NIH GUIDE for GRANTS and CONTRACTS

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

Vol. 7, No. 17, November 10, 1978

IN THIS ISSUE:

RESPONSIBILITY FOR CARE AND USE OF ANIMALS

Policy assigning responsibility for humane care and use of animals under NIH-supported grants, contracts, and other awards. Effective January 1, 1979. Page 1

GUIDELINES FOR ESTABLISHING AND OPERATING CONSORTIUM GRANTS

Revision of NIH's policy for establishment and operation of consortium grants. Effective for all grants having budget periods beginning on or after January 1, 1979. Page 9

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 20014, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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

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

NIH Guide for Grants and Contracts
Vol. 7, No. 17, November 10, 1978

RESPONSIBILITY FOR CARE AND USE OF ANIMALS

POLICY

A. PURPOSE This issuance assigns responsibility for humane care and use of animals under NIH grants, contracts, and other awards, and describes requirements and procedures to fulfill these responsibilities. It supersedes *NIH Guide for Grants and Contracts*, Vol. 1, No. 7, pages 3-5, June 14, 1971, and implements PHS Grants Manual Chapter 1-43.

B. DEFINITIONS OR TERMS

For purpose of this issuance:

Animal - Any live, vertebrate animal used or intended for use in research, experimentation, testing, training, or related purposes. (The requirement to follow the *Guide* does not apply to facilities for cold-blooded animals; however, the Principles for the Use of Animals [Appendix I] apply to all live vertebrate animals.)

Animal Facility - Any building, room, area, or vehicle designed to confine, transport, maintain, or use animals.

Assurance - The formal document submitted by a recipient or applicant institution fulfilling the requirements of E.1. below, and accepted by the NIH.

Guide - Guide for the Care and Use of Laboratory Animals, DHEW No. (NIH) 74-23, revised 1972 or succeeding editions.

Institution - Any public or private institution, organization, or agency including Federal, State, or local government agencies in the United States, the District of Columbia, the Commonwealth of Puerto Rico, or any territory or possession of the United States.

NIH Support - Any grant, contract, or other award from the NIH.

Principles - Principles for Use of Animals, National Institutes of Health (see Appendix I).

Proposal - Includes grant applications, contract proposals, or any other request for NIH support.

C. APPLICABILITY This policy is applicable to all NIH grants, contracts, or other awards, which involve the use of animals in research, training, testing, or other activities to be performed by the grantee or contractor institutions or by cooperating institutions.

D. POLICY Humane care and use of animals in NIH-awarded projects is the responsibility of investigators and the institution receiving an award. No award will be made to any institution for use of animals or animal facilities unless a responsible official of the institution has submitted an acceptable assurance as defined above and similar to the example in Appendix II. No such award will be made to an individual unless that individual is affiliated with an institution which has filed an acceptable assurance with NIH.

E. IMPLEMENTATION

1. Grantee or Contractor Implementation

a. Before receiving NIH awards for projects in which animals or animal facilities are used, the grantee or contractor institution must submit to the Office for Protection from Research Risks (OPRR), Office of the Director, NIH, an assurance that it is committed to follow the *Guide* and the Principles, and will meet the requirements set out in E.1.a.-i. below. An assurance shall be typed on the institution's letterhead and signed by an institutional official who has the authority to make such a commitment. OPRR will provide the grantee or contractor organization with necessary definitions, instructions, and examples of acceptable assurance formats.

b. Institutions are required to submit complete new assurance forms to OPRR once each five years.

> NOTE: The OPRR will be contacting institutions individually concerning the proposed scheduling for submission of new assurances.

c. Significant changes in existing assurance status or problems encountered in implementing this policy shall be reported immediately to OPRR. Review of these changes or problems may require renegotiation of the assurance, or such other action as may be appropriate.

d. Each institution shall appoint and maintain an institutional committee to maintain oversight of its animal facilities and procedures. The committee should be composed of at least five members who are knowledgeable regarding the care and use of animals in research, including at least one veterinarian. The names, position titles, and credentials of the committee members will be provided to OPRR and changes in membership will be reported annually to OPRR by the institution. (See Appendix II.)

e. Each institution shall establish a mechanism to review its animal facilities and procedures for compliance with the provisions of the *Guide*. Accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC) is the best means of demonstrating conformance to those provisions. An alternative to AAALAC accreditation is review, at least annually, of animal facilities and procedures by the institution's committee.

f. The awardee institution shall maintain records of committee activity, or accrediting body determinations. These records shall be available for inspection by the OPRR or other HEW-authorized representatives.

g. If the institution's committee or the OPRR determines that the institution is not in conformance to the *Guide*, an annual report to OPRR indicating progress toward full conformance will be required.

h. Grant applications and contract proposals shall indicate whether animals are involved in the proposed activity and should state the rationale for using animals. Information should be provided to confirm that the species and numbers of animals are appropriate, that unnecessary discomfort and injury to animals will be avoided, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated to minimize stress to the animals.

i. Review of individual proposals or projects by the institution's committee (or appropriate administrative review) is encouraged but not required. Proposals being reviewed by NIH may be referred to the committee of the applicant institution for review of apparent or potential violation of the Principles or any part of this policy. Approval of the committee will not be required but their findings will be reported to the NIH.

2. NIH's Implementation

a. OPRR Responsibilities

OPRR is responsible for compliance, general administration, and coordination of this policy as a whole and will:

- Request and accept assurances and related reports.
- Distribute to initial review groups and NIH awarding units cumulative lists of institutions that have filed acceptable assurances of compliance with this policy (AAALAC accreditation will be indicated on the list).
- Advise awarding units and awardee organizations on this policy and on resolution of problems or violations.

b. NIH Awarding Unit Responsibilities

(1) NIH staff and initial review groups who review applications and proposals will be alert for procedures or conditions in the application or proposal that may violate the Principles, and will bring them to the attention of awarding unit staff and advisory councils or boards.

(2) NIH awarding units may not make an award unless the applicant/offeror is on the OPRR's cumulative list of institutions which have filed an acceptable assurance of compliance.

(3) NIH awarding units are responsible for resolution of issues involving any questionable procedure before making an award. This may be done by negotiation with the applicant/offeror organization or by requiring review of the proposal by the institution's committee.

(4) If in the judgment of the NIH awarding unit an institution has failed to comply with the terms of this policy, OPRR should be consulted. If deemed appropriate, the NIH may refuse to make to that institution further awards involving the use of animals, suspend or terminate support of a specific project involving the use of animals, suspend or terminate support of project by a specific investigator, or suspend or terminate support of all projects involving animals at that institution.

F. EFFECTIVE DATE The provisions of this policy become effective January 1, 1979.

Appendix I

PRINCIPLES for Use of Animals

The Personnel

1. Experiments involving live, vertebrate animals and the procurement of tissues from living animals for research must be performed by, or under the immediate supervision of, a qualified biological, behavioral, or medical scientist.

2. The housing, care, and feeding of all experimental animals must be supervised by a properly qualified veterinarian or other scientist competent in such matters.

The Research

3. The research should be such as to yield fruitful results for the good of society and not random or unnecessary in nature.

4. The experiment should be based on knowledge of the disease or problem under study and so designed that the anticipated results will justify its performance.

5. Statistical analysis, mathematical models, or in vitro biological systems should be used when appropriate to complement animal experiments and to reduce numbers of animals used.

6. The experiment should be conducted so as to avoid all unnecessary suffering and injury to the animals.

7. The scientist in charge of the experiment must be prepared to terminate it whenever he/she believes that its continuation may result in unnecessary injury or suffering to the animals.

8. If the experiment or procedure is likely to cause greater discomfort than that attending anesthetization, the animals must first be rendered incapable of perceiving pain and be maintained in that condition until the experiment or procedure is ended. The only exception to this guideline should be in those cases where the anesthetization would defeat the purpose of the experiment and data cannot be obtained by any other humane procedure. Such procedures must be carefully supervised by the principal investigator or other qualified senior scientist.

9. Post-experimental care of animals must be such as to minimize discomfort and the consequences of any disability resulting from the experiment, in accordance with acceptable practices in veterinary medicine.

10. If it is necessary to kill an experimental animal, this must be accomplished in a humane manner, i.e., in such a way as to insure immediate death in accordance with procedures approved by an institutional committee. No animal shall be discarded until death is certain.

The Facilities

11. Standards for the construction and use of housing, service, and surgical facilities should meet those described in the publication, *Guide for the Care and Use of Laboratory Animals*, DHEW No. (NIH) 74-23, or as otherwise required by the U.S. Department of Agriculture regulations established under the terms of the Laboratory Animal Welfare Act (P.L. 89-544) as amended 1970 and 1976 (P.L. 91-579 and P.L. 94-279).

Transportation

12. Transportation of animals must be in accord with applicable standards and regulations, especially those intended to reduce discomfort, stress to the animals, or spread of disease. All animals being received for use as experimental subjects and having arrived at the terminal of a common carrier, must be promptly picked up and delivered, uncrated, and placed in acceptable permanent facilities.

Appendix II

Example of Acceptable Assurance

Assurances should be typed on the organization's letterhead, include the information provided on the sample assurance below, and be dated and signed by an authorized representative of the organization. The examples given below for committee membership are not intended to dictate numbers of, or qualifications for, committee members. However, except in unusual circumstances the committee should be of at least five members and include at least one veterinarian. Any such unusual circumstance should be explained in a statement accompanying the assurance. The following is provided to help you draft an acceptable assurance for your institution:

A S S U R A N C E

(Name of institution) takes responsibility for humane care and use of animals used in projects awarded by the NIH. We are committed to comply with the Principles for Use of Animals, the *Guide for the Care and Use of Laboratory Animals*, the provisions of the Animal Welfare Acts, and other applicable laws and regulations.

We have appointed and will maintain a committee of at least five members to maintain oversight of our animal care program. The members have appropriate education and experience to perform their duties with respect to the types of animals and species used and the kinds of projects to be undertaken. If the conduct of a specific project is to be reviewed, the quorum will not include any member having an active role in the project. Changes in membership will be reported annually to the Office of Protection from Research Risks, National Institutes of Health.

Current members are:

1. _____ (Each member enter name, degrees, position title, and at least a one line description of pertinent background, e.g., Jane Jones, Ph.D., M.D., Professor of Psychology, 13 years' experience in laboratory use of monkeys, dogs, and rats.)
2. _____
3. _____

etc., etc.

(Use a paragraph identical or similar to one of the following:)

Option 1 - The animal facilities of this institution are accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). Therefore, we are in compliance with the *Guide* and expect to remain so. The institutional committee will review our facilities and procedures for care and use of animals at least once each year to determine that AAALAC standards are being met.

OR

Appendix II

Example of Acceptable Assurance

Option 2 - The institutional committee has inspected our facilities and reviewed our procedures and find that we do comply with the *Guide*. The committee will review our facilities and procedures for care and use of animals at least once each year and make recommendations to the responsible officer of the institution.

OR

Option 3 - The institutional committee has inspected our facilities and reviewed our procedures and has recommended the following improvements:

1. Thirty larger dog cages
2. Improved maintenance of cage washing equipment.
3. Training program for animal technicians.
4. etc., etc.

The committee will review our facilities and procedures for care and use of animals at least once each year and make recommendations to the responsible officer of the institution.

(End of option - use one of above three options)

We will submit to the institution's administration and to the OPRR, NIH, an annual report of progress on recommended improvements. We will update and resubmit a complete assurance every fifth year to OPRR.

Responsible officials of this institution will receive and consider all reports from the committee, questions or complaints concerning welfare of our animal subjects from any source, and will act to fulfill the provisions of this assurance.

We will annually notify all interested institutional staff of the policy, the standards, and this assurance, and will supply copies on request. We will annually review this assurance and the committee activities for compliance. Records of committee meetings and related administrative actions will be kept and made available to NIH upon request.

Signature
Name
Position - Title
Date
Address
Telephone number

GUIDELINES FOR ESTABLISHING AND OPERATING CONSORTIUM GRANTS

POLICY

A. Purpose The purpose of this issuance is to provide 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. It is a revision and supersedes the policy as stated in the *NIH Guide for Grants and Contracts*, Vol. 4, No. 8, p. 4, September 19, 1975.

B. Background In recent years, 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 cooperative 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 cooperating 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 cooperative arrangement between or among the grantee institution and one or more other institutions (profit or nonprofit) which are separate legal entities, administratively independent of the grantee. The involvement of the non-grantee (cooperating) 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 repair, data processing, or equipment fabrication.

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 even though one or more institutions other than the grantee are cooperating 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 cooperating institution.

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.

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 cooperating 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 grantee institution and at the participating 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 all institutions for each year, as shown under b. above.

   d. An explanation of the programmatic, fiscal, and administrative arrangements made between the grantee institution and the cooperating institutions.

   e. The following statement 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 cooperating 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 cooperative 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 of the material.

As a general rule it should not be necessary to request detailed information concerning the written agreements during noncompetitive continuation application review unless the relationship between the grantee institution and its cooperating 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 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 cooperating 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 cooperating 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 cooperating 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 cooperating 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. Care and treatment of laboratory animals. Each cooperating institution using warm-blooded animals in the grant-supported project will comply with applicable portions of the Animal Welfare Act (P.L. 89-544 as amended) and will follow the guidelines prescribed in DHEW Publication No. 74-23 (NIH), "Guide for the Care and Use of Laboratory Animals."

b. Civil rights and equal employment opportunity. Each cooperating institution must comply with Title VI of the Civil Rights Act of 1964 and Executive Order 11246. The grantee must ensure that all cooperating institutions have a valid Assurance of Compliance with the Civil Rights Act of 1964 on file with the DHEW (Form HEW 441) and, if a contract is entered into, the contract will include paragraphs (1) through (7), Part II, Subpart B, Section 202, Executive Order 11246.

c. Protection of human subjects. The grantee institution and the cooperating institutions should refer to Code of Federal Regulations, 45 CFR Part 46, Subpart A, "Protection of Human Subjects," and specifically Section 46.107, "Special Assurances." In addition to assuring that initial requirements for protection of human subjects are met in agreements between the grantee institution and the cooperating institutions, procedures also must be established to assure continued monitoring and compliance with these requirements during the course of the project.

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 cooperating 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 cooperating 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." (Title IV, General Provisions of the DHEW Appropriations Act each year since FY 1970.)

f. Recombinant DNA Molecules (DNA). The grantee institution, the cooperating institutions, and their respective principal investigators should refer to the most recent guidelines 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 cooperating 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 cooperating institution(s). The expenditures are to be made in accordance with NIH policies generally applicable to research grants. The requests for costs such as foreign travel, alterations and renovations, and patient care must be accompanied by special justification.

It should be noted that no cooperating institution 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. In those rare instances where only a profit making organization can provide a required aspect of the cooperative research effort, a reasonable fee - if necessary - can be allowed as a component part of the fiscal arrangements made between the grantee and that organization but must be approved by the NIH awarding unit.

2. Indirect costs. Indirect costs for the grantee institution will be awarded routinely through the NIH Indirect Cost Management System (ICMS).

If indirect costs for a cooperating institution are required from the grant, they must be requested on the budget page as a direct cost. The amount to be requested is determined by applying the DHEW-negotiated indirect cost rate for the cooperating institution to the appropriate direct cost base being requested for that institution. In such cases, the indirect cost amounts requested for cooperating institutions should be viewed as fixed maximum amounts for each year. The amounts requested for a cooperating 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 cooperating 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.

H. Other Administrative Considerations

1. Rebudgeting authority of cooperating institutions. Rebudgeting between budget categories on the part of non-grantee cooperating 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 cooperating institutions. In any case, the grantee institution must be responsible for assuring that the combined rebudgetings of both the grantee institution and cooperating 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 cooperating 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 DHEW. The written agreement negotiated with each cooperating institution may include an arrangement whereby the cooperating 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. Title to all equipment purchased with grant funds resides with the grantee institution. The grantee institution has the responsibility for the inventory, accountability, and disposition of equipment in accordance with PHS policy.

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 cooperating institution(s) will maintain records as necessary for the grantee institution to fulfill its responsibility.

6. Publications. The grantee institution and the cooperating 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 cooperating 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 for all grants having budget periods beginning on or after January 1, 1979.

☆ U. S. GOVERNMENT PRINTING OFFICE : 1978 281-233/11