

NIH Guide for Grants and Contracts

Vol. 14, No. 7, June 21, 1985

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

IN THIS ISSUE:

Notice

To All Concerned With National Research
Service Awards (NRSA) Page 1
National Institutes of Health
Index - STIPENDS

Notice

Moratorium on Acceptance of Program Physician
Scientist Award Applications Page 2
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
Index - ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES

Notice

Five Year Project Periods for NIADDK Center Grants..... Page 3
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
Index - ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES

Notice

ADAMHA Peer Review Appeals System Page 4
Alcohol, Drug Abuse, and Mental
Health Administration
National Institute on Alcohol Abuse
and Alcoholism
National Institute on Drug Abuse
National Institute of Mental Health
Index - ALCOHOL, DRUG ABUSE, AND MENTAL
HEALTH ADMINISTRATION

Continued

The NIH 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.

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.

Page 2 - NIH Guide for Grants and Contracts - Vol. 14, No. 7, June 21, 1985

Errata - Announcement

**Availability of Request for Cooperative Agreement
Applications: 85-CA-13 - Clinical Evaluation
of Models of Biochemical Modulation Page 7
National Cancer Institute
Index - CANCER**

Announcement

**Availability of Request for Applications: RFA
85-CA-19 - Differentiating Agents in Human
Malignancies Page 8
National Cancer Institute
Index - CANCER**

Announcement

**Availability of Request for Applications: RFA
85-HD-11 - Mechanisms of Immunologic Infertility..... Page 10
National Institute of Child Health and
Human Development
Index - CHILD HEALTH AND HUMAN DEVELOPMENT**

Announcement

**Availability of Request for Applications: RFA
85-HL-27-H - Molecular Characterization of Ion
Channels in the Myocardial Sarcolemma Page 12
National Heart, Lung, and Blood Institute
Index - HEART, LUNG, AND BLOOD**

Announcement

**Availability of Request for Applications: RFA
85-HL-28-L - Alpha-1-Proteinase Inhibitor
Deficiency and Emphysema - Molecular Studies Page 14
National Heart, Lung, and Blood Institute
Index - HEART, LUNG, AND BLOOD**

Announcement

**Addendum to NIH Guide for Grants and Contracts -
Vol. 14, No. 5, April 26, 1985 - Minority
Institutional Research Training Program..... Page 15
National Heart, Lung, and Blood Institute
Index - HEART, LUNG, AND BLOOD**

Announcement

**Prevention Research on Mutual Support Approaches
with Bereaved Populations - MH-86-05 Page 16
National Institute of Mental Health
Index - NATIONAL INSTITUTE OF MENTAL HEALTH**

Continued

Announcement

Research on Methods for Studying Mental Health
Service Systems - MH-86-06 Page 19
National Institute of Mental Health
Index - NATIONAL INSTITUTE OF MENTAL HEALTH

Notice

Revised NIH Grant Policies and Procedures Page 23
National Institutes of Health
Index - NATIONAL INSTITUTES OF HEALTH

NOTICE

To All Concerned With National Research Service Awards (NRSA)

P.T. 22, K.W. 0720005

We have had many inquiries about the erroneous statement concerning the taxability of NRSA stipends which appeared in Publication 520 (Rev. Nov. 84) Scholarships and Fellowships.

A correction to publication 520 appeared in the March 12, 1985 (1985-8) Tax News issued by the Department of the Treasury, Internal Revenue Service. It reads:

"1. Correction to Publication 520

Publication 520, Scholarships and Fellowships, (revised November 1984) states that National Research Service awards received after 1983 by individuals under the Public Health Service Act of 1974 are not treated as scholarships or fellowship grants (which are excludable under section 117 of the Internal Revenue Code). This is incorrect. On the basis of a 1981 amendment to the Act, the awards are now treated as excludable from the recipients' gross incomes as scholarships or fellowship grants.* See Rev. Rul. 83-93, 1983-1 C.B. 364, which revoked Rev. Rul. 77-319, 1977-2 C.B. 48."

*Underlining added for emphasis

NOTICE**MORATORIUM ON ACCEPTANCE OF PROGRAM PHYSICIAN SCIENTIST AWARD APPLICATIONS**

P.T. 34; K.W. 1014002

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Beginning with the October 1, 1985 application receipt date, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) will no longer accept new or amended applications for Program Physician Scientist Awards. It is hoped that competing applications can again be accepted for review and possible funding at a future time.

Applications for individual Physician Scientist Awards will continue to be accepted by NIADDK.

NOTICE

FIVE YEAR PROJECT PERIODS FOR NIADDK CENTER GRANTS

P.T. 04; K.W. 1014002

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) supports a number of groups of investigators through the use of research center grant mechanisms. Currently, three such mechanisms are in use: the Comprehensive Research Center (P60), the Specialized Center of Research (P50), and the Core Center (P30). It has become increasingly clear that center grants awarded for project periods of less than five years are not optimal, and the NIADDK is adopting a policy of fixing the project periods of all center awards at five years except under very unusual circumstances. Beginning with the application receipt date of October 1, 1985, all applications for center awards assigned to NIADDK must request a project period of five years. Review groups will be instructed that special justification must accompany recommendations of project periods of less than five years. Similarly, individual components and core units should be approvable for periods of five years except under unusual conditions. Applicants proposing pilot and feasibility studies of one, two, or three years in duration should consult NIADDK staff regarding the appropriate format for proposing a five year program of such studies

The NIADDK believes that this policy will increase both efficiency and effectiveness of research activities supported by center grant mechanisms. Questions regarding this policy should be directed to:

Dr. Walter S. Stolz, Director
Division of Extramural Activities,
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
5333 Westbard Avenue - Room 657
Bethesda, Maryland 20205

Telephone: (301) 496-7277

NOTICE**ADAMHA PEER REVIEW APPEALS SYSTEM****P.T. 34, 44; K.W. 1014002****ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTE OF MENTAL HEALTH**

The Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) has initiated an appeals process whereby applicants may request an examination of their concerns about the referral and peer review of their applications for research grants, research training grants and fellowships, and cooperative agreements for research.

This process is intended to resolve those concerns which arise from perceived shortcomings or errors in the substance or procedure of peer review—i.e., from receipt and assignment of an application through its review by a National Advisory Council. Such concerns may involve refusal to accept an application; a disputed assignment of the application to an initial review group or to a particular Institute; perceived insufficient expertise on the initial review group or site visit team or conflict of interest on the part of one or more members; apparent factual or scientific errors, oversights, or bias associated with the review of an application at the initial or advisory council review; and perceived inappropriate handling of the review of the application.

However, the appeals process is not intended to resolve purely scientific disputes between peer reviewers and the investigator; to provide a mechanism for allowing investigators to submit information that should have been presented in the original proposal; or to provide a forum for disputing priority score determinations in the absence of specific and substantive evidence pointing to a flawed review.

The appeals process will not supersede or bypass the peer review process, but if serious shortcomings are found to have occurred in the review of an application, they will be rectified by one of the following actions: re-review by the same or another initial review group; special consideration by the advisory council; or administrative action authorized by the Institute Director or designated staff.

As in the past, investigators are urged to communicate and discuss their concerns regarding peer review with appropriate staff. Now, if investigators are still dissatisfied after a response is received to their communications, they also may request a further examination of these concerns.

Under the appeals system, all concerns must first be communicated to the unit which at the time is responsible for the application. Appropriate officials will thoroughly examine the investigator's concerns, frequently with the help of the initial reviewers or other experts, and, if shortcomings are found to have occurred, every effort will be made to rectify them in a timely manner.

If the principal investigator disagrees with the resolution of his/her concerns by the responsible Institute staff, an appeal, jointly signed by the PI and applicant organization, may be sent to the designated Institute Appeals Officer whose name and address appears

below. The appeal must include documentation of the original dispute, previous communications and interactions with staff in relation to the dispute, and a clear statement of the reasons for disagreeing with the resulting decision. To allow for a complete and independent examination of the appeal--which will frequently entail consultation with scientific or other experts--the application will be withdrawn from the regular review process until the appeal is resolved. An amended application submitted during consideration of the appeal will inactivate the original application and the accompanying appeal. The Institute Director will render the final decision on the appeal and communicate it to the applicant.

HOW TO USE THE APPEALS SYSTEM:

Communications before the Initial Review

After being notified about the assignment of an application to the initial review group and the awarding Institute, the principal investigator may direct his/her serious concerns about the assignment of the application to the ADAMHA Grants Referral and Review Officer, 5600 Fishers Lane, Room 13-103, Rockville, Maryland 20857. Concerns about the pending review of the application should be directed to the Executive Secretary of the assigned initial review group.

Communications after the Initial Review

After having received the summary statement, the principal investigator may direct his/her questions about the review to the Executive Secretary, who will respond or refer the communication to the appropriate person for response. Communications may be submitted at any time, including after National Advisory Council review, but investigators are encouraged to communicate their concerns as early as possible.

Appeals

After having received the reply to a communication, and if the principal investigator disagrees with the decision, he/she and the applicant organization may appeal by submitting the necessary documentation to the appropriate Institute Appeals Officer:

NIAAA

Deputy Director
National Institute on Alcohol and Alcoholism
Room 16-105

NIDA

Executive Officer
National Institute on Drug Abuse
Room 10-15

NIMH

Associate Director for Extramural Programs
National Institute of Mental Health
Room 17C-26

All of the above are located in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Effective Date

This appeals system is effective upon issuance of this notice for applications assigned to September 1985 National Advisory Councils.

Comments

Comments are invited on this policy which will be evaluated after some experience has been gained with using the appeals system.

ERRATA

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS:

85-CA-13

CLINICAL EVALUATION OF MODELS OF BIOCHEMICAL MODULATION

P.T. 37; K.W. 0745005, 0755020, 0755015, 0740015, 0710100

NATIONAL CANCER INSTITUTE

Application Receipt Date: September 15, 1985

Please correct paragraph 3 under II. RESEARCH GOALS AND SCOPE as follows:

Many of the NCI sponsored IND drugs are leading candidates with biochemical modulatory properties. Applications are encouraged which focus on these or other drugs with biochemical modulatory properties. We expect the results of these studies to be published in the scientific literature in order to provide leads to the most rational use of these chemotherapeutic agents and to improve the treatment of cancer patients.

Please correct paragraph 2 under III. MECHANISMS OF SUPPORT as follows:

NCI anticipates making multiple awards as a result of this request. It is anticipated that \$750,000 will be set aside to fund the initial year's awards. Awards will be made for a period of up to five years. It is anticipated that the starting date for the initial annual period will be between July 1, 1986 and September 30, 1986. No set-aside funds have been provided for renewals.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-19

DIFFERENTIATING AGENTS IN HUMAN MALIGNANCIES

P.T. 34; K.W. 1002004, 0760020, 0740020, 0785035

NATIONAL CANCER INSTITUTE

Application Receipt Date: October 15, 1985
Letter of Intent Receipt Date: August 15, 1985

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites grant applications from interested investigators for a tightly focused, cohesive research program at the interface of basic research and concurrent clinical trials involving differentiating agents in human tumors.

A series of clinical observations has led to the current interest in differentiating agents as potential therapy for human malignancies. The current concept that cancers are composed of cells blocked at an early stage of normal maturation has stimulated a search for agents with potential differentiating effects. Such agents are particularly attractive since, in principle, they should have few effects on normal tissue and therefore, avoid many of the toxicities of chemotherapy or radiation therapy. Retinoids were one of the first classes of agents studied and were observed to induce differentiation in a number of in vitro systems. A wide range of compounds have subsequently been discovered, including polar solvents, fatty acids, vitamin D analogues, and several cytotoxic agents (pyrimidines, purines, anthracyclines) which cause differentiation in vitro at doses below the cytotoxic level. A broad spectrum of cellular alterations has been observed after treatment of established human tumor cell lines with these compounds. In most cases, however, there is no clear cause and effect relationship and the specific sites of growth control at the cellular level remain obscure.

Such in vitro observations have led to sporadic, empirical clinical trials of several differentiating agents. These trials, however, have yielded conflicting results and have methodologic flaws. For example, with similar schedules of low doses of Ara-C, complete response rates in acute leukemia and myelodysplastic syndromes range from 10% to over 50%; the drug has appeared to act as a maturational agent in some series and as a cytotoxic agent in others. There are several possible explanations for these and other discrepancies. First, the tumors which have been most frequently studied include

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Acute Myelocytic Leukemia (AML), myelodysplastic syndromes, and neuroblastoma, which are relatively uncommon, and important subgroup analyses have been lacking. Second, there are at present no clearcut biochemical effects for these agents at the cellular level which have been correlated with clinical efficacy. Indeed, there are limited data as to the clinical relevance of any of the laboratory phenomena described thus far. The central issue is the lack of methodology which permits distinguishing between cellular differentiation and cytotoxicity followed by regeneration.

Thus, while there is a substantial amount of ongoing basic research and an obvious timeliness for entry of potential differentiating agents into organized clinical trials, currently, there are limited, spontaneous correlative studies ongoing and many tumor types and laboratory techniques remain unaddressed. The accurate and precise measurement of treatment effect at a clinical level remains a serious problem in clinical trial design. Research directed at the development of such measures, based on accumulated pre-clinical experience, is an essential step in further clinical research.

I. RESEARCH GOALS AND SCOPE

Studies should be proposed for a tightly focused, cohesive research program at the interface of basic research and concurrent clinical trials involving differentiating agents in human tumors. These studies should emphasize:

- 1) Laboratory exploration of in vitro/in vivo systems for measuring differentiation/maturation that could have clinical applicability; and
- 2) Establishment of the validity of these measures in the clinical setting.

Applications will be sought which will develop laboratory-clinical interactions.

II. LETTER OF INTENT

A potential applicant institution is encouraged to submit a one-page letter of intent, including a brief synopsis of the proposed research Dr. Bruce Cheson on or before August 15, 1985 and to consult with NCI staff before submitting an application. A letter of intent is not binding, is not a requirement for consideration, and does not enter into the review of a subsequent application.

III. STAFF CONTACT

A copy of the RFA describing the research goals and scope, the review criteria and method of applying can be obtained by contacting:

Dr. Bruce Cheson
Senior Investigator
Clinical Investigations Branch
Cancer Therapy Evaluation Program
National Cancer Institute
Landow Building - Room 4A14
Bethesda, Maryland 20205

Telephone: (301) 496-2522

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****85-HD-11****MECHANISMS OF IMMUNOLOGIC INFERTILITY****P.T. 34; K.W. 0413002, 0710070, 0710065, 0710075****NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT**

Application Receipt Date: October 15, 1985

The Reproductive Sciences Branch (RSB) of the Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD) announces the availability of a Request for Applications (RFA) on Mechanisms of Immunologic Infertility. The purpose of this initiative is to stimulate research in an area important to the CPR mission that is currently not supported at appropriate levels. The need for increased research in this area rises from the significant increases in human infertility rates over the last decade. Between 1980 and 1982 alone, physician office visits for infertility problems rose from 900,000 to over 2 million. It has been estimated that infertility secondary to immunological factors may occur in 15-20 percent of couples with unexplained infertility. In a significant subset of infertile couples, therefore, it appears that immunologic infertility is a circumstance for which effective therapy has not been clearly established.

The RFA being announced is specifically designed to encourage research on the immunology and immunogenetics of sterility, subfertility, or infertility in mammals. Responsive applications would include, for example, those focusing on immunologically-based functional or dysfunctional processes of mammalian gonads, gametes or reproductive tract tissues that are directly involved in gamete production or maturation, fertilization, preimplantation embryo survival and transport, or conceptus implantation processes. Excluded from responsiveness to this announcement's intent would be studies directly related to the processes of malignancies or sexually transmitted diseases, prenatal diagnosis via chorionic or amniotic cell analyses, perinatal immunology, acquired immune deficiency disorders, and general studies of autoimmune or endocrine disease aspects unrelated to direct mechanisms of infertility. It is not the intent of this announcement to solicit research proposals designed to conduct general studies of

This program is described in the Catalog of Federal Domestic Assistance number 13.864, Population 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 the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

autoimmune diseases or immunological disorders. In the absence of a major, extensive, and predominant emphasis on infertility or fertility, such applications would not be considered responsive to the RFA. This announcement should be of particular interest to investigators concerned with 1) the detection, definition and characterization of hormone, sperm, or egg antigens associated with critical events or processes of gamete production or function; 2) the detection, definition, or characterization of immune system mediated early conceptus implantation failures; 3) the immunopathology of immune or autoimmune ovarian or testicular failure; or 4) the immunological consequences of gonad transplantation.

It is anticipated that up to eight (8) awards will be made as a result of this announcement through the grant-in-aid (R01) mechanism used by NICHD. Grant applications will be reviewed as a single competition by an initial review group convened by the Division of Research Grants (DRG), NIH.

Requests for a more detailed RFA and information inquiries should be addressed to:

Michael E. McClure, Ph.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - Room 7C33
Bethesda, Maryland 20205

Telephone: 301/496-6515

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****85-HL-27-H****MOLECULAR CHARACTERIZATION OF ION CHANNELS IN THE MYOCARDIAL SARCOLEMMMA****P.T. 34; K.W. 1002004, 0710050, 1002059, 0785025, 1013004, 0765015****DIVISION OF HEART AND VASCULAR DISEASES****NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date: December 16, 1985

The Cardiac Functions Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject.

This program will support fundamental research on the structure, function, and regulation of ion channels in the myocardial sarcolemma at the molecular level. The major purpose of this special grant program is to encourage the application of modern cellular and molecular technologies, along with recent advances in electrophysiological techniques, in an effort to isolate and determine the molecular structure of ion channels, to correlate ion channel structure with physiological function, and to elucidate the regulatory processes governing ion channel activity. The Division of Heart and Vascular Diseases anticipates that approximately 6-8 grants will be awarded under this RFA program.

This announcement may be of particular interest to investigators in disciplines which include biochemistry, biophysics, cardiology, cellular biology, developmental biology, electrophysiology, genetics, molecular biology, and morphology.

TIMETABLE

Letter of Intent	August 15, 1985
Application Receipt Date	December 16, 1985
Technical Review	March 1986
Advisory Council Review	May 22-23, 1986
Award Date	June 1986

INQUIRIES

Inquiries concerning this program and requests for copies of the RFA should be addressed to:

Stephen C. Mockrin, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 304
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1627

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****85-HL-28-L****ALPHA-1-PROTEINASE INHIBITOR DEFICIENCY AND EMPHYSEMA - MOLECULAR STUDIES****P.T. 34; K.W. 0760035, 0715165, 0765010, 0765015****NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date: December 16, 1985

The Division of Lung Diseases invites grant applications for a single competition for support of research on synthesis and secretion of alpha-1-proteinase inhibitor (A1-Pi, also known as alpha-1-antitrypsin) which is believed to provide protection for the lung against proteolytic breakdown, thereby preventing the development of emphysema. The long term goal of this program is to generate information that will provide a basis for attempts to increase the level of this protein in PiZZ individuals through pharmacologic manipulation or gene therapy. The specific objectives of this RFA program are to elucidate the mechanisms of regulation of transcription and translation of the A1-Pi gene, the post-translational modification as well as secretion and turnover of the protein in PiZZ individuals, and to compare these processes to those in individuals with normal levels of the antiprotease. The Division of Lung Diseases anticipates that approximately 6-8 grants will be awarded under this RFA program.

Inquiries regarding this announcement may be directed to the program administrator:

Zakir H. Bengali, Ph.D.
Airways Diseases Branch
Division of Lung Diseases, NHLBI
National Institutes of Health
Westwood Building - Room 6A15
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: 301/496-7332

ANNOUNCEMENT

ADDENDUM TO NIH GUIDE FOR GRANTS AND CONTRACTS - VOL. 14, NO. 5, APRIL 26, 1985

MINORITY INSTITUTIONAL RESEARCH TRAINING PROGRAM

P.T.44, FF; K.W. 0720005, 0715040, 0715165, 0785070

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: August 15, 1985

THE PURPOSE OF THIS ADDENDUM IS TO EXTEND ELIGIBILITY TO MINORITY HEALTH PROFESSIONAL SCHOOLS AND MINORITY POSTGRADUATE SCHOOLS.

The National Heart, Lung and Blood Institute (NHLBI) announces a program to support full time research training for investigative careers at minority schools in areas related to cardiovascular, pulmonary or hematologic diseases. Minority schools seeking this support must have: (1) graduate students, or; (2) health professional students who will take a minimum of one year from professional training, or; (3) postdoctoral students. The support mechanism will be the National Institutes of Health (NIH) institutional research training grant. Copies of the program guidelines are currently available from staff of the NHLBI, listed below.

Grants in this program will be made to minority institutions, each of which will cooperate with a research center that has a well-established cardiovascular, pulmonary, or hematologic research and research training program. Each trainee will be placed with a mentor who is an accomplished investigator at the cooperating research center and who will assist the advisor at the minority institution in the trainee's development and research plan. Guidelines for this program may be obtained from any of the following:

George A. Hayden, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A10
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan M. Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and
and Blood Institute
Westwood Building - Room 6A12A
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Luis Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1537

ANNOUNCEMENT**PREVENTION RESEARCH ON MUTUAL SUPPORT APPROACHES WITH BEREAVED POPULATIONS****MH-86-05**

P.T. 34; K.W. 0745055, 0715195, 0403004, 0795005, 0411005, 0715070

NATIONAL INSTITUTE OF MENTAL HEALTH

The National Institute of Mental Health (NIMH) seeks applications for research on intervention with bereaved individuals and families through a mutual support approach.

I. SPECIFIC AREAS OF RESEARCH INTEREST

Areas of specific research interest under this announcement are:

- o The characteristics of different mutual support interventions and their ability to prevent negative health and mental health consequences, reduce psychological distress, and also promote social and emotional functioning.
- o The characteristics of individuals who seek or make use of mutual support interventions and the relationship of those characteristics to outcomes.
- o Controlled experiments of the development, implementation, outcome, and evaluation of new mutual support programs with bereaved persons.
- o The empirical testing with controlled research designs of existing mutual support programs for bereaved persons.
- o The comparison of members' characteristics, processes, and outcomes of specifically created mutual support programs with existing naturally occurring mutual support programs.
- o The comparison of mutual support interventions with psychotherapeutic and/or pharmacological interventions.
- o The differential effect of mutual support interventions designed for various phases and aspects of the bereavement process, e.g., anticipatory grieving, immediate distress, longer term social adaptation.
- o The refinement of methodologies for preventive intervention research for studying naturally occurring support, such as mutual support groups.
- o The refinement of existing measurement instruments to assess different aspects of support.
- o Empirical studies of bereaved individuals or groups for whom there are few research findings, e.g., community samples of bereaved children, non-Caucasian and non-middle class samples, adults who lose a parent or sibling, family units, survivors of suicide.

- o Research which follows up subjects for at least two years.
- o Research comparing bereavement with other life stressors.
- o Research documenting and refining risk factors for poor outcome following bereavement in preparation for designing interventions.
- o The differential impact of interventions on high- versus low-risk individuals.

II. APPLICATION CHARACTERISTICS

Applications submitted under this announcement should be based on hypotheses generated from basic research on both the grieving process and social support/mutual support, should focus on mutual support interventions with bereaved persons or families, and should also address:

- o Age, sex, socioeconomic status, ethnicity, and other relevant characteristics of subjects, e.g., relation to deceased, prior health and mental health status, and their relation to the intervention content and outcomes.
- o The nature of the death, e.g., accident, terminal illness, acute illness, suicide, violence.
- o The phase of bereavement to which the intervention is addressed.
- o An awareness of cultural diversity in reactions to bereavement.
- o Intervention content and goals.
- o Type of intervenor (professional, lay, religious) and relation to outcome.
- o Specification and justification of intervention outcomes and their measurement, e.g., behavioral, psychological, and social.
- o Comparison of self-report and objectively measured outcomes.
- o Linking of outcomes to be assessed to intervention content and goals.
- o Possible iatrogenic effects of intervention.

III. PREAPPLICATION PROCEDURES

Potential applicants are encouraged to seek preapplication consultation from:

Anita Eichler, Project Officer
Bereavement Research Initiative
Center for Prevention Research
Division of Prevention and Special Mental
Health Programs, NIMH
Parklawn Building - Room 11C-06
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4283

IV. REVIEW PROCEDURES

Applications will be reviewed in accordance with the standard review procedures of the Public Health Service and in accordance with the usual NIMH receipt, review, and award schedule.

V. REVIEW CRITERIA

Criteria for review of applications will include:

- o Significance and originality from a scientific or technical standpoint of the goals of the proposed research.
- o Adequacy of scientific basis for the intervention.
- o Appropriateness and adequacy of the methodology to carry out the research.
- o Appropriateness of specificity of intervention content.
- o Appropriateness of design for collection and analysis of data.
- o Qualifications and experience of the principal investigator and proposed professional staff.
- o Reasonable availability of resources necessary for the research.
- o Reasonableness of the proposed budget and duration in relation to the proposed research.
- o Potential cost effectiveness, replicability, and generalizability for proposed intervention models.
- o Adequacy of provisions for the protection of human subjects.

VI. AWARD CRITERIA

Applications recommended for approval will be considered for funding on the basis of:

- o Scientific and technical merit, as determined by the peer review process.
- o Potential contribution to the areas identified in this announcement and balance among those areas.
- o Availability of funds.

VII. FURTHER INFORMATION

For further information, terms and conditions of support, and a copy of the complete announcement, applicants should contact Anita Eichler, Project Officer (see above).

ANNOUNCEMENT

RESEARCH ON METHODS FOR STUDYING MENTAL HEALTH SERVICE SYSTEMS

MH-86-06

P.T. 34; K.W. 0730050, 0408000, 0417000, 1010011, 0404020, 1010013

NATIONAL INSTITUTE OF MENTAL HEALTH

I. PURPOSE AND OBJECTIVES

This announcement is to encourage research directed toward the improvement of methods by which to conceptualize, identify, measure, characterize, analyze, and describe features of mental health service systems at local community, State, or national (including comparisons with other nations) levels.

All research projects supported under this announcement must develop generalizable knowledge. Since the ultimate goals of the National Institute of Mental Health (NIMH) are increased mental health, decreased mental illness, and more effective clinical and administrative practice, the methods to be developed must be applicable to clinical and administrative practice in mental health services. Priority will be given to projects which propose methods that are economical to use and apply to a range of important research issues and situations.

II. RESEARCH TOPICS

Areas in which research will be supported are:

- o The development, testing, and refinement of methods for identifying, assessing, and analyzing the pattern of relationships among mental health service organizations within a mental health service system (community, State, region, or Nation), and between mental health service organizations and other components of the mental health service system (e.g., other types of service providers, those who need and/or seek services, and service regulators).
- o The development, testing, and refinement of theories, concepts, and research methods for characterizing the structure, boundaries, and functioning of mental health service systems (derived from any of a variety of research disciplines, including, but not exclusively, organizational sociology, economics, applied history, operations research, mental health administration, mental health services research, and clinical fields).
- o The development, testing, and refinement of methods of assessing power, identifying control points, and characterizing decision-making within the mental health service system.
- o The development, testing, and refinement of system measures, as they influence the delivery of care, and the reciprocal impacts of such services on the general social, economic, and political environment, and on the mental health service system itself.

- o The development, testing, and refinement of simulation, modeling, and other operations research procedures to characterize the functioning of various mental health service systems.
- o The demonstration of ways to adapt existing methods of measuring service system characteristics and customary procedures of recording program and service information to yield measures of use in comparative studies of service systems.
- o The development of procedures to answer statistical and logical problems of dealing with all the components of a system in aggregate (e.g., the ecological fallacy).

III. REVIEW

Applications will be reviewed in accordance with the usual Public Health Service peer review procedures. They will first be reviewed for scientific and technical merit by an initial review group (IRG) composed primarily of non-Federal scientific consultants. The results will be reviewed by the National Advisory Mental Health Council. Only applications recommended for approval by the Council will be considered for funding.

IV. REVIEW CRITERIA

In review of applications, the IRG will consider:

- o Clarity, specificity, and importance to the mental health field of project objectives.
- o Quality of project design and methodology as evidenced by a detailed research plan, including:
 - clear description of the proposed research
 - valuable, feasible, and reasoned aims for the study
 - cogent theory or practice relevant hypotheses to be tested
 - appropriate kinds of data to be obtained and appropriate means by which the data will be collected, analyzed, and interpreted
 - recognition of the limitations of the procedures proposed and reasonable plans to overcome possible pitfalls
 - realistic timetable for the accomplishment of the main steps in the project
- o Significance of the issue(s) and potential of the project for improving future research on the mental health service delivery system, scope of research topics, and situations to which the new or revised research methods will apply.
- o Appropriateness of the sponsorship and collaborative arrangements to the nature of the problem and potential use of results.

- o Evidence of cooperation and commitment from significant persons and organizations whose support will aid the accomplishment of the project and acceptance and use of its results.
- o Quality of the plan for disseminating results of the project to appropriate audiences in a manner that will facilitate the use of the information.

V. RECEIPT AND REVIEW SCHEDULE

<u>Receipt of Application</u>	<u>Initial Review</u>	<u>National Advisory Mental Health Council</u>	<u>Earliest Award Date</u>
Nov. 1, 1985	March 1986	May 1986	July 1986
March 1, 1986	June 1986	September 1986	December 1986
July 1, 1986	Oct. 1986	February 1987	April 1987

Thereafter, applications may be submitted as part of the regular grant cycle.

VI. AWARD CRITERIA

- o Quality of the proposed project as assessed during the review process.
- o Relationship of the project to the goals of the NIMH Service System Research Program, and the likelihood that, if funded, the project will contribute significantly to improving the quality, replicability, quantity or economy of future research on important problems on the mental health service system.
- o Speed with which study results will be available.
- o Balance among projects in terms of approaches used and phenomena to be measured, disciplinary perspectives employed, and types of application of methods.
- o Availability of funds.

VII. STAFF CONSULTATION

NIMH staff are available for consultation concerning proposal development in advance of or during the process of preparing an application. Potential applicants should contact NIMH as early as possible for information and guidance in initiating the application process. Inquiries regarding the relevance of potential projects to the broader Mental Health Service System Research Program or regarding the technical aspects of proposal submission, research design, and methodology should be directed to one of the following staff:

James W. Thompson, M.D., M.P.H., Chief
 Service System and Economics Research Branch
 Charles Windle, Ph.D., Chief
 Service System Research Program or
 Armand Checker, M.A., Research Statistician
 Service System Research Program

Division of Biometry and Epidemiology
Parklawn Building - Room 18C-03
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4233

For a copy of the complete announcement and further information, such as application characteristics, procedures, and terms and conditions of support, applicants should contact one of the staff listed above.

NOTICE

REVISED NIH GRANT POLICIES AND PROCEDURES

P.T. 34; K.W. 1014002

The six NIH grant policy and procedure issuances listed below represent recent revisions and are reprinted on the pages which follow:

- 4209 - Cost Sharing in Research Grants
- 4805 - Research Grants Awarded to Non-Affiliated Individuals
- 4811 - Notification and Treatment of Released Funds Resulting From Issuance of a Research or Academic Career Award
- 4820 - Establishing and Operating Consortium Grants
- 5002 - Notice of Disposition of Grant Unexpended Balance
- 5806 - Overdue Reports - Discretionary Grants

(See Attached)

4209 - COST SHARING IN RESEARCH GRANTS

- A. Purpose This issuance revises the NIH policy concerning cost sharing requirements applicable to research project grants, and provides guidance in the negotiation of project-by-project cost sharing agreements as applicable for NIH research grants. It implements PHS Grants Administration Manual Chapter 2-140 and 1-400, and supersedes other instructions inconsistent with the present policy and instructions.
- B. Applicability This policy is applicable to all research projects supported by NIH grants except those awarded to other Federal agencies which are exempted from the requirement of cost sharing.
- C. References
1. PHS Grants Administration Manual Chapter 2-140, Cost Sharing in Research Grants
 2. PHS Grants Administration Manual Chapter 1-400, Matching and Cost Sharing
 3. DHHS Publication No. OS 75-50009, A Guide to Institutional Cost Sharing Agreements for Research Grants and Contracts Supported by the DHHS
 4. 45 CFR, Part 74, Subpart G, Cost Sharing or Matching
 5. NIH Manual Chapter 5601, Disposition of Grant Related Income
 6. NIH Manual Chapter 4820, Guidelines for Establishing and Operating Consortium Grants
- D. Definitions
1. Competitive Segment The initial period of recommended support (1 to 5 years) or each successive competing continuation period of a project period.
 2. Cost Sharing A cost participation requirement, included in the Department of Health and Human Services' annual appropriation acts, stating that HHS funds cannot pay for the entire cost of a research project. Cost sharing is a contribution by the grantee which may be in cash, in kind, or both, derived from either the grantee institution or from third party institutions, organizations, or individuals.

4209 - COST SHARING IN RESEARCH GRANTS

- E. Policy Cost sharing shall be required on every NIH grant-supported research project except those awarded to other Federal agencies. Non-profit grantee institutions may share in the costs of grant-supported research either through an institutional agreement covering the aggregate of all PHS research grants subject to cost sharing or by separate agreements for each research project (project-by-project basis). For profit organizations must cost share under the latter method.

Cost sharing requirements on foreign grants, grants to individuals, and, usually, conference grants are met through nonpayment of indirect costs.

- F. Responsibility DHHS has delegated responsibility for cost sharing administration as follows:

1. The Public Health Service is responsible for negotiating and administering institutional cost sharing agreements on behalf of all DHHS agencies. The PHS shall provide the operating agencies with current listings of all institutions having a cost sharing agreement, indicating the types of agreements and the effective dates. Grantee institutions submitting institutional cost sharing proposals should direct them to:

Chief, Cost and Audit Management Branch
Division of Grants and Contracts
Public Health Service
Parklawn Building, Room 18A30
5600 Fishers Lane
Rockville, Maryland 20857
Telephone: (301) 443-3080

NIH awarding units needing information concerning institutional cost sharing agreements should contact the following NIH office which has liaison responsibility with the PHS office identified under F.1.

Grants Policy Office
Office of Extramural Research and Training
Building 31, Room 1B58
Telephone: 496-5967

2. The NIH awarding units are responsible for:
 - a. Ascertaining prior to award whether the proposed grant is covered by an institutional cost sharing agreement as shown on the list provided by PHS, and, if so, to indicate on awards that an institutional agreement is in effect, and to cite the effective date of the agreement.

4209 - COST SHARING IN RESEARCH GRANTS

- b. The negotiation and administration of an individual project cost sharing agreement in the absence of an institutional agreement for non-profit grantees and in all cases for for-profit grantee organizations.

G. Implementation

1. General Guidelines

As applicable, awarding units should encourage the use of institutional cost sharing plans covering all PHS research grants to non-profit institutions. Institutional plans (1) provide the most meaningful basis for showing the extent to which non-Federal funds contribute to the cost of research which is also supported from Department funds at a given institution, (2) give maximum flexibility to grantees as to the method used to meet the established cost sharing level, and (3) simplify administration of the research project application, review, negotiation, award and reporting procedures for both the institution and the awarding unit.

The amount of cost sharing may vary in accordance with a number of factors relating to the type of grantee organization and the character of the research effort. In the final analysis the amount of cost participation should reflect the mutual agreement of the parties, provided that it is consistent with any statutory requirements.

For specific guidance on extent of cost sharing and valuation of in-kind contributions from third parties see PHS Grants Administration Manual Chapters 2-140 and 1-400.

2. Project-by-Project Cost Sharing Agreements

In the absence of an institutional cost sharing agreement and in all cases involving for-profit grantees, project-by-project agreements will be negotiated and administered by the NIH awarding unit within the following guidelines:

- a. The awarding unit shall request the applicant institution to submit an individual cost sharing proposal for each competitive segment (1 to 5 years) at the time it is notified that a project will be funded. A suggested format containing the information required is attached (see Illustration I).

4209 - COST SHARING IN RESEARCH GRANTS

- b. The proposal will cover the entire competitive segment and will state the minimum percentage of total allowable project costs (i.e., the combined Federal and grantee shares) which the applicant proposes to contribute to the planned research. A proposal of less than 5% of non-Federal costs contribution for each competitive segment requires justification by the applicant and approval by the awarding unit's Grants Management Officer. The grant may not be awarded until the applicant and the awarding unit have agreed to a cost sharing percentage. This percentage shall be specified on the Notice of Grant Award to signify the awarding unit's acceptance of the applicant's proposal.
- c. There may be no contribution, or only a token contribution, in some years of the competitive segment provided that the agreed overall percentage for the project as a whole is met. Separate cost sharing proposals will not be required for subsequent noncompeting continuations and supplements of the same competitive segment. If there is an early termination of the project, the negotiated cost sharing percentage will apply to the actual abbreviated period of Federal support.
- d. The grantee contribution must be project-related and may be from any non-Federal source except for those made by a Veterans Administration hospital participating with the grantee in a project. Grantees will not be required to obtain prior awarding unit approval of the budget categories in which costs are to be contributed. The contribution may be in any allowable budget category or combination of categories such as salaries, equipment, supplies, travel, or indirect costs.
- e. Expenditure of the Federal share of grant-related income will not be allowed to meet cost sharing agreements except for grants under those programs where it is clear that legislative intent was to permit such income to be used for that purpose.
- f. Grantee institutions should not submit individual cost sharing proposals until notified by the NIH awarding unit that an application has been approved and that a cost sharing agreement is required.

4209 - COST SHARING IN RESEARCH GRANTS

- g. At the termination of each competitive segment, the awarding unit will verify the amount of cost sharing reported against the percentage agreed to at the initiation of the competitive segment. If the cost sharing percentage is less than that agreed to but still 5% or greater, the awarding unit shall review the contributing factors and make the determination as to its acceptability. If the cost sharing percentage is less than that agreed to and also less than 5%, a detailed explanation and justification should be requested from the grantee institution and the matter then referred to the awarding unit Grants Management Officer for resolution.
- h. Cost sharing agreements may be amended retroactively for a lower contribution to avoid unanticipated hardship on grantee institutions; however, this should be permitted only rarely.
- i. An amended agreement must be submitted anytime there is a name change or when the structure of the institution is changed through merger, successor in interest agreement or any other means.

3. Agreements With Cooperating Institutions Under Consortium Grants

Grantee institutions are responsible to the NIH awarding unit for the entire non-Federal contribution to the total cost of the research project, either under an individual or institutional cost sharing agreement. Written agreements negotiated by the grantee with each cooperating institution(s) may include an arrangement whereby the cooperating institution will cost share in proportion to its participation in the total project.

4. Reporting Requirements and Documentation

Grantees are required to report cost sharing for each budget period on a Financial Status Report as follows:

- a. For institutional agreements, show "institutional, and the effective date" in the remarks block on the form.
- b. For project-by-project agreements, show the amount of the non-Federal cost sharing for the period covered by the Financial Status Report. If there was no cost sharing during the reported period, indicate "no c.s." on the appropriate line of the form.

4209 - COST SHARING IN RESEARCH GRANTS

- c. If the grantee wishes to provide cost sharing in the indirect cost category, it should reduce the claim for indirect cost to which it would otherwise be entitled, indicating the total amount and the Federal share on the Financial Status Report as appropriate. In this event, an explanation should be included in the "Remarks" section of the report, that the claim for less than allowable indirect cost is intentional.

5. Application Review Process

The extent of cost sharing proposed by applicants should not influence judgments on merit or relevance and may not be a factor in the competition for research grants. Application forms will not request information on cost sharing nor are individual cost sharing proposals to be solicited until peer review has been completed and funding is assured. No aspect of cost sharing may be made available to consultants engaged by the NIH to evaluate the merit of research grant applications.

H. Audit

Records showing the manner and source of non-Federal support must be made available to Federal auditors upon request.

I. Effective Date

This policy is effective immediately.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205

Date _____	Recommended Competitive Segment _____
Grant No. _____	Recommended Direct Costs \$ _____
Principal Investigator _____	\$ _____
Title of Project _____	\$ _____
	\$ _____
TO :	\$ _____
FROM:	\$ _____

SUBJECT: Project-by-Project Cost Sharing in Research Grants

In keeping with the public Health Service policy on cost sharing in research grants, it is necessary to establish in advance of an award the extent of cost participation by the applicant institution. In the absence of an institutional cost sharing agreement with the PHS, a separate proposal will be required for each research project to be supported by an NIH grant.

Please provide the information required for project-by-project cost sharing as indicated below for the subject research project, which has been recommended for approval for the competitive segment indicated and in amounts not to exceed those shown for direct costs to which related indirect cost at a rate not to exceed that accepted by DHHS may be added.

In presenting the needed data, it is important to note (1) that the cost sharing percentage proposed applies to the total competitive segment rather than to annual budget periods, (2) total allowable costs of the project include both costs charged to the Federal grant funds and costs contributed by the grant organization, and will be determined in accordance with the cost principles designated by the granting agency, and (3) that any proposed contribution of less than five percent of the total allowable project costs must be accompanied by a detailed explanation and justification of the reason therefor.

Information Required for Project-by-Project Cost Sharing

_____ proposes to share in the costs of Grant
(Name of Applicant Organization)

No. _____ during the competitive segment _____ (of any
(Inclusive Dates)

subsequent revision of that competitive segment to the minimum extent of ____ percent of the total allowable costs of the project. It is understood if the competitive segment consists of more than one budget period, this minimum percentage will apply to the competitive segment as a whole but not necessarily to each budget period equally.

Signature and Title of Authorized Grantee Official

Date

4805 - RESEARCH GRANTS AWARDED TO NON-AFFILIATED INDIVIDUALS

- A. Purpose This issuance sets forth the policy which applies to research grants awarded to non-affiliated individuals as grantees rather than to an institution or organization.
- B. Applicability This policy is applicable to NIH research project grants.
- C. References
1. NIH Manual Chapter 4209, Cost Sharing in Research Grants
 2. NIH Manual Chapter 5202, Prior Approval of Use of NIH Grant Funds Including Rebudgeting
 3. NIH Manual Chapter 5602, Management of and Accountability for Equipment Acquired Under NIH Grants
- D. Policy In exceptional cases, a research project grant may be made to a non-affiliated individual in the United States rather than to an institution or organization. In such cases, special administrative features pertain (see E. Implementation below).
- E. Implementation
1. Allowances and Expenditures No indirect cost allowance will be provided to individuals as grantees; nor may they use grant funds for alterations or renovations, or for the purchase of fixed equipment. Otherwise, the expenditures policies applicable to research grants made to grantee institutions and organizations are applicable to grants made to individuals.
 2. Human and Animal Subject Research In accordance with Department of Health and Human Services Regulations, 45 CFR 46, and the Public Health Service Animal Welfare Policy, 1-43, no individual may receive NIH grant funds for non-exempt human subjects research or animal research unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under a written Assurance of Compliance or the individual makes other arrangements with the Department. For information concerning human subjects and/or animal assurances and related arrangements, contact the Office for Protection From Research Risks, Building 31, Room 4B09. Telephone: 496-7005.
 3. Cost Sharing The non-payment of indirect costs on grants to individuals satisfies cost sharing requirements.

4805 - RESEARCH GRANTS AWARDED TO NON-AFFILIATED INDIVIDUALS

4. Equipment Title to equipment acquired by an individual as a grantee shall vest upon acquisition in the Federal Government with final disposition to be determined by the awarding unit upon termination of the project.
 5. Payment of Grants Funds Individuals as grantees may obtain an advance of funds on a monthly basis in the amount of estimated disbursements to be made during a month, or on a reimbursable basis, by writing a letter identifying their grant number and cash requirements to:

Accounting and Indirect Cost Section
Federal Assistance Accounting Branch
Division of Financial Management
National Institutes of Health
Building 31, Room B1B04
9000 Rockville Pike
Bethesda, Maryland 20205
 6. Prior Approval Authority Individuals as grantees must obtain prior approval from the Grants Management Officer of the NIH awarding unit for all proposed programmatic changes and rebudgeting actions for which prior approval is required.
 7. Reporting The individual as a grantee has the same reporting requirements as a grantee institution or organization.
- F. Responsibility Although the individual is held entirely responsible for the grant, personal indemnity bonds are not required. The awarding unit Grants Management Officer and designated program official are jointly responsible for regular contact with the grantee individual to ensure that the terms of the grant are being met.
- G. Effective Date This policy is effective immediately.

4811 - NOTIFICATION AND TREATMENT OF RELEASED FUNDS
RESULTING FROM ISSUANCE OF A RESEARCH OR
ACADEMIC CAREER AWARD

- A. Purpose. This issuance sets forth the notification and adjustment procedure to be followed by all NIH bureaus, institutes, and divisions (BIDs) in the timely identification and treatment of grant funds budgeted for an individual's salary and applicable fringe benefits, but freed as a result of funding an NIH research or academic career award.
- B. Background. Since 1962, NIH has had a policy that grantee institutions may not automatically retain grant funds freed as a result of providing salary and applicable fringe benefits for an individual through an NIH research or academic career award and use them for other project-related purposes. Grantee institutions are required to seek prior approval from awarding units in order to retain such funds. Inasmuch as the current PHS Grants Administration Manual Chapters and the PHS Grants Policy Statement do not include detailed procedural guidelines or indicate under what circumstances it may be appropriate to allow the retention of such funds, it is intended that this document will guide NIH staff in carrying out this responsibility.
- C. Applicability. This policy is applicable to NIH research or academic career awards (application prefix code K) and affected NIH research and training grants.
- D. Policy. Funds budgeted in an NIH-supported research or training grant for an individual's salary and applicable fringe benefits, but freed as a result of funding a research or academic career award for that individual may not be used for any other purpose except when the career award recipient no longer participates in the grant-supported activity and another individual replaces him/her and requires comparable remuneration. Only under some highly unusual circumstance should consideration be given to approval for use of released funds for any other reason than the one described above. In any event, the proposed retention and utilization of funds released in this manner must receive prior written approval of the awarding unit.
- E. Implementation and Responsibility.
1. Prior to issuing a research or academic career award, awarding unit staff shall seek and receive in writing from the prospective grantee institution the following:

4811 - NOTIFICATION AND TREATMENT OF RELEASED FUNDS
RESULTING FROM ISSUANCE OF A RESEARCH OR
ACADEMIC CAREER AWARD

- a. Information about all current or pending salary and applicable fringe benefit support being provided by Federal funds to the proposed awardee;
- b. Identity of awarding agency or unit, grant or award number, grant or award period, and annual support amount; or
- c. A negative report that no such support is current or pending, if such is the case.

In soliciting such information, the awarding unit should restate the NIH policy concerning the treatment of freed funds as a result of funding a research or academic career award. (See D. above.)

An example of a format for obtaining the above information is included as Illustration 1.

2. After receiving the required information, the awarding unit grants management staff is responsible for immediately sending written notification to all other NIH BIDs, other PHS awarding units, and other Federal agencies which have been identified as providing current salary and applicable fringe benefit support to the prospective research career or academic awardee that such an award will be made by the NIH. The BID should also provide a copy of the letter notifying the applicant that the research or academic career award is to be made. This notification system alerting all identified current or potential awarding units should enable each to promptly determine the disposition of freed Federal funds in accordance with the requirement of this policy. For other than NIH awarding units, final determination concerning disposition is entirely at the discretion of that component. For NIH awarding units, the determination shall be made under the policy stated in D. above.
3. An NIH BID receiving notice that a grant awarded by them will contain released salary and applicable fringe benefit support shall act promptly to either approve the use of the released funds or to restrict or recover them in accordance with the policy provisions of D. above. Any adjustment to an active or pending grant must include consideration of the future years of recommended support as well as the current year.

4811 - NOTIFICATION AND TREATMENT OF RELEASED FUNDS
RESULTING FROM ISSUANCE OF A RESEARCH OR
ACADEMIC CAREER AWARD

4811

Page 3

F. Effective Date. This policy is effective immediately.

4811 NOTIFICATION AND TREATMENT OF RELEASED FUNDS RESULTING FROM ISSUANCE OF A RESEARCH OR ACADEMIC CAREER AWARD

Sample Format for Information Requested From Prospective Research and Academic Career Awardees

(NIH AWARDOING UNIT)

RESEARCH AND ACADEMIC CAREER AWARD PROGRAMS

REPORT OF CURRENT SALARY SUPPORT FROM FEDERAL FUNDS AND PENDING APPLICATIONS FOR FEDERAL SUPPORT

IDENTIFYING NUMBER
NAME OF AWARDEE
NAME OF SPONSORING INSTITUTION
SALARY RECOMMENDED

This is to inform you that an application for a Research or Academic Career Award has been approved in behalf of the above named individual. Any other Federal grant or contract award which provides salary and/or fringe benefit support for the anticipated Awardee will, therefore, no longer be required for that purpose. Funds thus released from other National Institutes of Health support mechanisms may not be retained by the recipient institution for any purpose, except when the award recipient no longer participates in the grant program(s) and another individual replaces him/her and requires comparable remuneration. Only for some highly unusual or special circumstance may prior approval be given for retaining released funds for any other reason than the one described above.

Please complete this form indicating all current or pending salary and/or fringe benefit support provided by Federal funds for the above named Awardee. Identify all pending support by "(P)" in the Grant or Award Number column below. Since it is not possible to issue this award until the completed form is received, please return the form promptly to the address shown below:

NIH AWARDOING UNIT OR OTHER FEDERAL AGENCY	GRANT OR AWARD NUMBER	GRANT OR AWARD PERIOD	AMOUNT OF ANNUAL SALARY AND FRINGE BENEFITS AUTHORIZED

If no other Federal funds contribute to the salary and/or fringe benefit support of the awardee, or if no application or proposal for such support is pending, check here:

INDICATE REQUESTED ACTIVATION DATE: _____

SIGNATURES

AWARDEE	DATE	DEPARTMENT CHAIRMAN OR SPONSOR	DATE
OFFICIAL AUTHORIZED TO SIGN FOR INSTITUTION			DATE

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

- A. Purpose This issuance revises policy for the establishment and operation of a consortium grant with a sound administrative base among the participating institutions and between the NIH awarding unit and the grantee institution.
- B. Background In the 1970s, NIH began to receive research grant applications in which support was sought for a single project involving multiple institutions. The inter-institutional administrative and programmatic arrangements were reflected by various types of collaborative agreements - some adequately serving their purposes and some not. As the need for, and interest in, the consortium type of grant grew, NIH began to receive an increasing number of consortium grant applications reflecting the involvement of a greater number of collaborating institutions applying their talents to an increasing portion of the research endeavors. Thus, this policy has evolved from experience with the first consortium grant and has been developed through cooperative efforts of grantee institutions and the NIH in recognition of the special needs of these particular grants.
- C. Applicability This policy is applicable to any NIH grant-supported research project which embodies the characteristics of the consortium grant as defined below.
- D. Definition A consortium grant is defined as: A grant to one institution in support of a research project in which any programmatic activity is carried out through a collaborative arrangement between or among the grantee institution and one or more other institutions or organizations which are separate legal entities, administratively independent of the grantee. The involvement of the non-grantee (collaborating) institution is that of actually performing a portion of the programmatic activity as opposed to simply providing a routine service to the grantee such as equipment fabrication or repair, data processing, or performing routine analytical testing services.
- E. Policy
1. The NIH may make an award for the support of a project to a grantee institution on behalf of a named principal investigator or program director even though one or more institutions other than the grantee are collaborating in the project by carrying out portions of the planned program activity. A proper certification reflecting inter-institutional understanding and basic agreement must be developed between the grantee and each individual collaborating institution.

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

2. To be eligible for the award of such a grant, the grantee institution must ensure that it will, in fact, perform a substantive role in the conduct of the planned research project activities and not be primarily a conduit for the transmission of funds to another party or multiple parties. In general it is expected that a significant portion of the research activity will be carried out at the grantee institution.
3. Consortium arrangements which have not been proposed and documented in a grant application may not be entered into after a grant award has been made without the specific written prior approval of the awarding unit.
4. Only the grantee institution will receive entitlement credit for a Biomedical Research Support Grant. No proration of entitlement to other consortium institutions is allowed.

F. Conditions of Application and Award

1. Agreement prior to application submission. Prior to submission of an application for a consortium grant the applicant institution and each collaborating institution should thoroughly explore and reach at least tentative agreement on the scientific, administrative, financial, and reporting requirements for the grant.
2. Application preparation. The application form for consortium grants is the same form used for other NIH research proposals (form PHS 398). For consortium arrangements the application must include the following additional information:
 - a. A list of all proposed performance sites both at the applicant institution and at the collaborating institutions.
 - b. A separate, detailed budget for the initial and future years for each institution and, where appropriate, for each unit of activity at each institution.
 - c. A composite budget for all units of activity at each institution for each year, as shown under b. above, as well as a composite budget for the total proposed budget for each year.
 - d. An explanation of the programmatic, fiscal, and administrative arrangements made between the grantee institution and the collaborating institutions.

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

- e. The following statement, accompanied by signatures of the appropriate administrative officials from each of the collaborating institutions, must be included as part of the application:

"The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the NIH consortium grant policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy."

3. Written agreement. The grantee institution must formalize in writing the agreement negotiated with each collaborating institution. The agreement must state the programmatic, fiscal, and administrative arrangement ensuring the compliance with all pertinent Federal regulations and policies and facilitating a smoothly functioning collaborative venture. Based upon the amount of information pertaining to the written agreement(s) which might be provided with the application, the awarding unit may determine that it is necessary to obtain more specifically detailed information from the grantee institution. The grantee can comply with such a requirement either by submitting copies of the actual written agreement(s) or by providing similarly clarifying information in some other format. Generally such information, needed for administrative review as to completeness will be required prior to the time of grant award statement issuance. Any review and acceptance by the awarding unit of the information provided does not constitute a legal endorsement of the written agreement(s) by the Federal Government. Nor does such acceptance establish NIH as a party to any of the agreement provisions. When requested, if it is not possible for the grantee institution to provide the NIH awarding unit with the additional documentation prior to award, it may be necessary to impose appropriate award restrictions, pending receipt and acceptance of the material.

As a general rule it should not be necessary to request detailed information concerning the written agreement during noncompetitive continuation application review unless the relationship between the grantee institution and its collaborating institution(s) is going to be significantly modified in any of the programmatic, fiscal, or administrative aspects. Accordingly, it is the responsibility of the grantee to provide an explanation of any significant proposed modification of the written agreement(s) in the continuation application or by letter if the decision on a change is made after application submission. Based on the type of explanation provided, the awarding unit will make a determination as to the possible need for more information to facilitate its

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

review. As in the above paragraph, the grantee when asked for more details on the approach taken in the agreement(s) would have the option of submitting copies of the actual agreement(s) or presenting similar information in some other format.

- a. Programmatic considerations. The agreement must identify the principal investigator and the responsible persons at each collaborating institution and describe their responsibilities in the project. Procedures for directing and monitoring the research effort must also be delineated.
 - b. Fiscal considerations. The agreement must cite specific procedures to be followed in reimbursing each collaborating institution for its effort and must include dollar ceiling, method and schedule of reimbursement, type of supporting documents required for reimbursement, and procedures for review and approval of expenditure of grant funds at each institution.
 - c. Administrative considerations. Where policies of the collaborating institution differ from those of the grantee institution, (e.g. travel, travel reimbursement, salaries and fringe benefits) a determination should be made and included in the agreement as to which policies will be applied. Usually the policies of the institution where the costs are generated are applied to those costs, provided any such policies are in compliance with those of NIH.
4. Assurances required by NIH. The grantee institution has the specific responsibility for ensuring that all required assurances are obtained. The written agreement between the grantee institution and each collaborating institution must reflect the intent to fulfill all the requirements of the NIH and incorporate an understanding concerning at least the applicable assurances listed below:
- a. Protection of Human Subjects. Title 45, Code of Federal Regulations, Part 46 (45 CFR 46) requires that grantee institutions and collaborating institutions, when conducting some or all of the research involving human subjects, must have on file with or must submit to HHS upon request an Assurance of Compliance, approved in accordance with the regulations, setting forth the institutional policies and procedures established for the protection of human research subjects. Further information on the requirements of 45 CFR 46 may be obtained from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20205.

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

- b. Care and treatment of laboratory animals In accord with PHS Grants Administration Manual Chapter 1-43 each grantee or collaborating institution receiving funds for research involving live, vertebrate animals must have on file with or submit upon request to PHS an Animal Welfare Assurance. The Assurance document commits the institution to comply with the Animal Welfare Act (P.L. 89-544, as amended) and the Guide for the Care and Use of Laboratory Animals (NIH Publication No. 80-23, Rev. 1978, or succeeding editions). Further information may be obtained from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20205.
- c. Non-Discrimination. Each domestic collaborating institution or organization must comply with Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, as amended (Handicapped Individuals). The grantee must ensure that all collaborating institutions have on file with the HHS Office for Civil Rights, valid Assurances of Compliance with the Civil Rights Act of 1964 (Form HHS 441) and Section 504 of the Rehabilitation Act of 1973, as amended (Form HHS 641).
- d. Patents and inventions. The fact that two or more institutions share in the grant-supported project does not alter the grantee institution's responsibilities concerning patents and inventions. The grantee institution should obtain appropriate patent agreements to fulfill the requirements from all persons who perform any part of the work under the grant and may be reasonably expected to make inventions. The grantee should insert into each such written agreement a clause making the patent and inventions policy applicable to each collaborating institution and its employees. Agreements should also be obtained by the grantee to govern disposition of rights to inventions resulting from screening compounds synthesized under the grant.
- e. Student unrest provisions. Each collaborating institution will be responsible for carrying out the provisions relating to remuneration from grant funds to any individual who has been engaged or involved in activities described as "student unrest." (General Provisions of the DHHS Appropriations Act each year since FY 1970.)

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

- f. Recombinant DNA Research. The grantee institution, the collaborating institutions, and their respective principal investigators should refer to the most recent guidance from NIH concerning recombinant DNA research to determine the requirements necessary for the preparation of applications involving recombinant DNA experiments.
- g. Other. Any other assurance normally required of the grantee institution for the program in question is also required of the collaborating institutions.

G. Eligible Costs

1. Direct Costs. In general, any item of cost that is allowable under NIH policy for research grants may be requested in the application on behalf of both the grantee and collaborating institution(s). The expenditures are to be made in accordance with the NIH policies generally applicable to research grants. The requests for costs such as foreign travel, alterations and renovations, and research patient care must be accompanied by special justification.

It should be noted that no collaborating institution or organization which otherwise meets the eligibility criteria for receiving NIH grants in its own right can be paid a fee (over and above allowable direct and indirect costs) from grant funds for its participation in the consortium arrangement.

2. Indirect costs. Indirect costs for the grantee institution will be awarded routinely through the NIH Indirect Cost Management System (ICMS) of the Federal Assistance Accounting Branch, Division of Financial Management.

If indirect costs for a collaborating institution are required from the grant, they must be requested on the application budget page as a direct cost. The amount to be requested is determined by applying the DHHS-negotiated indirect cost rate for the collaborating institution to the appropriate direct cost base being requested for that institution. In such cases, the indirect cost amounts requested for collaborating institutions should be viewed as fixed maximum amounts for each year. The amounts requested for a collaborating institution's indirect costs for future years should reflect anticipated increases or decreases in indirect cost rates for the periods of requested support. That is, indirect cost rates used for collaborating institutions may vary - up or down - from the rate applicable at the time the competitive (new, renewal, or supplemental) application is submitted. Any such variance from already negotiated rates should, however, be accompanied by an explanation.

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

While consortium arrangements may include the involvement of foreign institutions it should be noted that such institutions, whether serving as grantee or collaborator, cannot receive indirect costs.

H. Other Administrative Considerations

1. Rebudgeting authority of collaborating institutions. Rebudgeting between budget categories on the part of non-grantee collaborating institutions must have the prior approval of the grantee institution unless the grantee institution has established in the written agreement moderate levels of rebudgeting authority within PHS policy limitations with each of the collaborating institutions. In any case, the grantee institution must be responsible for assuring that the combined rebudgetings of both the grantee institution and collaborating institutions are consistent with PHS policy and that rebudgeting requests receive appropriate review (including those types of rebudgeting requests which require the review and prior approval of an awarding unit).
2. Audit guidelines. All costs incurred in the consortium grant will be subject to audit by the cognizant Federal audit agency. Upon request, cognizant Federal auditors will be provided access to records supporting grant-related costs of the collaborating institutions.
3. Cost sharing guidelines. The grantee institution is responsible to the NIH awarding unit for the entire non-Federal contribution to the total cost of the research project, under either an NIH individual (project-by-project) agreement or an institutional cost sharing agreement with the DHHS. In the event that the grantee is a for-profit organization, the project-by-project type of agreement must be utilized. The written agreement negotiated with each collaborating institution may include an arrangement whereby the collaborating institution will cost share in proportion to its participation in the total project. Any negotiated arrangement for multi-institutional cost sharing participation should be a part of the written agreement.
4. Equipment accountability and disposition. If the grantee is a non-profit organization, title to all equipment purchased with grant funds resides with the grantee. Further, if the grantee qualifies under a Federal statute as being exempt from further accountability to the Government for the equipment, the grantee may determine the disposition of the equipment at any appropriate

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

time. Such a determination could enable the grantee to make arrangements as part of the written agreement for transfer of equipment items to the collaborating organizations early in the project (perhaps at time of acquisition) or as late as the time of project termination.

If the grantee is a for-profit entity, title to all equipment purchased with grant funds is retained by the Federal Government. Disposition of such Government-owned equipment will be determined by the awarding unit at the time of project termination.

5. Grant related income. The written agreement should establish the understanding that the grantee institution is accountable to the NIH for all grant related income generated by the grant supported activities. In accordance with PHS policy, the grantee is responsible for maintaining records of the receipt and disposition of grant related income in the same manner as required for the grant funds that gave rise to the income. The collaborating institution(s) will maintain records as necessary for the grantee institution to fulfill its responsibility.
6. Publications. The grantee institution and the collaborating institution(s) should have an initial, general agreement regarding authorship on research reports and other publications.
 - I. Reporting Requirements In order for the grantee institution to satisfy all of the various reporting requirements (e.g. progress report, report of expenditures, invention statement), it is necessary for each collaborating institution to provide the grantee with certain kinds of documentation. The written agreement must reference this need by stating the kinds of documentation required by the grantee as well as the timing of their submission.
 - J. Effective Date This policy is effective immediately.

5002 NOTICE OF DISPOSITION OF GRANT
UNEXPENDED BALANCE

- A. Purpose This issuance states the procedure for determining the disposition of an unexpended balance of authorization at the close of a competitive segment (see definition) of grant support and for notifying the grantee organization and the awarding component.
- B. Applicability All research and training grants (except fellowships) and cooperative agreements awarded by the National Institutes of Health.
- C. Background In 1970 the Notice of Disposition of Grant Unexpended Balance (NDGUB), form NIH 1686, was first introduced by the NIH as a means of notifying the grantee institution's business officer of the disposition of an unexpended balance following the receipt at the NIH of an expenditures report for a grant budget period. In 1971 the NDGUB was modified to conform to a revised procedure for making grant award adjustments related to estimated and actual unexpended and unobligated grant balances (see NIH Manual Issuance 5005). However, notwithstanding that modification, issuance of the NDGUB continued to be tied to individual budget periods within a "project period" (as the term was defined prior to 1979).

In 1979 the definition of a project period was significantly revised to consider competing continuations as extensions of the initially recommended project period. Thus, instead of considering each competing segment to be a separate and individual project period, it became possible to have project periods lasting five, ten, fifteen, or more years. This revision impacted on a number of grant administration procedures, including the use of the NDGUB. As indicated below (Section F, Procedure), the NDGUB is now used to notify the grantee organization's business office and the NIH awarding component of the action taken concerning the disposition of grant funds remaining at the end of each competitive segment.

- D. References
1. NIH Manual Chapter 5005, "Grant Award Adjustments Related to the Estimated and Actual Unexpended and Unobligated Grant Balances."
 2. Financial Status Report, Standard Form 269 (7-76).

5002 NOTICE OF DISPOSITION OF GRANT
UNEXPENDED BALANCE

3. PHS Grants Administration Manual Chapter 1-85, "The Project Period System of Obligating Funds for Discretionary Project Grants."
4. NIH Guide for Grants and Contracts, Vol. 9, No. 2, January 25, 1980, Changes In The Project Period System For NIH Grants.
5. NIH Guide for Grants and Contracts, Vol. 9, No. 4, March 14, 1980, Changes In Project Period System For NIH Grants - A Clarification.

E. Definitions

Competitive Segment The initial period of recommended support (1 to 5 years) or each successive competing continuation period of a project period.

Budget Period The interval of time (usually 12 months) into which a multi-year period of assistance (project period) is divided for funding and reporting purposes.

Continuation An award which adds funds to support subsequent budget periods after the first. There are two basic kinds of continuations:

1. Noncompeting A continuation for a budget period that is within the approved competitive segment. These are noncompeting because they do not extend the existing project period by one or more budget periods.
2. Competing A continuation for a budget period that extends the currently established project period. These are competing because they add one or more budget periods to the existing project period.

Project Period The total time for which a project is approved for support, including any extensions thereof.

Final Expenditures Report A final Financial Status Report that must be submitted within 90 days of the completion of a grant, and must indicate the exact balance of unobligated funds and have no unliquidated obligations.

5002 NOTICE OF DISPOSITION OF GRANT
UNEXPENDED BALANCE

Annual Expenditures Report A Financial Status Report that must be submitted for each budget period no later than 90 days after the close of such period. It indicates the financial status of a grant according to the official accounting records of the grantee organization and may include unliquidated obligations.

Unexpended Balance The portion of Federal funds authorized consisting of the unobligated balance of Federal funds plus the Federal share of unliquidated obligations, if any.

Unliquidated Obligations For Financial Status Reports prepared on a cash basis, the amount of obligations incurred by the grantee that has not been paid. For Reports prepared on an accrual basis, the amount of obligations incurred by the grantee for which an outlay has not been recorded.

Unobligated Balance The portion of Federal funds authorized which has not been obligated by the grantee and is determined by deducting the grantee's cumulative obligations from the cumulative Federal funds authorized.

F. Procedure

1. Division of Financial Management (DFM)

- a. At the time the final or annual expenditures report is received, DFM will routinely take one of two actions concerning any unexpended balance shown on the report:
 - (1) If it is the terminal year of the project, the unexpended/unobligated balance will be withdrawn from the grantee organization. (If a competing continuation award has not been issued, DFM necessarily must assume that the report received for the last year of support of a competitive segment is for expenditures against the terminal year of the project. Should there be a hiatus of support, DFM will, upon receipt of the competing continuation award and certification of funds availability, restore to the grantee organization the balance previously withdrawn. An amended NDGUB will be processed and distributed according to F.l.b.(3) below.)

5002 NOTICE OF DISPOSITION OF GRANT
UNEXPENDED BALANCE

- (2) If it is within an approved project period, but at the end of a competitive segment, the unexpended balance will be carried forward to the next competing continuation award.
- b. The grantee organization and the awarding component will be notified of the action by means of the NDGUB, form NIH 1686 (Illustration 1). The Financial Status Report (or equivalent expenditures report) and the NDGUB will be processed as follows:
 - (1) The expenditures report is received in DFM for processing.
 - (2) A processed copy is coded to the NIH IMPAC System maintained by the Statistics and Analysis Branch, DRG, to reflect the receipt of the report.
 - (3) DFM prepares original and two copies of the NDGUB and distributes the original to the grantee organization; one copy goes to the awarding component, together with the original of the expenditures report; and DFM retains one copy, along with a copy of the expenditures report.

2. Grantee Notification

The NDGUB informs the grantee organization of the specific transfer of an unexpended balance from one competitive segment to another, and contains the following general information:

"Expenditures for the competing continuation period are limited to the sum total of (a) the approved budget (direct costs), (b) liquidation of reported prior year obligations and (c) applicable indirect costs."

"When the amount transferred, together with the amount awarded for a continuation period, results in overfunding, THE EXCESS IS NOT AVAILABLE FOR EXPENDITURE. The excess, excluding any unliquidated obligations, may be used by the awarding component to partially fund succeeding budget periods within the project period."

5002 NOTICE OF DISPOSITION OF GRANT
UNEXPENDED BALANCE

"On the other hand, if the grant is underfunded by \$250 or more, the awarding component will within 30 days issue a revised award notice or a supplemental award for the balance needed to meet the level of the current approved budget. For any underfunding of less than \$250, when the current budget will be adversely affected, a request for adjustment must be made in writing to the awarding component."

3. Awarding Component If the awarding component does not concur with the terms as shown on the individual NDGUB, DFM should be advised and a correction or adjustment made accordingly.

During a project period the awarding component may reduce the grant award but only by means of a revised Notice of Grant Award.

- G. Effective Date This procedure is effective immediately.

5002 NOTICE OF DISPOSITION OF GRANT
UNEXPENDED BALANCE

NIH Form 1686

NIH Manual 5002

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH Bethesda, Maryland 20205 NOTICE OF DISPOSITION OF GRANT UNEXPENDED BALANCE	DATE
	GRANT NO.
NAME OF GRANTEE ORGANIZATION	DOCUMENT NO.
	ORGANIZATION'S ID NO.
	ENTITY IDENTIFICATION NO.

We have received the Financial Status Report or equivalent expenditures report submitted under the above grant. The unexpended balance of \$ _____, which consists of the unobligated balance of Federal funds and the Federal share of unliquidated obligations, if any, has been processed as indicated below.

- Withdrawn from the reported grant project period.
- Transferred to the competing continuation award for the _____ year of support.

Grantees are reminded that expenditures for the competing continuation period are limited to the sum total of:

- (1) the approved budget (direct costs)
- (2) liquidation of reported prior year obligations and
- (3) applicable indirect costs.

When the amount transferred, together with the amount awarded for a continuation period, results in overfunding, THE EXCESS IS NOT AVAILABLE FOR EXPENDITURE. The excess, excluding any unliquidated obligations, may be used by the awarding component to partially fund succeeding budget periods within the project period.

On the other hand, if the grant is underfunded by \$250 or more, the awarding component will within 30 days, issue a revised award notice or a supplemental award for the balance needed to meet the level of the current approved budget. For any underfunding of less than \$250, when the current budget will be adversely affected, a request for adjustment must be made in writing to the awarding component.

Grants Section
 Federal Assistance Accounting Branch
 Division of Financial Management

5806 OVERDUE REPORTS -
DISCRETIONARY GRANTS

- A. Purpose This issuance states the guidelines for administrative action to be taken in assuring that grantees submit to NIH such reports as may be required as a condition of a grant award.
- B. Background A recurring problem in the administration of many NIH grant programs is the delinquency on the part of some grantees in submitting reports required as a condition of the grant award. These reports are divided into two general categories, identified as progress reports and management reports. Progress (performance) reports describe technical scientific accomplishments toward meeting project objectives. Management reports cover financial, administrative, or other non-technical (non-scientific) aspects of the grant-supported project.
- C. Applicability This issuance applies to all assistance programs (grants and cooperative agreements) in which the amount of the award and the decision to make the award are within the discretion of the NIH awarding unit.
- D. References
1. PHS Grants Administration Manual Chapter 1-42, Overdue Reports-Discretionary Grants
 2. NIH Manual Issuance 5805, Closeout of NIH Grants
 3. NIH Manual Issuance 5807, Submission and Acceptance of Revised Reports of Expenditures
 4. NIH Manual Issuance 5808, Establishment and Documentation of Files and Other Records, Including Monitoring Actions, for NIH Grant Programs
- E. Policy Each discretionary grant award is made subject to the condition that the grantee shall prepare certain technical progress reports and management reports and shall submit them on a predetermined basis to the appropriate unit at NIH. Awarding units shall take appropriate administrative action to assure the submission by grantees of required reports.
- F. Guidelines for Administrative Action The particular administrative action taken by the awarding unit will depend on the response, if any, received from the grantee to written requests for overdue required reports. The following procedures shall be followed by awarding units encountering a delinquent reporting situation:

5806 OVERDUE REPORTS -
DISCRETIONARY GRANTS

1. Delinquent Technical Progress Reports

When a grantee continues to be delinquent in submitting a required progress report or final report on the scientific and technical aspects of the grant (i.e., 30 days beyond the due date), the Grants Management Officer (GMO) of the awarding unit is responsible for the following actions:

- a. The GMO shall send a letter to the program director, principal investigator, or other person directly responsible for the report, notifying that person of the delinquency and requesting the report. The letter shall state that, if the report cannot be submitted promptly, the responsible individual should explain the reason and should state the date by which the awarding unit will receive the report.
- b. If neither the report nor an acceptable explanation for not submitting it is received within 30 days of the date of the first letter, the GMO shall promptly send a second letter. This letter shall be sent to the official of the grantee institution who is responsible for the administration of the grant notifying that official of the delinquency and of the prior attempt to obtain the required report. This letter may advise the grantee that failure to submit the report within 30 days could result in the awarding unit withholding any additional grants in which the principal investigator, or person responsible for the delinquent report, is involved until the overdue report is received.
- c. If neither the report nor an acceptable explanation for further delay is received within 30 days of the date of the second letter, the head of the grantee institution should be informed by letter from an awarding unit official at the Associate Director or Executive Officer level of the previous attempts to secure the required report. This letter may also state definitively that the awarding unit will not award any additional grants in which the program director, principal investigator, or person responsible for the delinquent report, is involved until the overdue report is received.
- d. If there is no acceptable response within 30 days of the above letter (it now being at least 120 days beyond the due date), the matter should be submitted to the Deputy Director for Extramural Research and Training (DDERT) with full documentation. (In the case of a final progress report, at least seven months have elapsed since the project ended.) The DDERT will determine alternative procedures which may be applied in order to try to obtain the missing report.

5806 OVERDUE REPORTS -
DISCRETIONARY GRANTS

2. Delinquent Management Reports

A delinquent management report is defined as: A management report which has not been received within seven months following expiration of the grant budget period it is to cover or, specifically with respect to a Financial Status Report (FSR), an FSR which has appeared on the Division of Financial Management (DFM) monthly delinquent report list for three months. (Under the DFM reporting schedule, FSRs that have appeared on the delinquent list three times are then roughly 4 months overdue or, in other words, approximately seven months have elapsed since the grant budget period ended.)

When, under the above definition, a grantee is delinquent in submitting a required management report, the GMO of the awarding unit is responsible for the following actions:

- a. The GMO shall send a letter to the grantee official responsible for the administration of the grant notifying that official of the delinquency and requesting submission of the report within 30 days of the date of the letter.
- b. If there is no reply within the 30 day period, the head of the grantee institution should be informed by letter from an awarding unit official at the Associate Director or Executive Officer level of the previous attempts (including the DFM delinquent report lists, if appropriate) to secure the required report. An acknowledgment of this letter within 2 weeks should be requested.
- c. Continued delinquency will result in the following actions:
 - (1) for active grants, no continuation award may be made if required reports have not been received.
 - (2) for both active and expired grants, if required reports have not been received prior to the normal anniversary date of the next grant (i.e., within a 12-month period), the case should be submitted to the DDERT with full documentation. The DDERT will determine alternative procedures which may be applied to try to obtain the missing reports.
- d. If a grantee institution is consistently delinquent on a general basis in the submission of required management reports, the situation will be called to the attention of the Division of Management Survey and Review, OA, NIH, for appropriate corrective action.

5806 OVERDUE REPORTS -
DISCRETIONARY GRANTS

3. No Report Received - Waiver Procedure

In unusual cases, the GMO of the awarding unit may waive the requirement for a progress or management report or extend the date for submission when the grantee can satisfactorily demonstrate that it cannot furnish the report in a timely manner for reasons legitimately beyond its control or the purposes for which the report is to be used will be accomplished through other means. Grant files must be adequately documented to support the awarding unit's action.

G. Effective Date This policy is effective immediately.