NIH GUIDE



and **CONTRACTS**

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Vol. 5, No. 19, November 15, 1976

IN THIS ISSUE:	N 28 BIO
RESEARCH FELLOWSHIPS TO SWEDEN AND SWITZERLAND	
Announcement of fellowships offered by Sweden and Switzerland.	Page 1
SENIOR INTERNATIONAL FELLOWSHIPS	
Announcement of fellowships offered by Fogarty International Center.	Page 2
NOTICE OF AVAILABILITY OF INTERFERON	
Limited amounts available to qualified scientists who have obtained support for their research.	Page 2
NONHUMAN PRIMATES AVAILABLE	
Rhesus monkeys available through regular commercial sale from Charles River Breeding Laboratories, Inc.; priority for purchase will be given to NIH and ADAMHA supported projects.	Page 3
SUBMISSION AND ACCEPTANCE OF REVISED REPORTS OF EXPENDITURES	

Policy and procedures on submission and acceptance.

Page 4

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HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Room 2A14, 5333 Westbard Avenue, National Institutes of Health, Bethesda, Maryland 20014, and attach your address label to your letter. Prompt notice of your change of address will prevent your name being removed from our mailing list.

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

Supplements, printed on yellow paper, are published by the respective awarding units concerning new projects, solicitations of sources, and requests for proposals.

IN THIS ISSUE: (continued)

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

Request for applications from Population and Reproduction Grants Branch, Center for Population Research, NICHD, for investigations of human infertility.

Page 7

INDEX TO NIH GUIDE FOR GRANTS AND CONTRACTS

This is a cumulative index for the *Guide*; following the index is a listing of all outdated pages and articles which may be discarded.

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NIH Guide for Grants and Contracts Vol. 5, No. 19, November 15, 1976

RESEARCH FELLOWSHIPS

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SWEDEN AND SWITZERLAND

ANNOUNCEMENT

The Fogarty International Center, National Institutes of Health, has been asked to announce that the Swedish Medical Research Council and the Swiss National Science Foundation will each make available in 1977 three research fellowships to qualified biomedical scientists. These fellowships will provide postdoctoral training in basic or clinical areas of medical research.

To be eligible candidates must be citizens of the United States and have been engaged in independent responsible research in one of the health sciences for at least two of the past four years. They must present evidence of aptitude and promise in basic sciences or clinical research, with an active interest in pursuing a research career in a health science field. Applicants must also provide evidence of acceptance by a training institution and preceptor. It is the applicant's responsibility to arrange for his research training with the preceptor and to present in his application a complete and explicit plan for research training. Affiliation with the preceptor is documented in the Facilities and Commitment Statement which must accompany each application.

The Swiss fellowship may begin at any time between September 1977 and April 1978. The swedish fellowship must be started within 10 months of the date of its award and each date must be set by mutual agreement of the applicant and the institution.

The fellowships provide for reimbursement of the cost of round trip tourist air fare tickets for the Fellow and his family. Health insurance is provided during the term of the fellowship. Stipends for the Swedish Medical Research Council Fellowships range from \$10,000 to \$13,600 per year, depending upon the number of years of postdoctoral research experience at the time of award. The Swiss National Science Foundation stipends range from 22,800 Swiss francs (approximately \$9,200) to 28,200 Swiss francs (approximately \$11,400) depending upon the age and experience of the applicant at the time of award. In addition, the Swiss National Science Foundation Fellowships provide 3,600 Swiss francs (approximately \$1,450) for the spouse, 1,200 Swiss francs (approximately \$480) for each child and a cost of living adjustment.

Application materials may be obtained from Scholars and Fellowships Program Branch, Fogarty International Center, National Institutes of Health, Bethesda, Maryland 20014. The deadline for receipt by NIH of completed applications is January 1, 1977. Applications will be reviewed for appropriateness and scientific merit at the Fogarty International Center. They will be forwarded to Sweden or Switzerland, as appropriate, for final selection and award in late Spring or mid-Summer 1977.

All correspondence with the Fogarty International Center concerning these fellowships must be clearly marked as either "Swedish Medical Research Council Fellowship" or "Swiss National Science Foundation Fellowship."

SENIOR INTERNATIONAL FELLOWSHIPS

The Fogarty International Center, National Institutes of Health, announces Senior International Fellowships for outstanding faculty members of U.S. schools of medicine, osteopathy, dentistry, and public health at mid-career level for research and study in the health sciences at foreign host institutions. It is intended that these awards be career-enhancing and provide mutual benefit to both the U.S. and foreign institutions. Selection is on a competitive basis depending upon qualifications of the applicant, scientific merit of the proposed work, and benefit to be derived from the collaboration. Awards are made for periods of three to twelve months.

Applicants must be U.S. citizens or permanent residents, hold full-time appointment at a U.S. institution, and have at least five years' experience beyond the doctorate. Applications require nomination by the U.S. institution and invitation by a foreign institution. Transportation, allowance for the foreign institution, and a stipend of up to \$18,000 are provided. Deadline for receipt of applications is December 1 and selections are announced in May.

For further information write to: Scholars and Fellowships Program Branch, Fogarty International Center, NIH, Bethesda, Maryland 20014.

NOTICE OF AVAILABILITY OF INTERFERON

In order to foster increased research on interferon in relation to cancer, the National Cancer Institute, NIH, is in the process of obtaining a supply of human leucocyte, human fibroblast (diploid) cell, and human lymphoblastoid cell interferons. This material will be made available to qualified scientists who have obtained support for their research, but are in need of interferon. The human leucocyte and fibroblast interferons are being prepared in a manner which will make them usable for clinical studies.

Scientists interested in obtaining some of this material should submit their request to the Interferon Working Group, NIH, which will be responsible for the distribution of this material. The request should specify the type and amount of interferon requested. It should include a complete description of the study for which the interferon is needed and the source of support. If it is to be used in a clinical study, the clinical protocol should also be included.

It should be stressed that limited amounts are available and only the most scientifically deserving proposals will be considered. Therefore, it is to the applicant's advantage to be complete.

Requests should be addressed to Chairman, Interferon Working Group, National Cancer Institute, National Institutes of Health, Room 3A03, Building 31, Bethesda, Maryland 20014.

NOTICE

NONHUMAN PRIMATES AVAILABLE

The Animal Resources Branch, Division of Research Resources, has a cooperative cost-sharing contract with Charles River Breeding Laboratories, Inc., to develop domestic production of rhesus monkeys (<u>Macaca mulatta</u>). The following animals will be available from this source:

Number	Age	Weight	Sex	Price	Last Date for Guaranteed <u>NIH-ADAMHA Priority</u>
24	12-15 months	1.0-1.5 Kg	Male	\$490	December 1
24	15-18 months	1.6-1.9 Kg	Male	\$490	December 1
3	18-24 months	2.0-2.5 Kg	Male	\$560	December 1
30	12-24 months	1.0-2.0 Kg	Male	\$490	January 1

These animals are produced from an isolated free ranging island colony. They, and the colony from which they come, have been uniformly negative to tests for <u>herpesvirus simiae</u> (B virus) antibody, tuberculin hypersensitivity, and Salmonella and Shigella organisms (testing details are available on request from Charles River Breeding Laboratories, Inc.). The animals have been cage accommodated for four to six weeks and unless specifically requested otherwise, will be vaccinated against measles. The price is F.O.B., Key West, Florida.

The animals are to be distributed through regular commercial sale, but Charles River Breeding Laboratories is to give priority to purchase of animals for use on National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) supported projects. Therefore, investigators desiring animals from this source for use on an NIH or ADAMHA supported grant or contract should include the title and identifying number of the grant or contract with their purchase request. Purchase orders should be sent directly to Charles River Breeding Laboratories, Inc., Wilmington, Massachusetts 01887. Animals will be held for priority purchase until the indicated dates.

Please note that these animals are from a different source, and a different distribution mechanism is to be used from those whose availability was announced in Vol. 5, No. 14, August 13, 1976, of the NIH Guide for Grants and Contracts.

NIH'S POLICY AND PROCEDURES ON SUBMISSION

AND ACCEPTANCE OF

REVISED REPORTS OF EXPENDITURES

- POLICY
- A. <u>PURPOSE</u> This issuance states the policy and describes the procedures which will be used by NIH in handling revised reports of expenditures submitted by grantee institutions.
- B. <u>APPLICABILITY</u> This policy covers all NIH grant awards for which the submission of a report of expenditures is required.
- C. BACKGROUND Current Public Health Service policy requires that annual or final reports of expenditures be submitted to NIH within 90 days from the end of the pertinent budget period or project period. However, there has never been any uniformly stated NIH guidelines or policy on the acceptance of revised annual or final reports. Grantee institutions from time to time submit revised reports months and sometimes even years after the initial annual or final reports of expenditures have been submitted to and processed by NIH. Often the report will relate to a grant which has been closed and the financial records purged from the DHEW Federal Assistance Financing System and the NIH Central Accounting System. In other cases the revised report may pertain to an early budget period in a still currently active grant where the previously reported actual balance has been used to partially fund a succeeding budget period within the project period. Under such circumstances, if a revised report claiming additional expenditures in the earlier budget period is processed, it results in an underfunding of the grant for the succeeding budget period. Through the collaborative review efforts of the NIH awarding units and the Division of Financial Management, NIH, many of the proposed revisions have been determined to be unreasonable and, accordingly, acceptance of the report has been denied. However, responding to the multiple requests from the grantee institutions with great time variances involved - has been difficult and obviously has not been handled in any uniform fashion.

D. POLICY

- 1. Annual or final reports of expenditures shall be submitted to NIH within 90 days from the end of the pertinent budget period.
- 2. The NIH expects the grantee institution to maintain good and timely accounting records with the proper classification of expenditures. Through full utilization of the 90 days available for submission of the annual or final reports of expenditures, the grantee must make every effort to check and correct its records so that accurately filed initial reports will keep the requirement for later revisions to a minimum.

NIH Guide for Grants and Contracts Vol. 5, No. 19, November 15, 1976

- 3. When the grantee detects an excessive claim on a previously submitted report of expenditures a revision must be submitted no matter how long the lapse of time.
- 4. When a revised report representing additional claims by the grantee is necessary, it should be submitted to NIH as promptly as possible and must be submitted with appropriate explanation no later than one year from the <u>due date</u> of the original report (15 months following termination date of the budget period).
- 5. If under unusual or exceptional circumstances a grantee finds that significant expenditures should have been charged against a grant budget for which the time limit of one year from the due date of the initial report has lapsed, a revised report may be presented for consideration provided complete documentation is submitted with the report explaining in detail both the reason for the adjustment and, particularly, the untimely delay in reporting. The awarding unit will decide, based on the circumstances surrounding the individual case, whether or not to accept the revision.

E. IMPLEMENTING GUIDELINES

- 1. The Grants Section, Federal Assistance Accounting Branch, Division of Financial Management, NIH, in exercising its responsibility for receipt, processing, and auditing of all annual and final reports of expenditures will not accept revised reports with additional claims by the grantee unless the revised report is received within one year from the <u>due date</u> of the initial report.
- 2. In those cases described in D.5. above where the grantee has submitted a revised report beyond the allowed time period but provided a detailed explanation of special or extenuating circumstances, the Grants Section will forward the material to the appropriate awarding unit for its acceptance or recommendation. The awarding unit must take decisive action within 30 days and return the materials to the Grants Section to process the revised report or notify the grantee of nonacceptance.
- 3. For those revised reports of expenditures which indicate a balance due the Government and are submitted without regard to timing limitations, the Grants Section will review and audit the report and advise the grantee as to the necessary action. If the project period involved has been closed in a prior fiscal year, the grantee will be requested to submit a check for the overpayment. If the project period is still active or was closed within the current fiscal year, the grantee institution's account will be adjusted through the DHEW Federal Assistance Financing System (DFAFS).
- F. <u>EFFECTIVE DATE</u> This policy is effective October 1, 1976.

NIH Guide for Grants and Contracts Vol. 5, No. 19, November 15, 1976

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

TITLE: HUMAN INFERTILITY

The Population and Reproduction Grants Branch (PRGB) of the Center for Population Research at the National Institute of Child Health and Human Development (CPR/NICHD) is inviting research grant applications for investigations of human infertility.

This type of solicitation (the RFA) is used when CPR wishes to stimulate investigator interest in a particular research area that is important to its mission. Unlike Request for Contract Proposals (termed RFP's), the RFA identifies the scope of the Center's interest but does not require that proposals conform to narrowly specified research requirements for methodology. Applications submitted in response to an RFA are supported through the customary NIH research project grant mechanism but differ from other research grants in that they are specifically problem-oriented. Ongoing evaluation, in addition to the usual review of formal progress, may include periodic visits.

This program announcement is for a single competition with a specified deadline (March 1, 1977) for receipt of applications. Applications in response to this RFA will compete for funding in the general, ongoing research grant program of NICHD and will be reviewed by a special review group or groups in the Division of Research Grants, NIH. The National Advisory Child Health and Human Development Council will review the applications in the Fall of 1977, and the earliest requested start date for the grants will be December 1, 1977. Applications should be prepared in accordance with the aims and requirements described in the following sections:

- I. PROGRAM SPECIFICATIONS
 - A. The PRGB Program
 - B. RFA Program Objectives
- **11. METHOD OF APPLYING**
 - A. Application Format
 - B. Application Procedure

If you have questions relating to this announcement, you may contact Dr. V. Jeffery Evans, RFA Officer, PRGB, CPR, NICHD at (301) 496-6515.

HUMAN INFERTILITY

I. PROGRAM SPECIFICATIONS

A. The PRGB Program

The Population and Reproduction Grants Branch, Center for Population Research, National Institute of Child Health and Human Development, supports population research on biomedical aspects of reproduction and on behavioral-social aspects of the antecedents and consequences of population change. This RFA is intended to encourage clinicians and other biomedical, behavioral and social scientists to submit research grant proposals designed to study the causes and treatment of human infertility.

B. RFA Program Objectives

Concern for human infertility has always been within the mandate of the CPR and has been designated as a problem of high priority. This competition will be limited to studies in men and women. Studies involving experimental animals will be accepted and reviewed in the traditional NIH research grant program. In this solicitation infertility is defined simply as the inability of a couple to have children when it wishes.

Five general areas of concern have been identified by the CPR for this RFA. Teamwork among clinical and other biomedical and behavioralsocial scientists may be necessary to achieve some of the objectives of the RFA. Such collaborations are encouraged where appropriate. The research areas for this RFA are:

1. Evaluation of current therapy

An important source of confusion in this field is the lack of precision in quantifying the effect of treatment currently employed. Modern techniques of epidemiological and statistical analysis should be applied to evaluate these methods.

2. Male factors

A variety of conditions in the male have been identified as warranting a special study. These include cryptorchidism, varicocoele (particularly its incidence and establishment of its true relationship to male infertility), infections (such as mycoplasma and PPLO infections), congenital and secondary occlusions of the male reproductive tract, environmental effects on sperm production (particularly toxins, drugs, and heat), the importance of genetic factors in abnormal sperm production (such as poor motility and necrospermia), the contribution of male factors to habitual abortion, local events affecting sperm (such as circulatory changes, local endocrine factors, and enzyme defects), autoimmunity, and psychological factors affecting sexual activity and semen quality.

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NIH Guide for Grants and Contracts Vol. 5, No. 19, November 15, 1976

3. Female factors

High priority problems in the female include studies of the cervix (such as the importance of certain infections including mycoplasma infections, mucus production, and the effect of cryosurgery and other treatments), the uterine environment (particularly the importance of infection and events preceding and concurring with implantation), tubal factors (particularly anatomical defects, biophysical and biochemical environmental factors, infection, the effect of ectopic pregnancy on subsequent infertility), and studies of the ovary (particularly ovarian dysfunction, polycystic disease, and local factors such as environmental toxins, effects of surgical treatment, etc.). Other problems identified for study include female sex behavior (leading to avoidance of intercourse, for example), the importance of psychological stress in producing infertility, endometriosis, and factors controlling follicular atresia and ovarian senescence. Also post-contraceptive infertility and habitual abortion require special study.

4. Couple factors

Topics in this category include immunological studies (with emphasis on the clinical significance of new developments in this field), marital and coital problems, and studies of the psychological effects of the processes leading to and involved in diagnosis and treatment.

5. Improved diagnostic and therapeutic techniques

Included in this category are semen analysis (with establishment of criteria for normal and abnormal findings, including agespecific parameters), new measures of analysis (including determination of sperm fertilizing ability and evaluation of spermatogenesis by morphological and biochemical means), methods for the detection of fertilization and implantation, means to monitor the migration of sperm in the female reproductive tract, and improved post-coital semen tests.

II. METHODS OF APPLYING

A. Application Format

Applications should be submitted on form NIH-398, the application form for the traditional research grant. The conventional presentation for research grant applications should be used.

B. Application Procedure

The original and six copies of the application must be received before 5:00 p.m. Eastern time on March 1, 1977. Applications should be sent or delivered to:

Division of Research Grants National Institutes of Health Westwood Building 5333 Westbard Avenue Bethesda, Maryland 20016

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A brief covering letter should accompany the application indicating that it is in response to this Program Announcement. The letter should specify the title of the application and scientific field and discipline of the principal investigator and the other scientists, if any, involved in the project. A copy of the covering letter should be sent to Dr. V. Jeffery Evans, RFA Officer, PRGB, CPR, NICHD, Room C-733, Landow Building, 7910 Woodmont Avenue, Bethesda, Maryland 20014.

INDEX

NIH GUIDE FOR GRANTS AND CONTRACTS (Vol. 1, No. 1, April 30, 1970, to Vol. 5, No. 18, October 8, 1976)

LEGEND FOR AWARD MECHANISMS AND FOR CONTRACTS:

Institutional Training Grants 1. Research Project Grants 6. 2. Program Project Grants 7. Individual Fellowships 3. Center Grants Academic or Clinical Investigator 8. Awards (K-7's) 4. Resource Grants 9. Minority Programs 5. Research Career Development 10. Research and Development Contracts Awards ACADEMIC CAREER AWARDS Treatment of released funds, Vol. 5, No. 18, p. 7 ACADEMIC INVESTIGATOR AWARDS NIAID, Vol. 4, No. 5, p. 11 (8) NIAMDD, Vol. 1, No. 18, p. 6 (8) NEI, Vol. 4, No. 12, p. 3 (8) NHLBI, Vol. 4, No. 5, p. 11 (8) NINCDS, Vol. 4, No. 5, p. 12 (8) ACCOUNTABILITY Disposition of NIH grant-related income, Vol. 1, No. 2, p. 5 Equipment acquired under NIH contracts acquisition and transfer, Vol. 1, No. 18, p. 19 Equipment acquired under NIH grants, Vol. 1, No. 16, p. 3 and p. 11; Vol. 3, No. 13, p. 5 transfer of, Vol. 1, No. 16, p. 15 ACKNOWLEDGMENT and citation, of NIH grant support, Vol. 4, No. 5, p. 8 ADJUSTMENTS Unobligated award balances, Vol. 1, No. 6, p. 5 AGING Availability of cultures, Vol. 5, No. 1, p. 4 Availability of nonhuman primate material, Vol. 5, No. 15, p. 13 Collaborative (contract) programs, Vol. 5, No. 4, p. 46 (10) Research support in cellular aging, Vol. 5, No. 6, p. 5 (1) Special research awards, Vol. 5, No. 6, p. 6 (1) ALLERGY AND INFECTIOUS DISEASES Academic investigator awards, Vol. 4, No. 5, p. 11 (8) Collaborative (contract) programs, Vol. 5, No. 4, p. 24 (10) Young investigator research grants, Vol. 5, No. 18, p. 1 (1) ANESTHESIOLOGY Research grants, NIGMS, Vol. 5, No. 15, p. 14 (1) ANIMAL CARE COSTS Justification of, on NIH grants and contracts, Vol. 3, No. 18, p. 7 ANIMAL RESOURCES BRANCH, DRR Research career development program, Vol. 4, No. 2, p. 1 (5) ANIMALS, LABORATORY Care and treatment of, Vol. 1, No. 7, p. 3 APHTHOUS STOMATITIS RESEARCH NIDR, Vol. 5, No. 15, p. 12 (1)

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APPEALS PROCEDURE Grant, Vol. 3, No. 18, p. 1 APPLICATION ACKNOWLEDGMENT SYSTEM, Vol. 4, No. 11, p. 15 APPLICATIONS Assignment information mailed to business offices, Vol. 5, No. 18, p. 8 Continuation grants, PHS 2590-1, Vol. 1, No. 6, p. 5 Fellowships - See NATIONAL RESEARCH SERVICE AWARDS Grants cessation of distribution of duplicated copies, Vol. 5, No. 18, p. 8 institutional control of forms, Vol. 2, No. 8, p. 1 kits for State and local governments, Vol. 3, No. 3, p. 5 signature required on, Vol. 2, No. 1, p. 3 training, research and nonresearch, Vol. 5, No. 10, p. 1 use of entity numbers, Vol. 3, No. 16, p. 9 ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES Clinical investigator awards, Vol. 1, No. 18, p. 6 (8); Vol. 5, No. 6, p. 7 (8) Collaborative (contract) programs, Vol. 5, No. 4, p. 28 (10) Diabetes research and training centers, establishment of, Vol. 5, No. 18, p. 6 (3) Digestive diseases and nutrition centers, Vol. 5, No. 12, p. 2 (3) Program project grant guidelines, Vol. 5, No. 12, p. 3 AUDITORY PROSTHESIS AND PROFOUND HEARING IMPAIRMENT Research grant support in the areas of, Vol. 4, No. 2, p. 5 (1) AWARDS - See NATIONAL RESEARCH SERVICE AWARDS AWARDS PROGRAMS - See PROGRAM ANNOUNCEMENTS BALANCE Unexpended and unobligated grant, Vol. 1, No. 6, p. 5 BIOMEDICAL AND BEHAVIORAL RESEARCH 1976 report on personnel needs, public comment invited, Vol. 5, No. 16, p. 1 BIOMEDICAL ENGINEERING CENTERS (NIGMS), Vol. 3, No. 4, p. 1 (3) BIOTECHNOLOGY RESOURCES PROGRAM List of facilities, Vol. 3, No. 8, p. 3 Sharing, Vol. 3, No. 7, p. 3 (4) BLADDER CANCER RESEARCH, Vol. 3, No. 1, p. 1 (1) BLOOD Diseases, national research and demonstration centers, Vol. 2, No. 6, p. 1 (3) CANCER Bladder research, Vol. 3, No. 1, p. 1 (1) Clinical education grants, Vol. 5, No. 3, p. 2 (1) Collaborative (contract) programs, Vol. 5, No. 4, p. 6 (10) Control program grant activities of, Vol. 4, No. 7, p. 3 (1) Research emphasis grants authority to establish, Vol. 4, No. 2, p. 8 request for applications, Vol. 5, No. 13, p. 5 (1) CORE guidelines, Vol. 5, No. 3, p. 2 Exploratory studies grant guidelines, Vol. 5, No. 3, p. 2 CAREER PROGRAMS NIH special research NIAID, Vol. 4, No. 5, p. 11 (8) NIAMDD, Vol. 5, No. 6, p. 7 (8) NEI, Vol. 4, No. 12, p. 3 (8) NHLBI, Vol. 4, No. 5, p. 11 (8) NINCDS, Vol. 4, No. 5, p. 12 (8)

CELLULAR AGING Research support in, Vol. 5, No. 6, p. 5 CENTERS National research and demonstration centers, NHLBI, Vol. 2, No. 6, p. 1 (3) CHANGES Change in grantee institution for a research career development awardee, Vol. 1, No. 22, p. 7 Continued research project support when principal investigator leaves grantee institution, Vol. 1, No. 16, p. 19 CHILD HEALTH AND HUMAN DEVELOPMENT Collaborative (contract) programs, Vol. 5, No. 4, p. 30 (10) Request for applications, Vol. 5, No. 3, p. 5 (1); Vol. 5, No. 8, p. 1 (1); Vol. 5, No. 12, p. 2 (1) CHIMPANZEES Availability of, for hepatitis research, Vol. 5, No. 6, p. 4 CITATION and acknowledgment of NIH grant support, Vol. 4, No. 5, p. 8 CLINICAL INVESTIGATOR AWARDS NIAMDD, Vol. 1, No. 18, p. 6 (8); Vol. 5, No. 6, p. 7 (8) COLLABORATIVE PROGRAMS Descriptions of, Vol. 5, No. 4, p. 1 (10) CONSERVATION AND ENERGY PRODUCTION RELATED TO HEALTH RESEARCH, Vol. 3, No. 19, p. 1 (1) CONSORTIUM GRANTS Guidelines for establishing and operating, Vol. 4, No. 8, p. 4 CONSTRUCTION Grants, restriction regarding historic places (P.L. 89-665), Vol. 1, No. 4, p. 4 Projects, employment and training requirements, model cities, Vol. 1, No. 13, p. 7 CONSULTANT FEES Use of grant funds for payment of, Vol. 3, No. 3, p. 3 CONTRACTORS Hiring requirements for, Vol. 1, No. 17, p. 4 Privacy Act requirements, Vol. 5, No. 5, p. 1 Supply sources, GSA, Vol. 2, No. 1, p. 5 CONTRACTS Criteria for clinical investigative use for therapeutic devices (NHLBI), Vol. 3, No. 11, p. 1 Justification of animal care costs, Vol. 3, No. 18, p. 7 NIH biomedical research contracts, Vol. 5, No. 4, p. 3 cost-reimbursement, special provision with educational institutions, Vol. 1, No. 20, p. 3 unsolicited proposals for, Vol. 1, No. 18, p. 3; Vol. 1, No. 21, p. 5 vesting title to equipment, Vol. 1, No. 18, p. 19 Procedures for announcement of proposals, Vol. 3, No. 2, p. 3 Report of awards of, Vol. 4, No. 5, p. 9 Use of entity number, Vol. 3, No. 16, p. 9 COPYRIGHT Amendment of policy, Vol. 2, No. 11, p. 1 and Freedom of Information Act of 1974, Vol. 5, No. 7, p. 1 Policy, Vol. 4, No. 5, p. 8 COST SHARING Disposition of NIH grant-related income, Vol. 1, No. 2, p. 5 Requirements applicable to research project grants, Vol. 1, No. 19, p. 7

-4-

COSTS Indirect project grants with final negotiated rates, Vol. 1, No. 12, p. 1 DEADLINES, applications, Vol. 5, No. 3, p. 1 DENTAL Aphthous stomatitis research grants, Vol. 5, No. 15, p. 12 (1) Collaborative (contract) programs, Vol. 5, No. 4, p. 34 (10) Craniofacial, acquired, disfigurement grants sought by NIDR, Vol. 4, No. 14, p. 2 (1) Herpes simplex virus, research grants, Vol. 5, No. 15, p. 11 (1) Nutrition research grant applications sought by NIDR, Vol. 5, No. 2, p. 17 (1) Special research award, Vol. 5, No. 2, p. 19 (1) DIABETES RESEARCH AND TRAINING CENTERS NIAMDD, Vol. 5, No. 18, p. 6 (3) DIGESTIVE DISEASES Awards in, Vol. 1, No. 18, p. 6 (8) Research grant support, Vol. 3, No. 13, p. 1 (1); Vol. 5, No. 12, p. 2 (3) DISTRIBUTION Cessation of distribution of duplicated copies of grant applications, Vol. 5, No. 18, p. 8 NIH GUIDE FOR GRANTS AND CONTRACTS, Vol. 5, No. 4, p. 47 DNA Environmental impact statement, draft, Vol. 5, No. 17, p. 1 ENERGY CRISIS, action to cope with, Vol. 3, No. 3, p. 9 ENERGY PRODUCTION AND CONSERVATION RELATED TO HEALTH RESEARCH, Vol. 3, No. 19, p. 1 ENERGY PRODUCTION AND DEVELOPMENT Occupational health research related to, Vol. 4, No. 2, p. 3 (1) ENTITY NUMBER Use of on grant applications and contract proposals, Vol. 3, No. 16, p. 9 ENVIRONMENTAL HEALTH SCIENCES Collaborative (contract) programs, Vol. 5, No. 4, p. 36 (10) ENVIRONMENTAL IMPACT STATEMENT Draft, recombinant DNA molecules, request for comments, Vol. 5, No. 17, p. 1 EQUIPMENT Acquired under NIH contracts, vesting title to, Vol. 1, No. 18, p. 19 Acquired under NIH grants accountability for and management of, Vol. 1, No. 16, pp. 3-9 and pp. 11-14 transfer of, Vol. 1, No. 16, p. 15 EYE INSTITUTE Academic investigator awards, Vol. 4, No. 12, p. 3 (8) Collaborative (contract) programs, Vol. 5, No. 4, p. 16 (10) Special visual sciences research awards, Vol. 5, No. 15, p. 18 (1) FEDERALLY SUPPORTED PROGRAMS RELATED TO NATIONAL HEART, LUNG, AND BLOOD INSTITUTE Availability of publication, Vol. 3, No. 18, p. 7 FEES Consultant, payment from grant funds, Vol. 3, No. 3, p. 3 Disposition of NIH grant-related income, general provisions, Vol. 1, No. 2, p. 5

FELLOWSHIPS Institutional grants for National Research Service Awards for research training, Vol. 4, No. 10, p. 1 (6); Vol. 5, No. 9, p. 7 (6); Vol. 5, No. 11, p. 1 (6) National Research Service Awards for individual postdoctoral fellows, Vol. 4, No. 10, p. 5 (7); Vol. 4, No. 12, p. 1 (7 and 9); Vol. 5, No. 9, p. 1 (7); Vcl. 5, No. 11, p. 5 (7) New program (Weinberger), Vol. 2, No. 10, p. 1 (6 and 7); Vol. 3, No. 9, p. 1 (6) NIH stipends and allowances, Vol. 3, No. 9, p. 7; Vol. 3, No. 16, p. 7; Vol. 4, No. 5, p. 1 Phaseout, Vol. 2, No. 1, p. 1 FETAL RESEARCH MORATORIUM, Vol. 3, No. 13, p. 3 FREEDOM OF INFORMATION ACT (PL. 90-23) - See INFORMATION FUNDING, contracts, incrementally funded, Vol. 1, No. 21, p. 3 GAS CHROMATOGRAPHY - MASS SPECTROMETRY Selected approaches to, in laboratory medicine, Vol. 4, No. 7, p. 6 GENERAL MEDICAL SCIENCES Anesthesiology research grants, Vol. 5, No. 15, p. 14 (1) Collaborative (contract) programs, Vol. 5, No. 4, p. 38 (10) Pediatric clinical pharmacology grants, Vol. 5, No. 10, p. 9 (1) GRANTEE INSTITUTIONS Change of for principal investigator, Vol. 1, No. 16, p. 19 for research career development awardee, Vol. 1, No. 22, p. 7 **GRANTS - See PROGRAM ANNOUNCEMENTS** GUIDE FOR GRANTS AND CONTRACTS Applicability, Vol. 4, No. 8, p. 1 Distribution, Vol. 5, No. 4, p. 47 HAZARDOUS MATERIAL Transportation of, Vol. 4, No. 1, p. 1 HEALTH COMMUNICATIONS, by satellite, Vol. 4, No. 6, p. 1 HEARING IMPAIRMENT Profound, and auditory prosthesis, research grant support in the areas of, Vol. 4, No. 2, p. 5 HEART, LUNG, AND BLOOD Academic investigator awards, Vol. 4, No. 5, p. 11 (8) Collaborative (contract) programs, Vol. 5, No. 4, p. 18 (10) Federally supported programs related to, availability of publication. Vol. 3, No. 18, p. 7 Minority hypertension research development program, Vol. 5, No. 10, p. 1 (6 and 7); Vol. 5, No. 18, p. 8 (6 and 7) National high blood pressure education research program, Vol. 2, No. 8, p. 3 (1 and 10) National research and demonstration centers, Vol. 2, No. 6, p. 1 (3) Young investigator research grants, Vol. 5, No. 10, p. 3 (1) HERPES SIMPLEX VIRUS Research grants sought by NIDR, Vol. 5, No. 15, p. 11 (1) HIRING REQUIREMENTS Contractors, Vol. 1, No. 17, p. 4 Grantee, employment of Vietnam veterans, Vol. 1, No. 21, p. 7

9**19**4

HISTORIC PLACES, protection of, (P.L. 89-665), Vol. 1, No. 4, p. 4 HUMAN SUBJECTS Fetal research moratorium, Vol. 3, No. 13, p. 3 Protection of, in grants involving, Vol. 1, No. 18, p. 7 Research projects, Vol. 3, No. 12, p. 1 INCOME, GRANT-RELATED Disposition of, general provisions, Vol. 1, No. 2, p. 5 Income derived from the sale of communications materials, Vol. 1, No. 10, p. 7 INDIRECT COSTS Awarding of for NIH research grants, Vol. 5, No. 1, p. 3 Settlement of, on project grants with final negotiated rates, Vol. 1, No. 12, p. 1 INFORMATION Access to, fellowships and RCDA's, Vol. 4, No. 11, p. 9 Release of, by NIH of research and research training grant records, Vol. 4, No. 5, p. 6 INSTITUTIONAL GRANTS FOR NATIONAL RESEARCH SERVICE AWARDS - See NATIONAL RESEARCH SERVICE AWARDS INSTITUTIONAL RESEARCH FELLOWSHIP AWARDS (NIH AND ADAMHA) - See NATIONAL RESEARCH SERVICE AWARDS INSTITUTIONS, GRANTEE - See GRANTEE INSTITUTIONS INTERNATIONAL MEETINGS Grant support of, Vol. 1, No. 9, p. 9 INVENTIONS, and Freedom of Information Act of 1974, Vol. 5, No. 7, p. 1 **ISOTOPE RESOURCE** Stable, availability of, Vol. 5, No. 13, p. 2 LUNG DISEASES National research and demonstration centers, Vol. 2, No. 6, p. 1 MANPOWER Postdoctoral stipend schedule, Vol. 3, No. 9, p. 8 Report, completion and submission of, Vol. 3, No. 13, p. 7; Vol. 5, No. 6, p. 9 MANPOWER PROGRAMS - WEINBERGER - See also NATIONAL RESEARCH SERVICE AWARDS Individual research, Vol. 2, No. 10, p. 1 Institutional research, Vol. 2, No. 10, p. 1; Vol. 3, No. 9, p. 1 MASS SPECTROMETRY Request for statement of interest and capabilities, Vol. 5, No. 13, p. 1 Selected approaches to, in laboratory medicine, Vol. 4, No. 7, p. 6 MEDICAL LIBRARY, resource project grant, Vol. 4, No. 6, p. 2 (4) MEETINGS, SCIENTIFIC, grant support of, Vol. 1., No. 9, p. 9 MINORITY ACCESS TO RESEARCH CAREERS, Vol. 5, No. 15, p. 19 (6, 7, and 9) MINORITY-OWNED BUSINESSES, use of, by NIH grantees, Vol. 1, No. 18, p. 11 MINORITY HYPERTENSION RESEARCH DEVELOPMENT PROGRAM, NHLBI, Vol. 5, No. 10, p. 1 (6 and 7); Vol. 5, No. 18, p. 8 (6 and 7) MORATORIUM ON FETAL RESEARCH, Vol. 3, No. 13, p. 3 MUTATIONS, development of tests for cell, Vol. 3, No. 10, p. 3 (1)

NATIONAL RESEARCH SERVICE AWARDS Individual postdoctoral awards (NIGMS), Vol. 3, No. 22, p. 3 (7); Vol. 4, No. 11, p. 4 (6); Vol. 5, No. 11, p. 4 (7) Individual postdoctoral fellows, Vol. 3, No. 15, p. 1 (7); Vol. 4, No. 2, p. 7 (7); Vol. 4, No. 10, p. 5 (7); Vol. 5, No. 9, p. 1 (7) Institutional grants for research training, Vol. 3, No. 20, p. 1 (6 and 7); Vol. 4, No. 10, p. 1 (6 and 7); Vol. 5, No. 9, p. 7 (6 and 7); Vol. 5, No. 10, p. 1 (6 and 7); Vol. 5, No. 18, p. 8 (6 and 7) Institutional grants for research training (NIGMS), Vol. 3, No. 22, p. 1, (6 and 7); Vol. 4, No. 11, p. 2 (6); Vol. 5, No. 11, p. 1 (6 and 7) Predoctoral and postdoctoral support, Vol. 4, No. 5, p. 1 Receipt and review dates, Vol. 5, No. 3, p. 1 Reference reports, access to, and the Privacy Act of 1974, Vol. 4, No. 11, p. 9 NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE Academic investigator awards, Vol. 4, No. 5, p. 12 (8) Collaborative (contract) programs, Vol. 5, No. 4, p. 40 (10) NIH GUIDE FOR GRANTS AND CONTRACTS - See GUIDE FOR GRANTS AND CONTRACTS NONHUMAN PRIMATES, availability of, Vol. 5, No. 14, p. 1; Vol. 5, No. 15, p. 13 NUTRITION Awards in, Vol. 1, No. 18, p. 6 (8) Grant applications sought by NIDR, Vol. 5, No. 2, p. 17 (1) PATENTS, and Freedom of Information Act of 1974, Vol. 5, No. 7, p. 1 PEDIATRIC CLINICAL PHARMACOLOGY GRANTS, Vol. 5, No. 10, p. 9 (1) PEER REVIEW, study team, establishment of an NIH grants, Vol. 4, No. 7, p. 2 PRINCIPAL INVESTIGATOR Change of grantee institution, Vol. 1, No. 16, p. 19 Responsibilities for direction of research project, Vol. 1, No. 5, p. 3 PRIOR APPROVAL, rebudgeting funds within NIH grants, Vol. 5, No. 15, p. 1 PRIVACY ACT Access to, fellowships and RCDA's, Vol. 4, No. 11, p. 9 Information requested in applications for NIH support, Vol. 5, No. 1, p. 1 Requirements for NIH contractors, Vol. 5, No. 5, p. 1 PROGRAM ANNOUNCEMENTS Division of Research Resources, Vol. 3, No. 7, p. 3 (4) National Institute on Aging, Vol. 5, No. 6, p. 5 (1); Vol. 5, No. 6, p. 6 (1) National Institute of Allergy and Infectious Diseases, Vol. 5, No. 18, p. 1 (1) National Institute of Arthritis, Metabolism, and Digestive Diseases, Vol. 3, No. 13, p. 1 (1); Vol. 5, No. 6, p. 7 (8); Vol. 5, No. 12, p. 2 (3); Vol. 5, No. 18, p. 6 (3) National Cancer Institute, Vol. 3, No. 1, p. 1 (1); Vol. 4, No. 7, p. 3 (1); Vol. 5, No. 3, p. 2 (1); Vol. 5, No. 13, p. 5 (1) National Institute of Child Health and Human Development, Vol. 5, No. 3, p. 5 (1); Vol. 5, No. 8, p. 1 (1); Vol. 5, No. 12, p. 2 (1) National Institute of Dental Research, Vol. 4, No. 7, p. 7 (1); Vol. 5, No. 2, p. 17 (1); Vol. 5, No. 2, p. 19 (1); Vol. 5, No. 14, p. 2 (1); Vol. 5, No. 15, p. 11 (1); Vol. 5, No. 15, p. 12 (1) National Institute of Environmental Health Sciences, Vol. 3, No. 10, p. 3 (1); Vol. 3, No. 19, p. 1 (1) National Eye Institute, Vol. 5, No. 15, p. 18 (1) National Institute of General Medical Sciences, Vol. 3, No. 4, p. 1 (3); Vol. 5, No. 10, p. 9 (1); Vol. 5, No. 15, p. 14 (1) National Heart, Lung, and Blood Institute, Vol. 2, No. 6, p. 1 (3); Vol. 2, No. 8, p. 3 (1 and 10); Vol. 5, No. 10, p. 1 (6 and 7); Vol. 5, No. 10, p. 3 (1); Vol. 5, No. 18, p. 8 (6 and 7)

15 125

PROGRAM ANNOUNCEMENTS (continued) National Library of Medicine, Vol. 4, No. 6, p. 2 (4) National Institute of Neurological and Communicative Disorders and Stroke, Vol. 4, No. 2, p. 5 (1) National Institute for Occupational Safety and Health, Vol. 4, No. 2, p. 3 (1) PROGRAM PROJECT GRANT GUIDELINES, NIAMDD, Vol. 5, No. 12, p. 3 PROGRAMS, COLLABORATIVE - See COLLABORATIVE PROGRAMS PROPOSALS, unsolicited, for research contracts, Vol. 1, No. 18, p. 3; Vol. 1, No. 21, p. 5 PUBLICATIONS GUIDE FOR GRANTS AND CONTRACTS, distribution of, Vol. 5, No. 4, p. 47 PUBLIC DISCLOSURE - See INFORMATION RATS AND MICE, availability of, Vol. 4, No. 12, p. 2 REBUDGETING, funds within NIH grants, Vol. 5, No. 15, p. 1 RECORDS Retention requirements, microfilming of checks (contracts and grants), Vol. 2, No. 2, p. 2 Retention requirements, for grantee institutions, Vol. 1, No. 20, p. 21 RELEASE OF INFORMATION - See INFORMATION REPORT OF AWARDS OF CONTRACTS, Vol. 4, No. 5, p. 9 REPORTS Equipment acquired with NIH contract funds, Vol. 1, No. 18, p. 19 NIH grant funds, Vol. 1, No. 16, p. 3 Equipment in project periods terminated prior to July 1, 1972, Vol. 1, No. 16, p. 11 Equipment, transfer of, Vol. 1, No. 16, p. 15; Vol. 1, No. 18, p. 19 NIH Manpower, completion and submission of, Vol. 3, No. 13, p. 7; Vol. 5, No. 6, p. 9 Reference, access to, and the Privacy Act of 1974, Vol. 4, No. 11, p. 9 REQUEST FOR APPLICATIONS Cancer research emphasis grants, Vol. 5, No. 2, p. 1 (1) Child Health and Human Development, Vol. 5, No. 3, p. 5 (1); Vol. 5, No. 12, p. 2 (1) RESEARCH CAREER DEVELOPMENT AWARDS Acceptance of applications from institutions, Vol. 4, No. 11, p. 1 (5); Vol. 5, No. 6, p. 8 (5) Acceptance of applications from institutions (NIGMS), Vol. 5, No. 6, p. 8 (5) Animal Resources Branch, DRR, Vol. 4, No. 2, p. 1 Change of institution by RCD awardee, Vol. 1, No. 22, p. 7 Fees earned, Vol. 1, No. 2, pp. 5 and 9 Released funds, treatment of, Vol. 5, No. 18, p. 7 RESEARCH CAREER PROGRAM AWARDS Research career programs, NIH, special, Vol. 4, No. 5, p. 10 RESEARCH RESOURCES, DIVISION OF Collaborative (contract) programs, Vol. 5, No. 4, p. 44 (10) REVIEW CYCLE New, for grant applications and National Research Service awards, Vol. 5, No. 3, p. 1

SATELLITE, HEALTH COMMUNICATIONS BY, Vol. 4, No. 6, p. 1 SIGNATURES Grant application requirements for, Vol. 1, No. 3, p. 8; Vol. 2, No. 1, p. 3 SMALL BUSINESSES, use of, by NIH grantees, Vol. 1, No. 18, p. 11 SPECIAL RESEARCH AWARDS Aging, Vol. 5, No. 6, p. 6 (1) Dental, to young scientists, Vol. 5, No. 2, p. 19 (1) Visual sciences, Vol. 5, No. 15, p. 18 (1) STATE AND LOCAL GOVERNMENTS Grant application kits, Vol. 3, No. 3, p. 5 STIPENDS and allowances on NIH fellowships and training grants, Vol. 3, No. 16, p. 7 Equalization of NIH, Vol. 3, No. 9, p. 7 "STUDENT UNREST", Vol. 3, No. 3, p. 1 SUPPLIES AND SERVICES, SOURCE OF Grantee institutions small businesses and minority-owned businesses, Vol. 1, No. 18, p. 11 SUPPLY SOURCES Contractors, GSA, Vol. 2, No. 1, p. 5 TESTS Development of, for detecting cell mutations, Vol. 3, No. 10, p. 3 THERAPEUTIC DEVICES (NHLBI) Criteria for clinical investigative use of, under contract, Vol. 3, No. 11, p. 1 TRAINEE AND FELLOWSHIP SUPPORT - See NATIONAL RESEARCH SERVICE AWARDS TRAINING Fellowships individual (NIH and ADAMHA), Vol. 2, No. 10, p. 1 (7) institutional (NIH and ADAMHA), Vol. 3, No. 9, p. 1 (6) phaseout, Vol. 2, No. 1, p. 1 (6 and 7) Research manpower programs stipends and allowances for, Vol. 3, No. 16, p. 7 (6 and 7) Special academic awards phaseout, Vol. 2, No. 1, p. 1 (6 and 7) Support predoctoral and postdoctoral, Vol. 4, No. 5, p. 1 (6 and 7) Traineeships phaseout, Vol. 2, No. 1, p. 1 (6 and 7) Training grants regular, phaseout, Vol. 2, No. 1, p. 1 (6 and 7) TRANSFERS Equipment acquired under NIH contracts, Vol. 1, No. 18, p. 19 acquired under NIH grants, Vol. 1, No. 16, p. 15 Research projects, Vol. 1, No. 16, p. 19 TRANSPORTATION OF HAZARDOUS MATERIALS, Vol. 4, No. 1, p. 1 VIETNAM VETERANS, employment of, Vol. 1, No. 17, p. 4; Vol. 1, No. 21, p. 7 VISUAL SCIENCES RESEARCH AWARDS, Eye Institute, Vol. 5, No. 15, p. 18 (1) YOUNG INVESTIGATOR RESEARCH GRANTS NIAID, Vol. 5, No. 18, p. 1 (1) NHLBI, Vol. 5, No. 10, p. 3 (1)

OUTDATED MATERIAL

NIH GUIDE FOR GRANTS AND CONTRACTS

DISCARD:

Vol. 1, No. 1	pages 1 through 5
2	pages 1 through 4
	pages 1 through 7
-	pages 9 and 10
1.	
4	pages 1 through 3
	page 5
5	pages 1 and 2
	pages 4 through 6
6	pages 1 through 4
	pages 7 through 10
7	pages 1 and 2
,	
0	pages 6 through 11
	page 1 to end
9	pages 1 through 7
	pages 14 through 20
10	pages 1 through 6
11	pages 1 through 7
12	none
13	pages 1 through 5
	pages 1 through 9
	pages 1 through 9
10	page 1
17	page 25
	pages 1 through 3
18	page 1
	page 5 - article on "Applicability of Policies and
	Procedures Published in the Guide"
	page 17
19	pages 1 through 6
20	page 1
	pages 17 through 19
21	pages 1 through 4
	pages 1 through 6
	pages 9 through 12
	pages y chrough 12
	pages 7 and 8
۷.	page 1
	page 3 to end
	page 1
	pages 1 through 8
5	pages 1 and 2
6	none
7	pages 1 through 35
8	none
	page 1 to end
	none
	none
**	none
	$ \begin{array}{c} 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ \underline{\text{Vol. 2, No. 1}}\\ 2\\ 3\\ 4\\ 5\\ 6\\ \end{array} $

<u>Vol. 3</u> , No. 1	none				
2	page 1				
3	pages 7 and 8				
4	none				
5	page 1				
6	page 1				
7	page 1				
	pages 5 and 6				
8	pages 1 and 2 and 9				
9	pages 5 and 6				
10	page 1				
11	none				
12	page 3				
13	page 5				
14	pages 1 and 2				
15	none				
16	pages 1 through 5				
17	pages 1 through 3				
18	none Str Ma - L - 50118				
19	HIN UU				
20	pages 4 through 6 979ELO ENOIVW BSVWOHL none				
21	pages 1 through 37				
22	none				
Vol. 4, No. 1	none				
2	none				
3	page 1				
4	pages 1 through 36				
5	page 9 - article on "NIH RCDA Program"				
2	Dage 10 - article on "NIH Special Pacement Company				
	page 10 - article on "NIH Special Research Career Programs" - discard only "National Eye				
	Institute"				
6	none				
7					
	i b and a decide on new neview bytte				
8	for Grant Applications" page 2 - article on "Research Fellowships to Sweden				
-	and Switzerland"				
	page 3				
	pages 11 through 20				
9	pages 1 through 6				
10	none				
11	pages 7 and 8				
~-	page 9 - article on "RFA - Lung Tissue Culture"				
	pages 10 through 18				
12	pages 1 and 2 - article on "MARC Program"				
	pages 5 through 9				
13	pages 1 through 7				
	7-0 outoaBu /				
<u>Vol. 5</u> , No. 1	page 2 - article on "Travel Between U.S. and Canada"				
12	page 1 - article on "MARC Program"				
15	pages 13 and 14 - article on "Prohibited or Restricted				
	Research"				
18	page 9				
