NIH GUIDE for GRANTS and CONTRACTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Vol. 11, No. 12, November 5, 1982

IN THIS ISSUE:

(Continued)

HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

The GUIDE is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Index (Continued)

NOTICE

SMALL GRANTS PROGRAM

The Division of Research Resources (DRR), National Eye Institute (NEI), National Institute on Aging (NIA), and the National Institute of Dental Research (NIDR) each has previously announced the availability of a small grant award. One of the most attractive features of these one-time awards of up to $15,000 is an accelerated cycle of receipt, review and award of four to five months. Some problems of special handling have arisen which could jeopardize this shortened cycle unless remedied.

NIH urges perspective small grant applicants to give careful attention to the following requirements or suggestions:

-- Obtain special information and instructions for preparation of the application from the appropriate Division or Institute.

-- Clearly identify the mailing envelope as containing a SMALL GRANT APPLICATION.

-- Do not package with other types of applications.

-- Submit the application to Division of Research Grants (DRG) (copies to the Institute) as early as possible, and in all cases in time to arrive at NIH by the published receipt dates of February 1, June 1, and October 1.

Adherence to the above should facilitate prompt processing of the applications within the accelerated period.

REMINDER NOTICE

DEADLINE FOR SUBMISSION OF ASSURANCES OF COMPLIANCE WITH REVISED HUMAN SUBJECTS PROTECTION REGULATIONS

On January 26, 1981, the Department of Health and Human Services (DHHS) published final regulations amending basic DHHS policy for the protection of human research subjects. Institutions holding an Assurance of Compliance were encouraged to implement new provisions of the regulations prior to the negotiation of a revised Assurance of Compliance. Since August, 1981, the Office for Protection from Research Risks (OPRR) has been negotiating Assurances of Compliance with the new regulations.

This notification establishes a deadline of December 31, 1982, for submission of a general (Multiple Project) assurance prepared in accord with DHHS regulations published in the Federal Register on January 16, 1981 (46 FR 8366).

Institutions are encouraged to submit an Assurance of Compliance at the earliest possible date. A sample assurance is available from OPRR (301 - 496-7041). Although it is possible that approval of a multiple project assurance might not be transmitted until sometime after December 31, 1982, institutions may continue to function under their former assurance until such time as approval for the revised assurance is given. Special (Single Project) assurances will continue to be approved on a single project basis. GENERAL ASSURANCES WHICH HAVE NOT BEEN REVISED TO MEET THE 1981 REQUIREMENTS AND SUBMITTED TO OPRR WILL BE TERMINATED EFFECTIVE JANUARY 1, 1983.

NOTICE

EFFECT ON GRANT RECIPIENTS OF PROMPT PAYMENT ACT (P.L. 97-177)

The Prompt Payment Act (P.L. 97-177), which was signed by the President on May 21, 1982, requires Federal agencies to pay their bills on time, to pay interest penalties when payments are made late, and to take discounts only when payments are made within the discount period. Interest penalties will apply to payments made under contracts issued on or after October 1, 1982.

Regarding grant recipients, Section 10 of the final issuance of OMB Circular A-125, "Prompt Payment" (published in the Federal Register, Vol. 47, No. 165, Wednesday, August 25, 1982), states:

> "Grant Recipients. Recipients of Federal assistance may pay interest penalties if so specified in their contracts with business concerns. However, obligations to pay such interest penalties will not be obligations of the United States. Federal funds may not be used for this purpose, nor may interest penalties be used to meet matching requirements of federally-assisted programs."

ANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANTS

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: February 15, 1982

I. BACKGROUND

As part of its mission to create, develop, and maintain research resources needed by NIH-supported biomedical investigators throughout the nation, the Division of Research Resources (DRR) is continuing its competitive biomedical shared instrumentation grant program initiated in Fiscal Year 1982. The program was established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available, to institutions with a high concentration of NIH extramural research awards, research instruments which can only be justified on a shared use basis and for which meritorious research projects are described.

Eligible institutions may submit more than one application for different instrumentation in the Fiscal Year 1984 review cycle.

II. RESEARCH GOALS AND SCOPE

This program is designed to meet the special problem of acquisition and updating of expensive shared-use instruments which are not generally available through other NIH mechanisms, such as the regular research, program project and center grant programs, the Biomedical Research Support (BRS) Grant Program and other DRR programs such as Animal Resources and the Biotechnology Resources Program. The latter program emphasizes development of the instrument and associated research methodology, research aspects which are not required in the new BRS Shared Instrumentation Program. The BRS Shared Instrumentation Program is intended for a broad community of the NIH supported investigators.

This program is described in the Catalog of Federal Domestic Assistance No. 13.337, Biomedical Research Support. Awards will be made under the authority of the Public Health Service Act, Secion 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

III. ELIGIBILITY

The shared instrumentation grant program is a subprogram of the BRS Grant Program of DRR. Awards are made under the authority of the authority of the BRS program and are made to institutions only, not to individuals. In FY 1984, eligibility is limited to those grantees which received a BRS grant award in FY 1983. NIH records will be used to verify eligibility. Applications will be received only once per year. The program is highly competitive. It is expected that a minimum of 25 and a maximum of 75 awards would be made in 1984, depending on the availability of FY 1984 funds.

IV. MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants provide support for expensive state-of-the-art instruments utilized in biomedical research. Aplications are limited to instruments that cost at least $100,000 per instrument or system. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or "stand alone" computer systems.

Awards will be made for the direct costs of acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is $300,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. If the amount of funds requested does not cover the total cost of the instrument, an award will not be made unless the remainder of the funding is assured. Description of the proposed co-funding must be presented with the application. Assurance of co-funding, signed by an appropriate institutional official, must be presented to DRR prior to the issuance of an award. The shared instrument will not be transferable outside of the institution to which it is awarded.

A major user group of three or more investigators should be identified. Each major user must have NIH peer-reviewed research support at the time of the award. The application must show a clear need for the instrumentation by projects supported by multiple NIH research awards and demonstrate that these projects will require at least 75% of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. NIH extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument can be made available to other users upon the advice of the advisory committee. These users need not be NIH awardees but priority should be given to NIH supported scientists engaged in biomedical research.

A progress report shall be required for each of the three years following receipt of the award. The report must describe the use of the instrument, listing all users, and indicate the value of the instrumentation to the research of the major users and to the institution as a whole.

V. ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. It is expected that in most cases, the BRS Program Director and extant BRS advisory apparatus, augmented with members having technical and scientific expertise regarding the instrumentation requested, can serve this function. However,there may be circumstances where other existing or proposed arrangements are more appropriate for the applicant institution.

In any event, the Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the grantee institution if the major user group is significantly altered and for continued support for the maximum utilization and maintenance of the instrument in the post award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

VI. REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups by the Division of Research Grants (DRG) for scientific and technical merit and by the BRS Subcommittee of the General Research Support Review Committee and the National Advisory Research Resources Council of the DRR for program considerations. Funding decisions are the responsibility of the DRR and will not be made prior to November 1, 1983.

Criteria for review of applications include the following:

1. The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.

2. The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.

3. The adequacy of the origanizational plan and the internal advisory committee for administration of the grant including sharing arrangements for use of the instrument.

4. The institution's commitment for continued support of the utilization and maintenance of the instrument.

5. The benefit of the proposed instrument to the overall research community it will serve.

VII. METHOD OF APPLYING

A. Application Format

Applications are to be submitted on the standard PHS research grant application form (PHS-398, Rev. 5/80) available from most institutional business offices or the Division of Research Grants, National Institutes of Health. Instructions supplied with these forms should be followed except for the following:

1. Face page of the application -

   a. Item 1. The instrument requested should be named in the title of the proposal.

   b. Item 2. Write in "DRR-BRS SHARED INSTRUMENTATION GRANT."

   c. Item 6. Write in January 1, 1984 - December 31, 1984.

   d. Item 12. Complete Item 12 and type in the institution's BRS grant number.

   (Note at the bottom of the page if a duplicate application has been sent to another agency.)

2. Application page 2. Identify the Principal Investigator, the major user group and the complete grant number(s) for each of the users currently active NIH research support.

3. Application page 4. A detailed breakdown of the direct costs requested will be shown on the budget page. Provide a complete description of the instrument including manufacturer, model number and cost including tax and import duties, if applicable. If possible, the model chosen should be justified by comparing its performance with other available instrumenmts.

4. Application page 5. Budget Estimates for All Years. Not applicable; do not submit.

5. Biographical Sketch. In addition to the personnel listed on page 2, include a biographical sketch of the person(s) who will be in charge of maintenance and operation of the instrument and a brief statement of the qualifications of the individual. Biographical sketches should not exceed 2 pages for each individual.

6. Section 2 of the application. Provide information relative to the points identified under criteria for review including:

   a. A description of similar instruments existing at the institution or at nearby institutions and a justification why new or updated equipment is needed. A clear justification should be given for the choice of the instrument and ancillary accessories requested.

b. A description, by major users, of the research projects for which the instrumentation is required. The descriptions need not be of the detail of a regular research grant application (should not exceed 4 pages per major user) but should point out the benefit of the proposed instrument to the research objectives of each major user. An estimate of the percentage use of each project should be given. If there are more than four major users, set up a table listing the names of the users, the NIH grant number, the estimated percentage use and the title of each research project.

c. A description of the organizational plan including the internal advisory committee for administration of the grant.

d. A specific plan and a statement of institutional commitment to operate and maintain the instrument for its useful life at the same utilization level after termination of the three-year reporting period to DRR.

B. Application Procedure

Applications must be received by February 15, 1983. Applications received after this date will not be accepted for review in this competition. The original and six copies should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
533 Westbard Avenue
Betheda, Maryland 20205

Iniquiries and three copies of the application should be addressed to

Biomedical Research Support Grant Program
Division of Research Resources
Building 31 - Room 5B23
National Institutes of Health
Bethesda, Maryland 20205

Information about eligibility for FY 1983 awards can be obtained by calling Mrs. Gilda Polletto (301) 496-5131)

ANNOUNCEMENT

THE NIEHS CLINICAL INVESTIGATOR AWARD

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Application Receipt Dates: February 1, June 1, October 1

I. SUMMARY AND PURPOSE

The National Institute of Environmental Health Sciences announces the availability of NIEHS Clinical Investigator Awards for the purpose of developing clinical investigators in the field of environmental health/human toxicology. The award is made to support the research development of clinicians to work with research teams on problems arising from the exposures of human populations to environmental chemicals. (It is not meant to support the activities of "poison centers" and related researchers who deal with the effects of acute exposures to self-inflicted or accidentally inflicted toxic materials or clinical research on the toxicities of pharmaceuticals and other drugs).

The award is designed to further the growth of superior candidates toward independent clinical research in this field and to assist in the development of clinical research programs in environmental health. It will enable successful candidates to investigate for a period not to exceed three years, a well-defined problem under the guidance of an active clinical researcher who has the knowledge, experience, and background required to be a mentor in this field. Usually this experience will take place at another institution or department. An additional two years of support is provided at the end of the research to allow the awardee to return to his/her home institution to develop a program in clinical research in this field. The institution providing for the early research development phase should be able to provide laboratory experience in experimental toxicology as well as the opportunity to study the clinical effects of human exposures to environmental agents. The preceptor should be a clinical investigator experienced in the identification, recognition and assessment of the health effects of such exposures.

The NIEHS Clinical Investigator Award seeks to foster new clinical research departments in the area of environmental toxicology by providing intensive guided research experience for investigators who will establish such departments. There are two acceptable programs; one where the preceptor(s) for the research development of the candidate is at the applicant institution and one in which the preceptor(s) is at another institution. In either case, the applicant institution is responsible for management of the award.

This program is described in the Catalog of Federal Domestic Assistance No. 13.894, Environmental Health Research Manpower Development Resources. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

II. ELIGIBILITY

A. Candidate:

Applications will be considered on behalf of individuals holding health professional degrees in the clinical sciences (M.D., D.O., or equivalent) who have not previously served as principal investigators on PHS supported research projects (including New Investigator Research Awards). Candidates should have at least two years of clinical training at the postdoctoral level by the projected start of the award. Individuals with experience levels falling outside these limits who believe they may still fulfill the intent of the award are invited to discuss their eligibility with staff and to submit special justification with their application. Candidates should have broad training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates should provide evidence of a serious intent for an academic career related to that area. This grant is intended to provide guided research experience for clinicians in the transition between fellowship or trainee experience and a career in independent investigation. It is not intended for those individuals whose stage of development would make them fully competitive for regular research project awards. Holders of the Ph.D. or comparable research degrees, either with or without an accompanying health professional degree, are not eligible for the Clinical Investigator Award.

A noncitizen is not eligible to apply unless lawfully admitted to the United States for permanent residence.

B. Institutions:

Both the grantee and/or research development institutions must be domestic universities, medical schools, or comparable institutions. The research development institution should have a strong, well-established, research and training program in the chosen area, an adequate number of highly experienced faculty in clinical and basic departments relevant to the chosen area, and interest and capacity to provide guidance to clinically trained individuals in the development of research independence. The grantee institution should include plans for program development commensurate with the training of the candidate.

C. Preceptor:

The candidate's primary preceptor must be a competent investigator in the area of the proposed research activity, who is currently active as an investigator, and who will personally provide the candidate a significant portion of the research supervision he receives. The preceptor may have either a basic science or clinical professional background.

Determination of the acceptability of applications is made by the National Institutes of Health.

III. CONDITIONS OF THE AWARD

The Clinical Investigator Award is made for a total nonrenewable and nontransferable period of five years (three years for research development

plus two years for program development as described under Summary and Purpose). Support is based on a full-time, twelve-month staff appointment. The award will provide salary support not to exceed $30,000 annually from NIEHS funds for the five-year period. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience, and rank. Up to a total of $10,000 annually will be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the Awardee's research program. Funds will be provided for the reimbursement of actual indirect costs at a rate of up to, but not to exceed, eight percent of the total allowable direct costs. When requested, the grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that proportion of the employee's salary provided by the NIEHS Clinical Investigator Award.

It is expected that the candidate will spend at least 80 percent of his/her time in research during the development period, with the remainder being divided among other activities such as teaching, practice and consultation, administration, receiving research training, and academic studies. The total of all percentages should equal 100. An appropriate sponsor must assume responsibility and provide guidance for the research development in the chosen areas.

Institutions may apply for awards on behalf of named individuals meeting the above criteria. It is not essential for the applicant institution to commit itself in the application to eventual placement of the candidate on its permanent, full-time faculty, but it is expected that institutions will choose candidates who will be able to meet the criteria for making that decision. Evidence of the commitment of the institution to the candidate's research development must be provided.

The Awardee should plan to submit a research project grant application in clinical environmental health sciences prior to the end of the five-year award. Proposals may be submitted at any time so that research support may be available at the completion of the research development experience. No salary support for the investigator may be requested from the research grant application for the time during which the salary support is from the Clinical Investigator Award. Funds to support research, travel, supplies, equipment may be requested.

IV. REVIEW CRITERIA:

Applications for the NIEHS Clinical Investigator Award receive initial merit review by an NIEHS review committee and subsequently by the National Advisory Environmental Health Sciences Council.

Criteria for review include:

- Candidate's development in research and clinical experience in the specified area of interest.
- Candidate's plans for research development.
- Candidate's potential for a career in independent research in the area proposed.

- Candidate's commitment to a research career in the area of interest.

- Technical merit of the research proposal.

- Research development institution's ability to provide the clinical research experience and guidance required to develop the candidate into an independent clinical investigator.

- Ability and plans of the preceptor (or preceptors) who will provide the candidate with the guidance and experience necessary for career development in biomedical research.

- Presence of highly qualified and experienced faculty at the research development institution.

- Applicant institution's commitment to providing the facilities and opportunities necessary to the individual's research development during years four and five.

- Applicant institution's plans for program development in clinical environmental health research upon return of the candidate.

V. APPLICATION AND FURTHER INFORMATION

Applications for NIEHS Clinical Investigator Awards are accepted in accord with the usual NIH application-receipt dates of February 1, June 1, and October 1. It is important that potential applicants consult with staff of the NIEHS prior to the submission of applications to determine if the proposed program fits the criteria and the mission of the Institute. Further information and application materials may be obtained from:

Christopher O. Schonwalder, Ph.D.
Program Director
Research Manpower Development Section
Scientific Programs Branch
Extramural Program

Telephone: (919) 541-7634

ANNOUNCEMENT

NIGMS SHARED INSTRUMENTATION GRANTS

NATIONAL INSTITUTE OF GENERAL MEDICAL SERVICES

Application Receipt Date: February 15

The National Institute of General Medical Sciences (NIGMS) reannounces the availability of a grant mechanism for the acquisition of new, or the updating of existing, major research instruments which cannot be justified fully for use on a single project but which can serve several projects on a shared basis. The intent of this grant is to provide NIGMS grantees with better access to modern instrumentation and to encourage the sharing of expensive equipment. Although the needs of NIGMS grantees are the primary basis on which these shared instrumentation grants will be awarded, access to the instruments provided by this mechanism will not be restricted to NIGMS grantees nor to investigators within the particular grantee institution.

Within any given year, limited funds may be available for this type of grant. Competing demands of regular research grants on the Institute's budget will be a factor in determining the number of awards to be made.

I. MECHANISM OF SUPPORT

Each NIGMS Shared Instrumentation Grant will provide support for an instrument, instrument system, or for the upgrading of an existing system. Each item or system must cost at least $30,000. Stand-alone computers or relatively routine general purpose equipment, such as scintillation counters or preparative ultracentrifuges, will not be considered for an award. Grants will be awarded for a period of up to three years and are not renewable. Besides the cost of the instrumentation, support for maintenance of the equipment may be requested for the period of the grant. In cases where at least 25% of the planned use of the equipment will be by users other than the major user group (see eligibility requirements, below), support for technical assistance up to a maximum of one-half the salary of a qualified technician may be requested for up to three years. Provisions for continued maintenance of the equipment and for technical support beyond the period of the grant must be made by the applicant institution and these plans must be detailed in the application.

Although there is no upper limit to the cost of instrumentation that can be requested, the maximum contribution from NIGMS in the equipment category will

This program is described in the Catalog of Federal Domestic Assistance Numbers 13.821, Physiology and Biomedical Engineering; 13.859, Pharmacology-Toxicology Research; 13.862, Genetics Research; and 13.863, Cellular and Molecular Basis of Disease Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

be $200,000 for any one award. If this amount does not cover the total cost of the equipment, an award will not be made unless the remainder of the funding is assured. Assurance of co-funding, signed by an appropriate institution official, must be presented prior to the issuance of an award.

Since the evaluation of an application involves several users and depends so heavily on the particular conditions at a given institution, a grant for shared instrumentation will, in general, not be transferrable between institutions.

II. ELIGIBILITY

The principal investigator on an application for a shared instrumentation grant must hold an active NIGMS research grant and must assume responsibility for the instrument and for all related administrative functions. A major user group of three or more investigators (including the Principal Investigator) must be identified who will use the equipment at least 75% of the time. At least one of this group must have sufficient expertise to instruct others in the use of the equipment and to oversee its appropriate use. Each major user must have NIH research support at the time of award and at least one-half, but a minimum of two, of the major users must hold NIGMS grants. If the major user group does not need the equipment for 100% of the available instrument time, up to 25% of the time may be made available to other users. These other users need not have NIH grant support.

III. APPLICATION PROCEDURES

A. Application Format

Applications are to be submitted on the standard PHS research grant application form (PHS-398, Rev. 5/80) available from most institutional business offices or from the Division of Research Grants, NIH. Instructions supplied with these forms should be followed except as described below:

1. Face page of the application

   a. Item 1. The instrument requested should be named in the title of the proposal.

   b. Item 2. Write in "NIGMS SHARED INSTRUMENT GRANT"

2. Application page 2. Identify the principal investigator and each member of the major user group. Identify, by grant number, the currently active NIH research support for these individuals.

3. Application page 4. A detailed breakdown of the direct costs requested should be shown on the budget page. Provide a complete description of the instrument including manufacturer, model number and cost including tax and import duties, if applicable. If possible, the model chosen should be justified by comparing its performance with other available instruments.

4. Biographical Sketch. In addition to the personnel listed on page 2, include a biographical sketch of the person(s) who will be in charge of maintenance and operation of the instrument and a brief statement of the qualifications of that individual. Biographical sketches should not exceed two pages for each individual.

Section 2 of the application. Provide information relative to the points identified under criteria for review including:

1. A description of similar instruments existing at the institution or at nearby institutions and a justification as to why new or updated equipment is needed. A clear justification should be given for the choice of the instrument and for ancillary accessories requested.

2. A description, by major users, of the research projects for which the instrumentation is required. The descriptions need not be of the detail found in a regular research grant application (should not exceed 4 pages) but should point out the benefit of the proposed instrument to the research objectives of each major user. An estimate of the percentage use of the instrument time for each project should be given. In cases where the instrumentation will be available to users other than the major user group, a plan for providing access to those users should be detailed.

3. A description of the organizational plan for administration of the grant.

4. A specific plan and a statement of institutional commitment to operate and maintain the instrument for its useful life at the same utilization level after termination of the three-year period of NIGMS support. A commitment from the institution for necessary space or renovation will be required.

IV. CRITERIA FOR REVIEW

A. The following factors will be considered in the peer review of shared instrumentation grants.

1. Need for instrumentation. The needs of both the major user group and other potential users will be considered in assessing need.

2. The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.

3. Appropriate expertise within the major user group for use of the instrumentation.

4. Adequacy of arrangements for sharing of the equipment and for making it accessible to users other than the major user group when this is part of the justification for the instrument.

5. Institutional commitment for continued support and maintenance of the equipment - this may be through user charges if adequate grant support can be demonstrated.

V. CRITERIA FOR AWARDS

A. Due to the limitation of funds available to this program, additional criteria may be considered by the Institute in making funding decisions. They may include:

1. Geographic distribution of awards.

2. Balance between types of instruments supported.

VI. RECEIPT AND REVIEW

There will be one receipt date annually - February 15 of each year. Review will be by review groups specially constituted according to the types of applications received. Applications will go to Council in October of the same year and awards will be made no earlier than December 1 of that year.

Inquiries can be addressed to:

Dr. Marvin Cassman
National Institute of General
Medical Sciences
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7463

At the time a formal application is mailed to the Division of Research Grants, the applicant should inform the individual designated above, in writing, that the application has been submitted. The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENT

RESEARCH ON INFECTIOUS DISEASES IN THE ELDERLY

NATIONAL INSTITUTE ON AGING

NATIONAL INSTITUTE ON ALLERGY AND INFECTIOUS DISEASES

Application Receipt Dates: February 1, June 1, and October 1

The National Institute on Aging (NIA) and the National Institute of Allergy and Infectious Diseases (NIAID) announce a continuing interest in supporting research on infectious diseases in the elderly.

I. BACKGROUND

Morbidity and mortality from infections increase markedly with age. Influenza, pneumonia, and other infections account for a large share of deaths in the elderly. Chronic diseases increase the risk and complications of many infections in older persons. The prevention and treatment of infections in nursing homes and other long-term care settings present problems which have not been systematically studied. Optimal prevention and treatment of infections in the elderly require research on the effects of age-related factors on occurrence and outcomes of infection.

II. RESEARCH GOALS AND SCOPE

A. Epidemiology

1. Prevalence and incidence data are needed regarding many important aspects of infections in the elderly. For infections at several sites (e.g. decubitus ulcers, enteric infections) and by many agents (e.g., respiratory syncytial virus) epidemiologic data are lacking. Altered presentation of tuberculosis and other infections in the elderly may contribute to erroneous prevalence and incidence estimates. Studies of alternative surveillance techniques are needed to clarify this question. Probable differences in patterns of infection between the "young-old" and "old-old" accentuate the need for age-stratified data. Epidemiologic data are needed on nosocomial infections in nursing homes and other long-term care settings.

This program is described in the Catalog of Federal Domestic Assistance Nos. 13.866, Aging Research, and 13.856, Microbiology and Infectious Disease. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

2. Retrospective and prospective studies of infections and their complications in the elderly could clarify their relationship to risk factors such as:

   a. various chronic diseases (e.g., diabetes mellitus and chronic obstructive pulmonary disease);

   b. ambulatory, nutritional, functional, and mental status;

   c. specific types of care settings (acute care hospitals, nursing homes, etc.);

   d. "normal" age-associated changes in the immune system, mucociliary clearance mechanisms, and other functions affecting susceptibility to infection.

B. Pathogenesis and Complications of Infections in the Elderly

The extent, specificity and causes of age-related changes in susceptibility to various human pathogens require further exploration. The relative prevalence of the major pathogenic species and strains in bacterial pneumonia appears to be altered in the elderly. The cause of such changes and the extent to which they are found in other infections remain mostly undertermined. The contribution of age-associated physiologic changes to the reactivation of infections such as tuberculosis and varicella zoster virus also needs examination.

Though age-related changes in some aspects of the immune system (e.g., lymphocyte subpopulations and responses to certain mitogens) have been well-documented in humans, their relationship to the risk of specific infections in the elderly has not been clarified. Additional data are needed on the extent to which possible age-related changes in macrophage and neutrophil function, complement and other "cascade" pathways, chemotactic mechanisms, and the secretory immune system may affect resistance to infections.

There is suggestive evidence that age-related alterations at mucosal surfaces may affect susceptibility to infection. Research is needed on the effects of changes in normal bacterial flora, bacterial adherence, epithelial responses to viral infection (which may in turn affect susceptibility to secondary bacterial infection), and mucociliary clearance mechanisms. The role of other age-associated physiologic changes (such as increased residual bladder volume and increased propensity to aspirate oropharyngeal secretions) needs further study. The effects of deficiencies in phyridoxine and other nutrients on resistance to infection in the elderly also merit consideration.

Complications of many infections appear to be increased in the elderly. Cardiovascular mortality associated with influenza infections appears to be heightened in the elderly. In certain infections, the elderly may be more prone to septicemia and disseminated intravascular coagulation. Research is needed on the potential role of age-associated physiologic changes in predisposing to these and other complications of infections.

For many infections, the effects of "normal" aging on pathogenesis and complications of infections may be less important than the effects of chronic

diseases of the elderly and the medical, surgical and diagnostic interventions (e.g., urinary catheterization, prostatectomy, cystoscopy, administration of neurolepticagents) which accompany them. Hence, studies on the pathogenesis of infections in the elderly should address the effects of both aging and chronic disease, and make clear distinctions between them.

C. Diagnosis

Prompt and accurate diagnosis is particularly important in the elderly, who have a reduced rate of recovery from many infections. Despite numerous anecdotal reports of altered presentation of many infections in older persons, there is little objective information on this point, or on the sensitivity and specificity of various diagnostic techniques in the elderly. Reactivity to tuberculin skin tests in the aged shows considerable variability. Increased oropharyngeal colonization in elderly persons with potential bacterial pathogens aggravates problems in the use of sputum cultures in diagnosing pneumonia. Comparisons of the sensitivity and specificity of alternative strategies are needed to increase accuracy and efficiency in diagnosing these and other infections in the elderly.

D. Therapy and Prevention

Age-stratified data are needed on the efficacy, and frequency of side-effects, of current antibiotic therapies for infections. The risks vs. benefits of treating asymptomatic bacteriuria in older persons are not clear; prospective studies could contribute critical information. Since the relative prevalence of common pathogens in bacterial pneumonia and other infections of the elderly appears to depend in part on institutional setting and underlying diseases, the possibility of differences in optimal "empiric" antibiotic therapy for various subgroups of elderly patients needs examination.

Despite long-standing recommendations for influenza vaccination for the elderly, only about 20% of older persons receive immunization annually. Although the elderly account for the major share of tetanus-associated mortality in this country, a similar problem exists with low rates of immunization with tetanus toxoid. Studies on factors affecting the elderly's participation in vaccine programs could help to improve these rates.

The immune response to certain vaccines appears to be substantially impaired in many elderly. After vaccination, the time cause of antibody response, the persistence of effective titers, and the degree of protection conferred by a given titer may be altered with increasing age. Also, since the secondary response to many antigens may decrease less with age than the primary response, efficacy in the elderly of certain vaccines might be improved by primary immunization in early rather than later life. Evaluating the causes and degree of impaired response to vaccines in the elderly could help in improving immunization strategies and developing alternative prophylactic approaches.

Since risk for infections such as influenza and pneumonia varies widely among the elderly, efficacy studies on specific subpopulations (e.g., nursing home residents) could help improve targeting and cost-effectiveness evaluation of immunization and other prevention programs. The prevalence of nonvaccine serotypes in pneumococcal pneumonia in immunized and nonimmunized

elderly populations needs close monitoring with regard to the future application and development of this vaccine. Other preventive measures, such as influenza vaccination for nursing home employees, need evaluation. The extent to which improved nutrition and ambulation may reduce infections in certain subgroups of elderly has not yet been thoroughly studied.

Other potential prevention strategies require preliminary studies: Optimal application in the elderly of new vaccines for viral and bacterial agents will depend on understanding age-related factors affecting pathogenesis and host response. Since T-cell function may be particularly impaired in older persons, the possibility that "T-independent" vaccines may be more effective in the elderly merits consideration. New techniques for production of pure antibody species suggest an increased potential role for passive immunization of the elderly, whose immune responses are commonly slowed. The possibility of preventing infections in the elderly by replacement therapy to correct immunologic deficits remains experimentally unexplored. In vitro assays of the effects of specific factors on human antiviral and antimicrobial cell function may be useful in preliminary studies on this question.

The above research areas illustrate the breadth of fertile topics for investigation; they are not intended to limit applications in any research area related to infectious diseases in the elderly. The NIA and NIAID are interested in all innovative research on the epidemiology, pathogenesis, diagnosis, prevention and treatment of this problem. A bibliography on infections in the elderly, developed by participants in an NIA/NIAID workshop on this topic, is available from the NIA and NIAID staff contacts listed at the end of this announcement.

III. MECHANISMS OF SUPPORT

Applications may be submitted for any of the conventional NIH grant support mechanisms, including the individual research project grant, program project, Clinical Investigator, New Investigator, Research Career Development, and Special Initiative Awards, and individual and institutional post-doctoral Research Service Awards (NRSAs). 1/ (The NIAID will accept program project applications only in response to a specific Request for Applications and not as a result of this announcement.) The above list is not exhaustive; potential applicants are encouraged to communicate with the NIA and NIAID staff contacts listed at the end of this announcement regarding funding mechanisms and project design. Potential applicants for program project awards should contact NIA and NIAID staff very early in the planning stages.

1/ NRSAs will be supported under the authority of the Public Health Service Act, Section 472, 42 USC 2891-1, and administered under PHS grants policy and Federal Regulation 42 CFR Part 66.

IV. APPLICATION AND REVIEW PROCEDURES

Applications should be submitted on PHS Form 398 (research grants), PHS Form 6025 (institutional NRSA) or PHS Forms 416-1, 416-2, and 416-3 (individual NRSA).

Applicants may obtain information and the appropriate application kits from their institution's grants office or by writing or calling:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

Applicants are strongly encouraged to send a letter of intent to the NIA and NIAID staff contacts listed at the conclusion of this announcement at least 30 days before sending the completed application to the Division of Research Grants (address below). The letter of intent should include the title of the application, name of principal investigator and institutional address. If not, a brief abstract should be sent, followed as soon as possible by a copy of the completed application.

Applicants should enter the phrase "NIA/NIAID Program Announcement: Infectious Diseases in the Elderly" in response to Item 2 (Response to a Specific Program Announcement) on the first (face) page of their application. Applications should be submitted according to the deadlines for the appropriate review schedule and mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

One copy of the face page of the application should also be sent at this time to NIA and NIAID staff contacts listed at the end of this announcement. Applications will be reviewed for scientific merit either by an appropriate study section of the Division of Research Grants or by NIA or NIAID review committees, depending on the funding mechanism being sought. Review will be conducted in accordance with NIH policy and procedure involving peer review. Awards will be made on a competitive basis with all applications competing for NIA and NIAID funding.

V. APPLICATION RECEIPT DATES

For institutional and individual NRSAs, clinical investigator awards, senior fellowships, RCDAs, program projects, and competing continuations, the deadline dates are February 1, July 1, and October 1.

For new research grant applications not identified above, the deadline dates are March 1, July 1, and November 1.

VI. INQUIRIES AND CORRESPONDENCE

Correspondence, including requests for information, letters of intent, and advice should be directed to:

Evan Hadley, M.D.
Biomedical Research and Clinical
Medicine Program
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C-21
Bethesda, Maryland 20205

Telephone: (301) 496-1033

and

Dr. John LaMontagne
Microbiology and Infectious
Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 750
Bethesda, Maryland 20205

Telephone: (301) 496-7051

ANNOUNCEMENT

FUNDAMENTAL NEUROSCIENCES PROGRAM

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Application Receipt Dates: March 1, July 1 and November 1

The Fundamental Neurosciences Program (FNP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is reissuing this program announcement designed to encourage the submission of applications for research grants in the neurophysiology of cognitive processes.

I. PURPOSE

This announcement is intended to stimulate new approaches to the experimental and conceptual aspects of research on those types of cognitive processes which can be studied at the neural level in both animal and human research. A primary goal should be to characterize the sources and time course of neural activity (where feasible in its relation to unit activity) related to these processes.

II. SCOPE

Projects of the following types illustrate this area:

A. Animal research:

1. Involving innovative methods and concepts for the definition and analysis of cognitive processes in experiments that are designed in response to new knowledge about the nervous system.

2. Applying recently established knowledge about cognitive processes in humans to the design of neurophysiological experiments in animals.

3. Requiring collaboration between scientists who are expert in the cognitive sciences and those who are expert in the neurobiological sciences.

This program is described in the Catalog of Federal Domestic Assistance,No. 13.854, Fundamental Neurosciences. 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 grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems review.

B. Human research:

1. Developing new methods, concepts, and paradigms for research on cognitive processes that lead specifically toward studies of the underlying neural activities.

2. Applying recent advances in neurobiology to experiments using clinical neurophysiological and/or neuropsychological approaches to the study of cognitive processes.

3. Bringing experts in neurobiological research into collaboration with cognitive scientists.

III. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on form PHS 398 following instructions contained in the application kit. The applications will be judged solely on scientific merit in accord with NIH policy and procedures involving peer review. Initial review will be by the appropriate study section of the Division of Research Grants. The final review will be by the National Advisory Neurological and Communicative Disorders and Stroke Council. Applications judged more responsive to program interests of other Institutes will be assigned accordingly.

Deadline dates for the receipt of the applications are March 1, July 1, and November 1.

The phrase, "THE NEUROPHYSIOLOGY OF COGNITIVE PROCESSES," should be typed in Section 2 on the front page of the grant application form. The original and six copies of the application should be mailed to the following address:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

One copy of the application is to be sent to the address below. Also, for further information applicants may contact

Dr. W. Watson Alberts
Deputy Director
Fundamental Neurosciences Program
National Institute of Neurological
and Communicative Disorders and Stoke
Federal Building - Room 916
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (310) 496-1447

☆ U.S. GOVERNMENT PRINTING OFFICE: 1982-381-144:208