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NIH GUIDE

for GRANTS and CONTRACTS

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

7/29/71 No. 9

MANAGEMENT OF AND ACCOUNTABILITY FOR EQUIPMENT ACQUIRED UNDER NIH GRANTS (NIH 5602)

POLICY

1. PURPOSE The purpose of this issuance is to prescribe the policies and procedures for accountability and property management of equipment purchased with NIH grant funds. It implements DHEW Grants Administration Manual Chapter 1-410, and supersedes all other instructions inconsistent with the present instructions.
2. APPLICABILITY Subject to such legal limitations as may be prescribed by program legislation (e.g., NIH construction programs), this policy is applicable to all current grants administered by the National Institutes of Health. It is not applicable to NIH contracts or to grants having project periods with termination dates prior to July 1, 1971.
3. BACKGROUND Under authority of the PHS Act (42 USC 201 et. seq.), NIH makes funds available through grants for the support of approved research, training, special projects, institutional grants, and demonstration projects. Such funds may be used for the purchase of equipment necessary to the successful prosecution of the activities being supported. Title to equipment purchased from grant funds is vested in the grantee institution or organization, subject to accountability to the Federal Government at the completion of the project for which the grant was made.

Public Law 85-934, 42 USC § 1891 et. seq. authorizes the waiver of accountability for equipment purchased with funds from research grants awarded to nonprofit institutions of higher education and nonprofit organizations whose primary purpose is the conduct of scientific research. Accountability may not be waived for equipment purchased with funds from research grants awarded to other types of institutions nor for equipment purchased from any type of grant other than research grants.

Certain equipment is sufficiently general in nature that it can be utilized by the grantee institution in connection with other grant-supported or grant-eligible activities. Therefore continued retention by the grantee of such equipment, where statutory authority exists, serves the collateral purpose of the creation or enhancement of the research and training capability of the grantee institution and furtherance of the objectives of the National Institutes of Health.

4. DEFINITIONS

- a. Equipment: For the purposes of this issuance, an item of equipment is an article of property procured or fabricated, which is complete in itself, is of a durable nature, and has an expected service life of more than one year.
- b. Supplies: Items which are consumed or expended when put to use or which have an expected service of less than one year. (The provisions of this issuance do not apply to supplies.)

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

- c. Budget Period: That portion of a project period (usually 12 months) so designated for budgeting and accounting purposes.
- d. Project Period: The interval of time for which the support of a project has been approved by the NIH as specified in the grant award document. (In some programs, e.g., General Research Support Grants, each yearly award is a new grant and awarded for a single budget period. In such programs the term "project period" is not used.)
- e. Grantee: The university, college, hospital, public agency, other nonprofit research organization, or an individual receiving a grant for support of such activities as are prescribed by the Public Health Service Act.
- f. Title: As used herein, "title" indicates or designates the right to ownership, subject to accountability requirements.
- g. Accountability: The obligation of a grantee to return to the National Institutes of Health the residue or residual value of equipment purchased with grant funds in accordance with the law and applicable Federal regulations. Such residue includes as much of the equipment, or a fair market value thereof, as represented by the proportion of the initial cost of the equipment charged to the grant account.

5. POLICY Title to equipment acquired with NIH grant funds is vested in the grantee institution unless specifically stated otherwise on the Notice of Grant Awarded. Grantees are expected to apply to equipment acquired with NIH funds the same policies, procedures, and controls normally applied to all of their other equipment, provided that the minimum management standards contained in this issuance are met.

Under authority of P.L. 85-934, nonprofit institutions of higher education and nonprofit organizations whose primary purpose is the conduct of scientific research may be exempted, in whole or in part, from the obligation for further accounting to the Federal Government for the residual value of equipment remaining at the termination of a grant-supported research project. Except in those instances where the awarding unit sees a specific need to claim title to or transfer certain items after the project period is concluded, the NIH awarding unit will waive further accountability upon request by an eligible grantee institution. The reservation to claim such equipment by the NIH may be exercised at any time up to twelve (12) months following the end of the project period but not later than such date as a formal waiver of accountability has been made by the appropriate NIH awarding unit.

No institution may be relieved of accountability for equipment purchased with training grant funds or with funds from other nonresearch project grants.

In those unusual instances where an individual is the grantee, no waiver of the obligation for such a final accounting may be made.

6. IMPLEMENTATION BY GRANTEE INSTITUTION

- a. Inventory: The NIH will not formally require the submission of an inventory for equipment until the termination of the project period during which the item was purchased in whole or in part as a direct charge to grant funds. The following procedures will be used.:

- (1) Upon completion of a project period, and at the time of submission of the final report of expenditures for that project period, grantees shall over the signature of an authorized individual submit to the appropriate NIH awarding unit two (2) copies of the NIH equipment reporting form titled "Equipment Acquired with NIH Grant Funds, Accountability and Disposition." (Exhibit form attached.) In the event that funds from more than one NIH grant have been used to purchase an item of equipment, that item of equipment will be inventoried to the grant which provided the largest amount of funds for its purchase.
 - (2) Grantees shall list, on the equipment reporting form, all equipment purchased in whole or in part from NIH grant funds, where the initial acquisition cost of the equipment was \$300 or more, unless:
 - (a) the grantee has formally determined that the equipment is no longer useful; or,
 - (b) the equipment has a residual or scrap value of less than \$100; or,
 - (c) the equipment has otherwise been reported in accordance with paragraph a.(1) above; or,
 - (d) accountability has been waived pursuant to statutory authority.
 - (3) Where there is no equipment to be reported, grantees shall submit the required form, stating "No accountable equipment."
 - (4) Grantee institutions will, on the equipment reporting form, select a proposed method for satisfying accountability as described in paragraphs b. and c. below.
- b. Waiver of Accountability (Accountability Requirements for Grants Governed by P.L. 85-934)

Where the grantee is a nonprofit institution of higher education or a nonprofit organization whose primary purpose is the conduct of scientific research, the obligation to account for the residual value of equipment purchased with research grant funds may be waived as follows:

- (1) The NIH awarding unit will determine whether or not the full authority available under P.L. 85-934 will be utilized.
- (2) When an item of equipment has been purchased with funds from grants provided by several NIH Institutes or Divisions, the awarding unit which has supplied the largest contribution toward the purchase of the equipment will decide its disposition. (See 6.a.(1) above.)
- (3) When waiver of accountability is not approved, the options listed under paragraph c., below, will be available for use by the grantee, subject to approval by the awarding unit.

c. Accountability Requirements for Grants Other than Those Governed by P.L. 85-934

The requirement for accountability for equipment purchased with grant funds may not be waived for those institutions and grants not covered by P.L. 85-934. Thus accountability for the residual value of equipment purchased with training grant funds, nonresearch grant funds, and research grants made to institutions other than those covered by the provisions of P.L. 85-934, may be satisfied by using one or more of the following options:

- (1) Refund to the NIH * an amount equivalent to the fair market value of the equipment.
- (2) Return the equipment to the NIH**.
- (3) Retain the equipment for use on biomedical and health-related research, training, or education projects of the grantee institution which are within the scope of the PHS Act.
- (4) Transfer equipment and responsibility for accountability to another grantee organization.

If option "(3)" is authorized, it must be carried out under the conditions that during the period of use, no use charge for depreciation, amortization, or charge for other use of the equipment shall be made against any Federal grant or contract. (The only exception to this policy is included in the Principles of Reimbursement for Provider Costs that allows hospitals and nursing homes providing Medicare services to depreciate Government-provided assets.) Also, if within the useful life of the equipment it is sold or not continued to be used in health-related research or training, the fair market value at the time of disposition shall be payable to the NIH as outlined in "(1)" above.

If option "(4)" is elected, grantees should follow the procedures prescribed in Guide issuance 5603 (to be issued).

7. IMPLEMENTATION BY NIH AWARDING UNIT

- a. The awarding unit will review the information reported on the equipment form and the grantee's proposed disposition of the equipment and make a determination as to the disposition of each item listed. The method most appropriate to the circumstances will be selected by taking into consideration such factors as the nature and purpose of the grant, the existence of other health-related projects at the institution, the condition of the equipment, the cost of transfer or shipment, and the potential for effective utilization at the NIH or on other research or training projects.

* Checks should be made payable to the DHEW, NIH, and forwarded to the Director, Office of Financial Management, NIH, Bethesda, Maryland 20014. Checks must identify the relevant grant account and the reason for payment.

** This option to be followed only after receiving instructions from the appropriate NIH awarding unit.

- b. The awarding unit will authorize a method of disposition for each item of equipment and indicate such disposition on the equipment form. One signed copy of the equipment reporting form will be placed in the NIH official grant file and one copy will be returned, along with any special instructions for disposition, to the grantee.

8. GRANTS AWARDED TO INDIVIDUALS Determination as to the method of disposition of equipment purchased with grant funds awarded to an individual will be made by the NIH awarding unit upon termination of support of the project.

9. GRANTEE MANAGEMENT REQUIREMENTS

- a. Acquisition: Grantees are required to be prudent in the acquisition and management of equipment acquired with grant funds. Careful screening should take place to assure that equipment is needed and that the need cannot be met with equipment already in the possession of the institution. A grantee may be reimbursed for an item of equipment already owned by the institution only when such equipment is in the institution's central purchasing department and held in a central stock room for issuance and sale to a using activity.

For purposes of charging NIH grants, the cost of a single item or piece of equipment includes necessary accessories, duty, excise and sales taxes. If the institution policy provides that charges for transportation, protective in-transit insurance, and installation are a part of the cost of equipment, such charges may be included as direct costs of equipment on NIH grants accounts.

- b. Sale or Trade: When equipment is sold by a grantee during the project period in which it was purchased, the net proceeds of sale must be credited to the grant account. Equipment for which accountability has not been waived may be disposed of by the grantee after termination of the project period provided the grant account is credited with the fair market value as of the date of disposition of such equipment. The accounting obligation shall apply to that portion of new equipment that has been purchased by using accountable equipment as a credit or trade-in. (This is not applicable to equipment which has a residual value of less than \$100.)
- c. Lost, Damaged, or Destroyed Equipment: When accountability has not been waived, the grantee will be responsible, using other than NIH grant funds, for replacement or repair of, or compensating the grant account for equipment that is lost, damaged, or destroyed due to negligence on the part of the grantee.
- d. Depreciation and Use Charges: Depreciation or use charges for any equipment or portion of such equipment acquired with Federal funds may not be charged against NIH funds either as a direct or indirect cost. The records of grantee institutions must therefore identify equipment purchased with NIH funds to assure exclusion of such equipment from depreciation or use charges claimed for Federal participation. (The only exception to this policy is included in the Principles of Reimbursement for Provider Costs, which allows hospitals and nursing homes providing Medicare services to depreciate Government-provided assets.)

10. TRANSFER OF RESEARCH PROJECTS All research grants shall be made under the condition that equipment acquired with grant funds, and for which the grantee is accountable, will be made available for transfer upon request of the awarding unit in those cases where the project is transferred to another institution and an NIH grant is made to the new institution to continue that project.

11. EFFECTIVE DATE The policy stated in this issuance is effective July 1, 1971.

References

- (1) DHEW Grants Administration Manual Chapter 1-410, Management of Equipment and Supplies Acquired under Project Grants, April 2, 1969.
- (2) Code of Federal Regulations, Title 42, Public Health, Part 52, Grants for Research Projects, Section 52.42.
- (3) Public Law 85-934, 42 USC § 1891 et. seq. (Vesting of title to equipment without further obligation to the Government.)
- (4) PHS Grants for Research Projects, Policy Statement, PHS Pub. No. 1301.
- (5) PHS Grants for Training Projects, Policy Statement, PHS Pub. No. 1302.
- (6) OMB Circular No. A-101, January 9, 1971, "Standard Policies and Practices for Administration of Research Projects at Educational Institutions in the United States."

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE - NATIONAL INSTITUTES OF HEALTH

NAME AND ADDRESS OF GRANTEE INSTITUTION

GRANT NUMBER

**EQUIPMENT ACQUIRED WITH NIH GRANT FUNDS
ACCOUNTABILITY AND DISPOSITION**

PROJECT PERIOD

PRINCIPAL INVESTIGATOR OR EQUIVALENT

NOTE: For each grant, list items of equipment with an initial acquisition cost of \$300 or more, still useful, and which have a residual or scrap value of more than \$100, purchased during the above project period. Public Law 85-934 authorizes Federal agencies to waive accountability for equipment purchased under RESEARCH GRANTS, provided the grantee is a non-profit institution of higher education or a non-profit organization whose primary purpose is the conduct of scientific research. For ALL OTHER TYPES OF GRANTS and grantee institutions, the grantee is accountable for equipment purchased with grant funds. Submit the original and one copy with final Report of Expenditures for each project period. If additional pages are required, enter grant number on each page. If no equipment was purchased, write "none," sign, and return.

FOR USE OF GRANTEE INSTITUTION

DESCRIPTION Item-(Grantee identification code)	DATE OF PURCHASE	ACQUISITION COST CHARGED TO GRANT	CONDITION (Check one)			DISPOSITION PROPOSED BY GRANTEE (Check one)						LEAVE BLANK (Authorized Disposition By National Institutes of Health Awarding Unit)	
			Good - Excellent	Needs Repair	Scrap Only	Waive	Accountability	Refund Fair	Market Value	Return to NIH	Retain for Health-Related Research and Education		Other (Explain under Remarks)

EXHIBIT

REMARKS

This is to certify that the above named institution is eligible under Public Law 85-934 (see NOTE above), to request a waiver of further accountability for equipment purchased.
(Check one) Yes No

NAME AND TITLE OF AUTHORIZED INSTITUTION OFFICIAL

NIH AWARDING UNIT APPROVING OFFICIAL

SIGNATURE

DATE

SIGNATURE

DATE

GRANT SUPPORT OF SCIENTIFIC MEETINGS (NIH 4105-1)**POLICY**

1. PURPOSE This issuance states policy concerning the review, award, administration, and reporting required when NIH funds are utilized for the support of domestic and international scientific meetings.

2. APPLICABILITY These policies are applicable to NIH research and training grants, usually identified by number code prefixes R 13 and T 14. NIH awarding units, however, may at the time of award apply them as additional conditions to any NIH grant in support of a scientific meeting.

3. DEFINITIONS The following definitions apply to terms used in this issuance:

International Meeting: A meeting so designated by its sponsor, or one to which open invitations are issued on an equal basis to potential participants in two or more countries. The meeting may be held in any country, including the United States.

Domestic Meeting: A meeting held in the U.S. or Canada primarily for U.S.-Canadian participation, but does not exclude those with invited foreign speakers.

Eligible Grantee: A U.S. institution eligible to receive research or training grants, established scientific or professional societies, or in the case of an international meeting, the U.S. representative organization of an established international scientific or professional society.

Bloc Travel Grant: An award of travel funds to a sponsoring organization who will, using an approved mechanism, select the individuals whose travel will be supported.

4. POLICY The National Institutes of Health recognizes a responsibility to assist in the support of scientific meetings planned for the purpose of coordinating, exchanging, and disseminating information when such activities are directed toward objectives clearly within the areas of NIH scientific program interests. The NIH policy is to participate with other scientific organizations in the support of meetings, where practicable, rather than to provide the sole support. In view of the diversity of interests of the various awarding units, and in order to give maximum flexibility, the NIH will not set rigid requirements concerning the types of scientific meetings which may be supported, or the method used for review and approval of the proposal. Each awarding unit may elect to support those meetings clearly within its interests and mission. The general policies governing the administration of research and training grants are applicable to grants in support of meetings.

a. The following general policy guidelines are applicable in providing support for domestic or international meetings.

(1) For domestic meetings or international meetings held in the U.S. or Canada

Research or training grant funds may be awarded to assist in the general support of selected scientific meetings. Research grants may be awarded to eligible grantee organizations to provide limited bloc travel support to attend the meeting for individuals to be selected by the applicant organization. Training grants may NOT be awarded for bloc travel support.

(2) For international meetings held outside the U.S. and Canada

Research and training grants may be used only for support of specific scientific aspects of an international meeting such as a selected symposium or workshop, including the cost of planning, travel of U.S. participants, and other clearly related expenses.

Bloc travel support may be provided through research grants only. Such travel allowance may not exceed economy class fares and per diem allowance will be limited to days of attendance at the meeting at a rate no higher than that allowed Federal employees. Any other restrictions which the NIH has concerning foreign travel current at the time of award will be followed.

5. RESPONSIBILITIES Grants received under authority of the Public Health Service Act are in the nature of trust funds and responsibility of grantees and their officers in handling these funds is similar to that of a trustee. NIH does not intend to restrict grantee organizations to any set plan in developing meetings. However, except for those costs which have received prior approval by the awarding unit, only the items that fall within the categories described under Costs (paragraph 7. below) may be charged to an NIH grant.

- a. Expenditure Reports and Audit An expenditure report is required from the grantee (usually the treasurer or other financial officer of the grantee organization) at the termination of each budget period. The grant account must be maintained separately either on different ledgers or different parts of ledgers, with substantiating invoices, receipts, and payrolls readily available at all times for Government audit. All records shall be retained for audit purposes for a period of five years after the end of the budget period which they cover or until a Federal audit is completed and all resulting questions are resolved, whichever occurs first.
- b. Terminal Progress Reports A report of the meeting must be prepared and five copies submitted to the awarding unit that supported the meeting within six months after the termination of the grant. The report should include (a) the grant number, (b) the title of the meeting, (c) the name of the person shown on the application as the conference director, principal investigator, or program director, (d) the name of the organization that conducted the meeting, and (e) a list of the individuals who participated as speakers or discussants in the formally planned sessions of the meeting. Copies of proceedings or publications resulting from the meeting, including items (a) through (e) listed above, may be substituted for the final progress report, with approval of the NIH awarding unit.

6. APPLICATIONS Prospective applicants are encouraged to inquire in advance concerning NIH's interest in the proposed meeting and to request detailed instructions for preparation of an application.

7. COSTS Except for the specific restrictions applicable to support of international meetings held outside the U.S. (see paragraph 4.a.(2) above), the cost policies below are applicable to all grants in support of meetings.

a. Direct Cost Expenditures Grant funds may NOT be used for alterations, renovations, or the purchase of equipment. Allowable expenditures and the specific policies applicable to meeting grants are listed below:

- (1) Salaries In accordance with the policy of the grantee organization, grant funds may be used to provide salaries, in whole or in part, of professional personnel, clerical assistants, editorial assistants, and other nonprofessional staff but only in proportion to the time or effort spent directly on the meeting.
- (2) Equipment Grant funds may be used for the rental of necessary equipment. Funds may not be used for the purchase of equipment.
- (3) Travel and Personal Expenses Funds requested must be restricted to those purposes identified by the grantee as required for the operation of the conference. Funds may NOT be used for travel unless prior approval has been obtained from the NIH awarding unit. Travel expenses for grantee organization employees will be paid in accordance with travel regulations of the grantee organization when such policies have been established. In the absence of such regulations and policies, U.S. Standardized Government Travel regulations will apply. Transportation costs for attendees and participants at the meeting may not exceed economy class fares and per diem allowance will be limited to the days of attendance at the meeting. In all cases, where available, U.S. Flag Carriers will be used.

Where meals and/or lodging are furnished without charge or at a nominal cost (e.g., as part of the registration fee) an appropriate deduction will be made from the authorized per diem.

Grant funds may not be used for visas, passport charges, entertainment, tips, bar charges, personal telephone calls, or laundry charges of participants or guests.

Grant funds may not be used to pay travel or other expenses of local participants in the conference (persons not in travel status) except under unusual circumstances and with the prior approval of the awarding unit.

- (4) Supplies Grant funds may be used for the purchase of supplies for the meeting, provided the supplies are received during the project period.
- (5) Conference Services Grant funds may be used for necessary recording of proceedings, simultaneous translation, etc., and subsequent transcriptions.
- (6) Publication Costs Subject to prior approval from the NIH awarding unit, grant funds may be used to cover the costs of publishing the proceedings of a scientific meeting or of special papers presented.

When grant funds are awarded to pay for either the entire or the partial cost of publication of proceedings or of a book or pamphlet, such costs are considered to cover special plates, charts, diagrams, printing, distributing, mailing, postage, and general handling, unless otherwise specified at the time the grant is made.

- (7) Registration Fees Registration fees may be paid from grant funds, provided such fees cover only those costs properly chargeable to the grant.
 - (8) Dues Dues to organizations, federations, or societies exclusive of registration fees, are NOT allowed as a charge against the grant.
 - (9) Entertainment Grant funds may NOT be used to cover the costs of banquets, luncheons, coffee breaks, theater, or entertainment of any sort.
 - (10) Federal Employees Grant funds may NOT be used to cover any payment to a full-time Federal employee.
 - (11) Honoraria Honoraria may NOT be paid from grant funds.
- b. Indirect Costs Indirect costs will not be allowed on grants in support of meetings except in the most unusual circumstances and then only after negotiation in advance of the award between the applicant organization and the awarding unit.

8. PUBLICATION AND COPYRIGHT If the grantee organization wishes to publish material for which support has been provided in whole or in part with NIH funds, the material may be distributed free of charge. On the other hand, there may be occasions where the distribution of the published material would be limited and the grantee organization would prefer to make a charge for the material. Under these circumstances an open account must be maintained for five years from the date of publication. That part of the net proceeds from such sales, up to the proportionate amount charged to the grant for publishing or producing the material, must be returned to the U.S. Treasury. Special agreement on the distribution of published material should be negotiated in advance with the NIH awarding unit in each case.

Unless otherwise specified by the awarding unit, five copies of any publication resulting from a meeting should be sent to the awarding unit that provided support for the meeting.

Acknowledgment of NIH's support should be given on the program of the meeting and on any publication resulting from the meeting. The following statement, "The NIH participated in the support of this meeting under grant No. _____, from _____ (Awarding Unit) _____," will suffice. Responsibility for the conduct or sponsorship of the meeting must NOT be ascribed to the NIH.

Unless otherwise provided for in the conditions of the award, the author is free to arrange for copyright of any publication resulting from work supported by the NIH. Any such copyrighted publication, however, shall be subject to a nonexclusive, irrevocable, royalty-free license to the Government to reproduce, translate, publish, and dispose of such material, and to authorize others to do so.

9. EFFECTIVE DATE This policy is effective on date of release.

References

- (1) PHS Grants for Research Projects, Policy Statement, PHS Pub. 1301.
- (2) PHS Grants for Training Projects, Policy Statement, PHS Pub. 1302.
- (3) NIH Grants Policy Guide No. 2, June 19, 1970, pp.5-6, Disposition of Grant-Related Income (NIH 5601).

AWARDS IN DIGESTIVE DISEASES AND NUTRITION

ANNOUNCEMENT

1. The National Institute of Arthritis and Metabolic Diseases, NIH, is accepting applications for awards on a national competition basis from those holding health professional degrees in the clinical sciences (MD, DO, DMD, DVM, or equivalent) and whose interests are in the areas of digestive diseases and nutrition. A limited number of awards will be made in the following areas:

- a. Clinical Investigator Award in Digestive Diseases and Nutrition
- b. Academic Career Development Award in Digestive Diseases and Nutrition.

2. Salaries for each award will be individually negotiated between the sponsoring institution and NIAMD.

3. Deadline for submission of applications is September 1, 1971. Additional information regarding the policies governing the award, instructions for applying and application forms may be obtained by writing to:

Digestive Diseases and Nutrition Programs
National Institute of Arthritis and Metabolic Diseases
National Institutes of Health
Bethesda, Maryland 20014.

COLLABORATIVE (CONTRACT) PROGRAMS IN POPULATION RESEARCH,
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The Institute uses the contract mechanism when the initiative for carrying out a research project, including design, direction, and methodology, originates primarily within the National Institute of Child Health and Human Development (NICHD) or when the research requires extensive participation by staff in its development. Contracts are used (1) to stimulate research in gap areas; (2) to develop resources, methodology, instrumentation, or specific products; (3) to provide services to investigators; (4) when staff can function as both stimulator for collaborative efforts and coordinator of research among a number of investigators; (5) to provide for innovative, creative, pioneering projects where an unusual insight or a timely or fortuitous opportunity may have enormous payoff to the scientific community if followed through; (6) to give coherence to a relatively unstructured field; (7) to support organizational activities such as conferences which are program or mission oriented and provide for information exchange or the development of methods.

The Center for Population Research, NICHD, currently has contracts in the following areas:

1. Contraceptive Development
 - a. Development of new contraceptive drugs, including obtaining, synthesizing, and testing of compounds to determine the extent and nature of antifertility activity.
 - b. Development of systems and/or materials for uninterrupted administration of antifertility drugs; and evaluation of biological evidence concerning slow and constant release of potential contraceptive drugs.
 - c. Development of new techniques for sterilization in both males and females. Design of devices that are safe and effective, reversible, easily implantable, and acceptable to various population groups; testing and evaluation of these devices.
 - d. Studies of how sperm mature and acquire the capacity to fertilize ova; functions of the male duct system and accessory glands; factors affecting the transport of sperm to the site of fertilization; and the survival of sperm in the female tract.
 - e. Development of techniques for observing the normal function of segments of the oviduct in ovum pick-up and transport, and studies of the effect of hormones and physical factors on the oviduct.
 - f. Studies of hormones involved in reproduction and of methods for measuring them; the role of hormones in the initiation and maintenance of pregnancy; function of the corpus luteum; and hormonal events of the menstrual cycle.

- g. Studies of the ovum, including formation and ovulation; the physiology of egg membranes and possible alteration of them for contraceptive purposes; biochemical function of the fertilized egg before implantation; and the dynamics of decidualization and implantation.

2. Evaluation of Existing Contraceptive Methods

- a. Clinical and laboratory studies of selected subjects (particularly long-term oral contraceptive users) which will elucidate elements of excess risk, estimates of extent of risk, unique properties of presently available drugs, and interaction between steroid drugs and commonly used prescription drugs.
- b. In vitro and in vivo (human and animal) studies of the absorption, metabolism, and excretion of steroid contraceptive drugs.
- c. Studies to further clarify the effects of oral contraceptives on blood pressure, including extent and magnitude of risk, characteristics of high-risk subpopulations; unique properties of certain contraceptive formulations; physiological mechanism of production of increased blood pressure; and desirable methods of treatment.
- d. Human studies which will lead to a more precise estimation of the minimal dose of a drug which will provide acceptable contraceptive effect and/or minimal biochemical or toxic effects; evaluation of potentially toxic effects may be done in animal models.
- e. Studies of the effects and mechanism of action of intrauterine contraceptive devices.
- f. Studies to ascertain whether vasectomy is a relatively innocuous surgical procedure or whether it may be associated with acute adverse effects and/or significant long-term medical complications.

3. Social Science Research Related to Population

- a. Studies of the interrelations between social change and population size, structure, and distribution; and the determinants and consequences of population change.
- b. Analyses of trends in fertility, age at marriage, divorce, abortion, and related variable; studies of the interrelations of fertility trends and other socioeconomic variables, such as income, education, religion, and residence.
- c. Studies of family structure, sexual behavior, and the relation between childbearing patterns and child development; decisions which determine a couple's number and spacing of children; attitudes toward methods of fertility control; and alternatives to childbearing which couples perceive and how these perceptions affect fertility.
- d. Evaluation of policies aimed at regulating population and of policies which indirectly affect population growth or distribution. Past and present policies--including family allowances, direct incentives, and family planning programs--are evaluated for their impact on population.

COLLABORATIVE (CONTRACT) PROGRAMS - DIVISION OF BIOLOGICS STANDARDS

The mission of the Division of Biologics Standards (DBS) is the exercise of controls on the safety, purity, and potency of biological products through a system of licensing of manufacturing establishments and of the products, as well as the conduct of research related to these objectives in order that decisions made and actions taken can be based on sound information.

To discharge its responsibility, the Division establishes standards for all biological products such as vaccines, serums, blood and its derivatives, and like products. These include written standards, eventually promulgated as regulations, some of which apply to individual products and some to products in general; and physical standards, i.e., biological preparations whose properties and qualities have been extensively characterized. The latter are issued to manufacturers and other research laboratories concerned with biologics standardization for evaluation with their products, particularly with respect to potency, or strength.

As newer vaccines and other products are developed and the Division's responsibilities have increased, a collaborative or contracts program was established in 1966 in order to perform certain functions beyond the capabilities of the intramural program. This program is truly an extension of the intramural research program. It is set up to develop information concerning individual biological products in toto as to their purity, safety, and potency, and components, additives, production substrates and containers and devices for administration. This information is necessary so that written standards for new products can be developed and regulations for old products can be updated. Furthermore, newer testing methods must constantly be developed to improve the safety and usefulness of all biological products. To these ends, the program supports investigations into:

Possible oncogenicity of vaccines.

Toxic and undesirable properties of vaccine components and additives.

Long-term epidemiologic follow-up of recipients of biological products.

Adventitious materials present in biological products.

Purification and definition of active components of biological products.

Development of new substrates for the production of vaccines.

Monitoring of blood for presence of certain undesirable properties such as an antigen associated with serum hepatitis.

COLLABORATIVE (CONTRACT) PROGRAMS OF THE
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

1. The collaborative research program of the National Institute of Environmental Health Sciences (NIEHS) is directed to support and achievement of research efforts and goals considered essential to the mission of the Institute. Collaborative projects include both research contracts and interagency agreements and are restricted to activities which, by virtue of required expertise or logistics, lie beyond the scope of the Institute's intramural or research grants programs.
2. Proposals are solicited on a competitive basis through published announcements and direct contact with research groups of recognized competency. Both solicited and nonsolicited proposals are reviewed and evaluated initially, in terms of mission relevancy, competing priorities, and cost, by the Scientific Directorate of the Institute. Secondary evaluation involves a site visit by an ad hoc expert committee. Final evaluation, including technical review of the site visit report, is conducted by the Scientific Directorate.
3. The current collaborative research program of NIEHS is of limited magnitude and includes projects in the areas of biologic effects of ionizing radiation, phyto-toxins, heavy metal toxicity, somatic mutations, and special risk groups. While present plans do not call for expansion of effort in the aforementioned or other areas, any future need for expanded or new collaborative research effort will be announced through the usual mechanisms.

INTERACTION OF OTOTOXIC DRUG AND NOISE
EXPOSURE ON HEARING LOSS IN ANIMALS

ANNOUNCEMENT

The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, is interested in organizations having the capability of carrying out studies in the area of combined effects of noise exposure and ototoxic drugs, e.g., kanamycin, neomycin, etc. on hearing loss and mechanism thereof in animals. Particular attention shall be paid to method of assay of temporary and permanent threshold shifts and underlying processes which result in these shifts. Therefore, competence in the area of measuring hearing levels in animals and in fundamental cochlea processes will be mandatory. Resumes are invited from organizations having the above capabilities. Resumes should contain (1) information which will clearly establish the organizations' qualifications, experience, and achievement in the area, (2) information concerning personnel available for the project, (3) a brief statement of awareness of problems and factors involved in the subject project and (4) a description of equipment and facilities available for the project.

It is emphasized that expression of interest must relate to the specific project which falls within the scope of the area outlined above and include a rationale for the project that can be scientifically evaluated. Compilation of organizational reports, C.V.'s, and general expression of capabilities alone will not suffice.

This synopsis is not a request for a proposal. Only those sources deemed, after a review of the resumes, to be fully qualified for this project will be invited to submit proposals. The decision to request proposals for the conduct of the project will be based on the evaluation by the NIEHS staff and its consultants of the responding organizations' prior experience in this field and the feasibility and adequacy of their outlined approaches. Other respondents will not be notified of the results of the evaluation.

Ten copies of the resume of experience and capabilities should be submitted to:

Executive Officer
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

before close of business on August 16, 1971.

Telephone calls will not be honored and all inquiries must be in writing and addressed to the office listed above. In order that all prospective contractors be treated on an equal basis, any questions raised by individual prospective contractors and the answer thereto will be made available upon request to all potential contractors.

EFFECTS OF NOISE ON DRUG
ACTION AND DRUG METABOLISM

ANNOUNCEMENT

The National Institute of Environmental Health Sciences (NIEHS), NIH, is interested in organizations having the capability of determining the effects of noise on drug disposition in animals. This will include studies of noise effects on the biological half-life of drugs, the normal circadian rhythm of plasma adrenal steroid hormones, drug clearances, and biotransformation, and on the metabolism of drugs in vitro by tissues from normal vs. noise-exposed animals. Provision must be made to differentiate the effects of noise per se from non-aural components and from generalized "stress."

Evidence of demonstrated competency in the areas of separation and quantification of drugs, steroids and their metabolites is essential. Expertise in determining drug and steroid metabolizing enzyme system activities in various tissues is required. A pharmacologist (Ph.D.) must be a part of the scientific personnel assigned to the project. Knowledge of variables important to noise as a possible effector of drug disposition must be documented.

It is emphasized that expression of interest must relate to the specific project which falls within the scope of the area outlined above and include a rationale for the project that can be scientifically evaluated. Compilation of organizational reports, C.V.'s, and general expression of capabilities alone will not suffice. Only those sources deemed to be fully qualified to carry out the specific project of interest to NIEHS will be considered when proposals are solicited. Other respondents will not be notified of the results of evaluation. Results of all studies that are conducted under contracts that may be established are to be reportable to the NIEHS as specified by the Project Officer.

Resumes are invited from organizations having the above capabilities. Resumes should contain (1) information which will clearly establish the organization, qualifications, experience, and achievement in the area, (2) information concerning personnel available on the project, (3) a brief statement of awareness of problems and factors involved in the subject project, and (4) a description of equipment and facilities available for the project.

This synopsis is not a request for a proposal. Only those sources deemed, after a review of the resumes, to be fully qualified for this project will be invited to submit proposals. Other respondents will not be notified of the results of the evaluation.

Ten copies of the resume of experience and capabilities should be submitted to:

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