which lead PHS to conclude that it would be in the best interest of the Government to remove the expanded authority from a particular institution.

This Circular sets forth additional authorities which PHS is extending to recipients of PHS research grants.

B. APPLICABILITY

The expanded authorities in this Circular are applicable to all PHS research grants with the following exceptions: (1) Cooperative agreements, (2) awards to individuals or foreign institutions, (3) class deviations granted by the Office of the Assistant Secretary for Health (OASH) for a particular program or class of grants, and (4) when circumstances dictate that the expanded authority should not be extended to a specific research grant (because of action such as the designation of the recipient as "high risk").

NIH and ADAMHA have received a class deviation from OASH and are applying the expanded authorities only to the "R" series of research grants with the following exceptions: R10, Cooperative Clinical Research Grants; R18, Research Demonstration and Dissemination Projects; R43, Small Business Innovation Research Grants - Phase I; and R44, Small Business Innovation Research Grants - Phase II.

The Notice of Grant Award issued within the covered research programs will state whether or not the expanded authorities are applicable.

C. EXPANDED AUTHORITIES

Several of the expanded authorities have specific deadlines for submission of reports or for timely notification to the PHS awarding component. Grantees should be aware that any pattern of failure to adhere to those deadlines for reporting or notification shall be grounds for excluding that grantee institution from these special provisions.

1. EXTENSIONS WITHOUT ADDITIONAL FUNDS

The grantee organization may extend the final budget of a research project ONE TIME for a period of UP TO 1 YEAR beyond the original expiration date shown on the Notice of Grant Award. Such an extension may be made when no additional funds are required to be obligated by the awarding office, there will be no change in the project's originally approved scope or objectives, AND any one of the following applies:

a. Additional time beyond the established expiration date is required to assure adequate completion of the originally approved project; or

b. Continuity of PHS grant support is required while a competing continuation application is under review; or

c. The extension is necessary to permit an orderly phaseout of a project that will not receive continued support.

The fact that funds remain at the expiration date of the grant is not in itself sufficient justification for an extension without additional funds.

The grantee organization must notify the PHS awarding component in writing of the extension 10 DAYS PRIOR TO the expiration date of the project period. Upon notification, the PHS awarding component will issue a revised Notice of Grant Award to reflect the change of the expiration date. Grantees may not extend project periods previously extended by the PHS awarding component.

In extending the final budget period of the grant through this process, the grantee agrees to automatically extend the applicability of all certifications required for funding of the original budget period of the grant to the new extended period of support, e.g., animal welfare, drug free workplace, human subjects, misconduct in science, etc.

2. PREAWARD COSTS

A grantee organization may, at its own risk, incur obligations and expenditures to cover costs prior to the beginning date of an award provided the following criteria are met:

a. The costs concerned are considered necessary for the conduct of the project;

b. The costs are allowable under the POTENTIAL award; and

c. PHS written prior approval is obtained when required.

Such preaward costs may be incurred within 90 days prior to the beginning date of the award without PHS prior approval. Preaward costs incurred more than 90 days prior to the beginning date of the award require PHS written prior approval.

PHS expects the grantee organization to be fully aware that preaward costs must not impair its ability to accomplish project objectives or in any way adversely affect the conduct of the project. Additionally, the incurrence of costs prior to the award of a grant imposes no obligation on PHS to make an award.

Please note that this authority is identical to existing PHS policy contained in the Grants Policy Statement EXCEPT that this Circular deletes the requirement that the application has been recommended for approval by an objective review group or by a National Advisory Council.

3. CARRYOVER OF UNOBLIGATED BALANCES

Except for funds restricted on a Notice of Grant Award, grantee organizations are authorized to carry over unobligated research grant funds remaining at the end of a budget period.

The grantee organization must notify the PHS awarding component whether they have elected to carry over unobligated balances and the amount to be carried over. The notification shall be provided in item 12, "Remarks," of the Financial Status Report (FSR). A revised Notice of Grant Award will NOT be issued to reflect the carryover. Any unobligated balance not specified for carryover on the FSR shall be available for disposition by the PHS awarding component. Grantee organizations are required to submit the FSR within 90 days after the expiration of a budget period.

4. COST-RELATED PRIOR APPROVALS

The requirements for prior Federal approval of expenditures under the applicable cost principles are waived, with the following two exceptions: Prior approval for capital expenditures for land and buildings IS NOT waived because such capital expenditures are allowable only when the program's legislation or regulations so permit. Prior approval for indemnification against liabilities to third parties and any other loss or damage not compensated by insurance or otherwise IS NOT waived because the Government is obligated to indemnify the organization only to the extent expressly provided in the award.

Requirements for allowability, reasonableness, allocability, and consistency of costs are still applicable.

5. USE OF PROGRAM INCOME

The grantee organization may use the additional costs alternative for the use of program income, unless regulations or the Notice of Grant Award specify another alternative or a combination of alternatives.

D. PRIOR APPROVAL AUTHORITIES RETAINED BY PHS

1. CHANGE OF SCOPE OR RESEARCH OBJECTIVES.

The grantee organization is required to seek approval from the PHS awarding component when there is a change in the scope or research objectives of the project. Actions likely to be considered a change in the scope or objectives include, but are not limited to, the following:

a. A change in the specific aims approved at the time of award;

b. Substitution of one animal model for another;

c. Any change from the approved use of animals or human subjects;

d. Shifting the emphasis of the research from one disease area to another;

e. Applying a new technology, i.e., changing assays from those approved to use of a different type of assay;

f. Transferring the performance of substantive programmatic work to a third party by contract or any other means;

g. Change in key personnel whose expertise is critical to the approved project;

h. Significant rebudgeting whether or not it requires approval under rules governing budget changes; and

i. Incurrence of patient care costs where the need has not previously been approved by PHS and/or when a grantee desires to rebudget funds OUT OF the patient care category.

This list clearly is not all-inclusive. In the event of uncertainty as to whether a particular change is significant enough to require prior approval, questions should be referred to the Grants Management Officer (GMO) of the PHS awarding component for final determination.

2. CHANGE IN PRINCIPAL INVESTIGATOR (PI)

The grantee organization is required to seek approval in writing before a substitute PI is appointed to replace an absent or departed PI. If the PI is absent from the project for a period of 3 months or more, a substitute PI must be proposed by the grantee organization and must be approved by the PHS awarding component. The request for approval of a substitute PI should include a justification for the change, the curriculum vitae of the individual proposed, and any budgetary changes resulting from the proposed change.

3. CHANGE OF GRANTEE ORGANIZATION

PHS awarding component approval is required to transfer a grant from one grantee organization to another. PHS awarding component approval is also required for successor-in-interest situations. A successor-in-interest may occur as a result of a merger, divestiture, or other corporate change in which all or part of the assets involved in the performance of the grant-supported activity(ies) are transferred to another entity.

4. ACTIONS REQUIRING ADDITIONAL FEDERAL FUNDS

PHS awarding component prior approval is required if the grantee organization takes action that generates a need for additional Federal funding to carry out the project.

5. RETENTION OF RESEARCH GRANT FUNDS WHEN A RESEARCH CAREER DEVELOPMENT AWARD (RCDA) IS AWARDED

Funds budgeted in a PHS-supported research grant for an individual's salary and/or fringe benefits, but freed as a result of receiving an RCDA for that individual, may not be used for any other purpose without the prior approval of the PHS awarding component.

6. AWARD TERMS AND CONDITIONS

Deviations from special terms or conditions stated on the Notice of Grant Award require prior approval from the PHS awarding component.

7. CLOSELY-RELATED WORK

When salaries and/or other activities are being supported by two or more PHS grant projects from the same awarding component, grantees may charge costs to the project for which the costs are originally approved or to another closely-related PHS project only after approval by the GMO.

8. APPROVAL BY THE OFFICE OF THE ASSISTANT SECRETARY FOR PUBLIC AFFAIRS OF PUBLICATIONS AND AUDIOVISUAL MATERIALS OVER $25,000 FOR A SINGLE ITEM

9. PREAWARD COSTS INCURRED MORE THAN 90 DAYS PRIOR TO THE EFFECTIVE DATE OF ANY NEW OR COMPETING CONTINUATION AWARD

10. DRAWINGS/SPECIFICATIONS FOR ALTERATIONS AND RENOVATIONS OVER $25,000.

In addition, costs for alterations and renovations may not exceed the lesser of $150,000 or 25 percent of total direct costs during any consecutive 3-year period unless a waiver is obtained.

11. INDEMNIFICATION AGAINST THIRD PARTIES

12. CAPITAL EXPENDITURES FOR LAND AND BUILDINGS

13. RETROACTIVE APPROVAL

E. METHOD OF OBTAINING PHS AWARDING COMPONENT PRIOR APPROVAL

All requests that require prior approval must be submitted in writing to the GMO designated on the Notice of Grant Award. All requests must bear the signature of an authorized official of the business office of the grantee organization as well as the P.I. The GMO is responsible for informing the grantee, in writing, of the final disposition of the request. Grantees should ensure that the written approval or disapproval of such requests is signed by the GMO who signed the Notice of Grant Award, or his/her designee. Grantees who take action on the basis of letters or telephone conversations from unauthorized officials do so at their own risk. Such responses will not be considered binding by PHS.

F. EFFECTIVE DATE

The provisions of this policy have previously been announced through other mechanisms. Therefore, this Circular is effective for all research grant awards covered by the provisions of this Circular which are made on or after October 1, 1988.

G. EXPIRATION DATE

This Circular will remain in effect until cancelled or until its content is incorporated into the main body of the PHS Grants Administration Manual.

DATED ANNOUNCEMENTS (RFPs AND RFAs)

THE DEVELOPMENT AND USE OF SENSITIVE, SPECIFIC, RAPID DIAGNOSTIC TESTS FOR CLINICALLY IMPORTANT MICROBIAL AGENTS

RFA AVAILABLE: 90-AI-01

P.T. 34; K.W. 0755010, 0715125, 0715165, 0715182, 0745020

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: December 1, 1989
Application Receipt Date: January 16, 1990

The National Institute of Allergy and Infectious Diseases (NIAID) invites grant applications for basic research which will lead to the improvement or development of rapid, sensitive and specific diagnostic tests for clinically significant viruses, bacteria, and other microorganisms. The targeted infectious diseases include, but are not limited to, respiratory diseases, cytomegalovirus, hepatitis and other enteric diseases, and sexually transmitted diseases (STDs). Research on diagnostic tests for HIV are supported by a separate program.

RESEARCH GOALS AND SCOPE

The purpose of this Request for Applications (RFA) is to stimulate basic research that is expected to lead to the development of novel diagnostic tests. The research proposed should select strategies that will lead to improvements in sensitivity, specificity or speed in the diagnosis of a clinically important infectious disease. The tests should be valid for individuals of either sex and various ethnic populations. Specifically the research should be targeted towards diagnostic tests for:

1. Infectious diseases that are currently difficult to diagnose; especially for diseases for which there is clinical urgency to select an appropriate therapy.

2. Infections for which only cumbersome or invasive diagnostic methods are available. Non-invasive procedures and simpler tests are needed.

3. Infectious diseases for which the current tests lack suitable specificity, sensitivity, or rapidity.

4. Infectious diseases for which more economical tests are needed.

5. Diagnosis of numerous agents in the same specimen at the same time.

Inclusion of women and minorities are encouraged. If they are excluded, reasons for this exclusion must be included in the application.

The targeted infectious diseases include but are not limited to respiratory diseases, cytomegalovirus, hepatitis and other enteric infections, and sexually transmitted diseases (excluding AIDS).

MECHANISM OF SUPPORT

Award(s) will be made as Cooperative Agreements. These are assistance relationships with substantial involvement of NIAID staff. Universities, medical colleges, hospitals, and laboratories or other public, private, or for profit institutions are eligible.

This RFA is a one-time solicitation. NIAID anticipates making four awards as a result of this RFA. However these anticipated awards are dependent upon receipt of a sufficient number of applications of high scientific merit and upon the availability of funds. The earliest possible award date is June 1, 1990. It is the intent of the Rapid Diagnosis Program to fund applications in a manner which will ensure the support of a variety of approaches to the diagnosis of a variety of diseases caused by viruses and/or other microorganisms.

INQUIRIES

Investigators seeking information relevant to this RFA should contact Dr. Catherine Laughlin at the address below. Requests for copies of the complete RFA and questions regarding review procedures should be addressed to Dr. Preble at the address below.

Dr. Olivia Preble
Acting Chief, Microbiology and Immunology Review Section
Program and Project Review Branch
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Westwood Building, Room 3A10
Bethesda, Maryland 20892
Telephone: (301) 496-8208

Dr. Catherine Laughlin
Acting Chief, Antiviral Research Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 753
Bethesda, Maryland 20892
Telephone: (301) 496-8285

DIGESTIVE DISEASES CORE CENTERS

RFA AVAILABLE: 90-DK-01

P.T. 04; K.W. 0715085, 0710030, 0785035, 0715026

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: December 16, 1989
Application Receipt Date: February 15, 1990

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for Digestive Diseases Core Center Grants to be awarded in Fiscal Year 1991. NIDDK anticipates the award of up to four competitive Digestive Diseases Core Center Grants in Fiscal Year 1991.

BACKGROUND

The NIDDK-supported Digestive Diseases Core Centers are part of an integrated program of digestive disease-related research support provided by NIDDK. These centers have provided a focus for increasing collaboration and improving the cost effectiveness of supported research among groups of successful investigators at institutions with established comprehensive digestive disease research base. At least 50 percent of the research base of a Center must be supported by NIDDK.

OBJECTIVE AND SCOPE

The objective of the Core Centers is to bring together investigators from relevant disciplines to enhance and extend the effectiveness of research related to digestive diseases and their complications. A Core Center must be an identifiable unit within a single university medical center or a consortium of cooperating institutions, including an affiliated university. The overall goal of the Core Center is to bring together clinical and basic science investigators in a manner which will enrich the effectiveness of digestive disease research. An existing program of excellence in biomedical research in the area of digestive disease disorders is required. This research should be in the form of NIH-funded research projects, program projects, or other peer-reviewed research that is in existence at the time of submission of a center application. Close cooperation, communication, and collaboration among all involved personnel of all professional disciplines are ultimate objectives.

The Core Centers should have a central focus of research investigation. The central focus should be a digestive disease or group of diseases and at least half of the research should focus on this area. Examples of a central focus of research investigation include (but are not restricted to) inflammatory bowel disease, peptic ulcer disease, pancreatic disease, liver disease and pediatric gastrointestinal disease. A major area of programmatic interest in digestive diseases at NIDDK is inflammatory bowel disease including Crohn's disease and ulcerative colitis. Accordingly, as a part of this Request for Applications (RFA), NIDDK intends to fund at least one digestive disease center whose focus of research interest is inflammatory bowel disease. Applicants should consult with NIDDK staff concerning plans for the development of the center and the organization of the application.

Digestive Diseases Core Centers are based on the core concept. Cores are defined as shared resources that enhance productivity or in other ways benefit a group of investigators working in digestive diseases centers to accomplish the stated goals of the center. Two other types of activities may also be supported with center funding--a pilot and feasibility program and an enrichment program. The pilot and feasibility program provides modest support for new initiatives or feasibility research studies. This program is directed at new investigators and at investigators established in other research disciplines where their expertise may be applied to digestive disease research. The Core Center Grant may also include limited funds for program enrichment such as seminars, visiting scientists, consultants, workshops, etc.

MECHANISM OF SUPPORT

NIDDK expects to award up to four Digestive Diseases Core Center Grants in Fiscal Year 1991 on a competitive basis. The receipt of four competitive continuation applications is anticipated. These applications will compete for awards along with other applications received in response to this announcement. Foreign institutions are not eligible to apply. The anticipated awards will be for five years and are contingent upon the availability of appropriated funds. The complete RFA (general description and

Guidelines for the digestive disease centers) and consultation may be obtained from:

Maria H. Sjogren, M.D., Director
Digestive Disease Centers Program
Division of Digestive Diseases and Nutrition
Westwood Building, Room 3A15
National Institute of Diabetes and Digestive and Kidney Diseases
Bethesda, Maryland 20892
Telephone: (301) 496-9717

REVIEW PROCEDURES

Applications for the Core Center Grants will be evaluated in national competition by the NIH grant peer review process. 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.

METHOD OF APPLYING

Potential applicants are urged to submit a letter of intent by December 16, 1989, regarding their application. The letter of intent is nonbinding and is not a precondition for an award. The letter of intent should include the name(s) of the principal investigator and principal collaborators, descriptive titles of the core facilities and pilot/feasibility projects, and the organization(s) involved. Applications must be submitted using PHS Form 398 (Rev. 10/88). Check the "Yes" box in line 2 of the application face page and insert "DIGESTIVE DISEASES CORE CENTERS, RFA 90-DK-01." THE RFA LABEL CONTAINED IN THE APPLICATION KIT MUST BE AFFIXED TO THE BOTTOM OF THE FACE PAGE OF THE ORIGINAL COPY OF THE APPLICATION. FAILURE TO USE THIS LABEL COULD RESULT IN DELAYED PROCESSING AND REVIEW OF THE APPLICATION.

Mail the completed application (original and four copies) to:

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

Simultaneously submit two copies to:

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

The special single receipt date for submissions in response to this announcement is February 15, 1990, with earliest funding December 1, 1990.

ONGOING PROGRAM ANNOUNCEMENTS

HUMAN GENOME PROGRAM CENTER GRANTS (P30, P50)

P.T. 34; K.W. 1215018, 0710030, 1002058, 0755045, 1004017, 0780000

National Center for Human Genome Research

First receipt date: February 1, 1990

THIS ANNOUNCEMENT SUPERCEDES AND REPLACES THE ANNOUNCEMENT OF HUMAN GENOME PROGRAM CENTER GRANTS ISSUED IN VOLUME 18, NO. 25, JULY 21, 1989, OF THE NIH GUIDE TO GRANTS AND CONTRACTS.

The National Center for Human Genome Research (NCHGR) is interested in facilitating the establishment of a number of centers in which research is focussed on achieving the goals of the Human Genome Initiative. To this end, an announcement was published in the NIH Guide to Grants and Contracts (referenced above) soliciting applications for Human Genome Program Center Core Grants (P30s). After receiving comments from the scientific community, the proposed organizational model for Human Genome Program Centers has been considered further, and the NCHGR believes that the goals of the Human Genome Initiative can, at present, best be achieved through support of both center core grants (P30s) and grants for specialized centers (P50s).

This announcement contains a restatement of the characteristics of Human Genome Program Centers and solicits applications for Human Genome Program Center Grants using both the P30 and P50 mechanisms. The intent in allowing the use of either mechanism is to give each applicant institution flexibility in designing a center structure appropriate to its needs and capabilities. In general, the P30 center core grant will be most appropriate for institutions where there is a significant amount of ongoing and closely related genome research already funded. The P50 specialized center grant will allow institutions to propose a center that will include a significant amount of new research. In either case, the overall research program of each proposed Human Genome Program Center must address a specific defined goal of the Human Genome Initiative and directly facilitate progress toward the goals of the program as a whole.

BACKGROUND

The National Institutes of Health are currently engaged, along with several other Federal, private, and international organizations, in a research program designed to characterize the human genome and the genomes of selected model organisms. This research program, which has been named the Human Genome Initiative, has the following interrelated goals: (1) the construction of high resolution genetic linkage maps; (2) the development of physical maps, with an emphasis on methodology that allows investigators access to the mapped DNA; (3) the determination of the complete nucleotide sequence of the DNA of selected organisms, including the human; (4) the development of the capability for collecting, storing, distributing and analyzing the data; and (5) the development of appropriate new technologies to achieve these goals. The product of the Human Genome Initiative will be a set of information and material resources available to the entire research community to facilitate further research as well as application of the knowledge gained to the prevention, diagnosis, and therapy of disease.

Attaining the goals of the Human Genome Initiative will require research projects of different magnitudes and complexities. While many important projects will be of a scope appropriate to a single investigator or a small number of investigators, other research projects envisioned will be large undertakings that can only be addressed adequately by groups of investigators, representing diverse disciplines, working cooperatively in centers focussed on a goal of the Human Genome Initiative.

As one means of stimulating the development of directed, large-scale projects, the NCHGR proposes to encourage the establishment of Human Genome Program Centers (HGP Centers). It is envisioned that a substantial fraction of the funds earmarked for the genome program will eventually be devoted to the support of such centers, with the award of as many as 20 center grants over a period of years.

Because the NIH Human Genome Program has been charged with reaching specific goals within relatively short time periods, the P30 and P50 center grant mechanisms will be used to facilitate the creation of HGP Centers in which major goals of the program can be addressed in a focussed and comprehensive way. The center grants will allow research programs to go forward that could not be supported effectively by the R01 or P01 mechanisms. Center grants will support new or significantly expanded research objectives. In addition, while the center must be highly coherent in its research objective, it should also be a hub for collaboration and outreach to the broader scientific community. It is anticipated that a well-integrated and robust center will become a resource for the genome community as a whole.

OBJECTIVES AND SCOPE OF HGP CENTERS

The primary purposes of the HGP Centers will be to develop the new technology needed to accomplish the goals of the Human Genome Initiative and to apply these technologies to the large-scale generation of mapping and sequencing information. Each center must have tangible and, where possible, quantifiable aims that define a specific goal that the center intends to accomplish during the granting period. The center will be accountable for the attainment of such milestones through yearly progress reports, an annual center directors meeting and the competitive renewal process.

The specific objectives of the HGP Centers will be to:

1. Provide support for a group of investigators to collaborate in addressing a major research goal of the Human Genome Initiative in a comprehensive and coordinated way;

2. Expedite research by providing needed core resources;

3. Recruit new investigators, including nonbiologists;

4. Provide an environment in which large-scale projects can be accommodated and receive stable support;

5. Stimulate interdisciplinary collaboration and sharing of data and ideas with investigators who are not part of the center and with private sector organizations.

In the case of a P30 center core grant, the goal of the center must be derived from research that is already funded at the institution whereas for a P50 specialized center, new research may be proposed to define the goal. Additional components that will be supported include an administrative structure that will relieve individual investigators of the administrative burden otherwise associated with a large-scale research program, resources to be shared by the research groups within the center, recruitment of new scientists into the center, and pilot projects. In many cases, the activity proposed for the HGP Centers will demand new research directions for some participants; this is encouraged. The principal investigator of the center grant will be expected to provide scientific, intellectual and administrative leadership to the entire HGP Center effort.

ELIGIBILITY

Investigators at academic, nonprofit, or for-profit institutions in the United States are eligible. Only one center will be funded at any one institution. While a single institution must be the applicant, multi-institutional arrangements (consortia) are possible if there is a compelling reason for them and if there is clear evidence of close interaction among the participants.

Collaboration with industry is encouraged. In such a collaboration the industrial contribution should be well-integrated into the design and operation of the center, to encourage cross-fertilization of ideas and rapid application of the research to practical purposes.

ALLOWABLE COMPONENTS OF HGP CENTER GRANT (P30 and P50) APPLICATIONS

1. Administrative core. This component will include the costs of administering the entire HGP Center. The portion of the salaries of the principal investigator and other key individuals corresponding to the percentage of time devoted to center administration can be included. The center director must serve on a full-time or significant part-time basis and should have authority over appointments and space within the center. Costs of advisory committees, steering committees, and consultants can be included in the administrative core. Such committees are not required, but it is strongly recommended that the applicant outline an effective mechanism for obtaining independent advice to ensure guidance of the center toward the attainment of the stated goals.

2. Technical Core Facilities. Under this component the applicant should request any shared facilities or equipment that will be required by the proposed research program. Examples of shared facilities include a polynucleotide or protein sequencing laboratory; a cytogenetics laboratory; shared equipment; a data management and computational resource; or an instrument development laboratory. This list of core facilities is not intended to be limiting, nor is it expected that each center will include all of those listed. Applicants should examine the needs of their particular programs and request the technical core facilities that would best be suited to fill these individual needs. It is expected that there will be considerable diversity among centers in this regard. Resources necessary for distribution of data or materials to external investigators should be taken into account, where relevant, in requesting funds for core facilities.

3. Alterations and Renovations. Funds needed for renovation of existing space may be requested, if such space is needed to house core facilities or new or expanded research activities. The Public Health Service Grant Management Policy limits the dollar amount to the lesser of $150,000 or 25 percent of total direct costs over a three-year period. Waivers may be sought by the NCHGR in exceptional cases. Detailed justification and plans for use of the space must be provided. Costs of equipping renovated laboratories may be included if the items are directly related to the research being conducted in the center.

4. Developmental Funds. The purpose of developmental funding is to provide a flexible means for the center director to promote growth of the center and progress toward achieving the research goals of the center. This component may include: (1) the costs of recruiting new investigators; (2) research support of new investigators for up to three years, until independent research

support is obtained; (3) support for innovative pilot projects not supported under existing research funding or proposed as a part of the research component of the center; (4) funds for the development of new resources or core facilities.

ADDITIONAL COMPONENTS ALLOWABLE IN P30 CENTER CORE GRANTS

Within the administrative core, salary support for the principal investigators of grants that will be part of the HGP Center may be requested to the extent such salary is not recovered on the individual research grant(s). The limit is 50 percent of the salary of the principal investigator involved. Only the percent of time and effort devoted to the specific research project included in the center may be claimed. Additionally, interim funds for HGP Center investigators whose renewal applications were approved but not funded, may be requested within the developmental funds.

ADDITIONAL COMPONENTS ALLOWABLE IN P50 SPECIALIZED CENTER GRANTS

At least three related, integrated and high quality research projects that provide a unified approach to a goal of the Human Genome Initiative must be proposed in the P50 specialized center application. The contribution made by each project to the focussed theme of the center must be clearly established. Projects currently supported by existing research grants (RO1s) or program project grants (PO1s) may be proposed for incorporation into the HGP Center Grant if they fit closely into the goals of the center. In this case, the applicant must provide an explanation of the advantage of including the research program in the center as opposed to maintaining it as a separately funded entity.

TERM OF SUPPORT

The Human Genome Initiative has established a series of specific goals to be accomplished in a limited period of time. As the initial goals are reached, the focus of the HGP Centers and of individual grants will change. In order to ensure that centers remain focussed on appropriate goals and make sufficient progress, frequent scientific and programmatic reviews will be necessary. In addition to yearly staff review through progress reports and center directors meetings, this will be accomplished by allowing an initial term of five years with review of any request for renewal of support after the end of the third year. In the event that the review is not favorable, review after the end of the first three years will allow sufficient time for submission and review of a revised application or for orderly phase-out of the grant. Further terms of support will be for a three- to five-year period.

Many institutions may find that the specialized center mechanism (P50) best fits their needs at present since they do not have a substantial number of closely related genome research projects in place. However, at the time of renewal, the center core grant (P30) mechanism may be the most appropriate mechanism for continuation and expansion of the center. Such a transition from a P50 grant to a P30 grant will be encouraged in order to enhance the flexibility of the center and ensure that high quality research continues to be supported by NCHGR funds. It is anticipated that as the focus of the Human Genome Initiative shifts there may be relocation of center grants to different institutions where expertise exists to attain further goals in the program.

REVIEW PROCEDURES

The first receipt date for applications will be February 1, 1990. Thereafter, the regular NIH receipt dates for center grant applications will pertain: June 1, October 1, and February 1 of each year. In order to be considered for funding in Fiscal Year 1990 (before September 30, 1990), applications must be received by February 1, 1990.

Applications will be evaluated for scientific merit by an appropriate review committee constituted for the purpose of evaluating Center Grant applications. Site visits may be conducted as part of the review process. However, applicants should present a complete and well-justified written proposal and not depend on site visits to amplify their application. Subsequent to evaluation by the initial review committee, applications will be reviewed by a National Advisory Council.

METHOD OF APPLYING

Applicants should use Standard Form PHS 398, revised 10/88, available from most institutional business offices or from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Bethesda, Maryland 20892. In order to assure proper identification of

the application, line 2 of the application form should state "Human Genome Program Research Centers" and check the "YES" box.

INQUIRIES

Applicants are strongly urged to contact the individual listed below by telephone to indicate that they intend to submit an application for a HGP Center Grant. The purposes of such contact are to provide guidance to the applicant on the eligibility and acceptability of the proposed center grant structure and to assist staff in planning the review workload. In addition, individuals who intend to apply for a HGP Center Grant should request a copy of the complete application guidelines before initiating the application process from:

Jane L. Peterson, Ph.D.
Chief, Research Centers Branch
National Center for Human Genome Research
Building 38A, Room 613
National Institutes of Health
Bethesda, Maryland 20894
Telephone: (301) 496-7531

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

5333 Westbard Avenue
Bethesda, Maryland 20816

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