

NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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SPECIAL EDITION

LABORATORY ANIMAL WELFARE

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

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

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LOCATION OF DOCUMENTS

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INTRODUCTION

This Special Edition of the NIH Guide for Grants and Contracts contains four documents relevant to the care and use of laboratory animals:

- (1) The revised Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions. This policy revision represents several years of careful review and consideration of the PHS Extramural Animal Welfare Policy promulgated in 1979. A proposed draft of the policy was published for public comment in an April 5, 1984, Special Edition of the NIH Guide for Grants and Contracts. Approximately 340 comments on the proposal were received, both in writing and at three open hearings held during the summer of 1984 in Kansas City, Boston and Seattle. All of the comments were given careful consideration in the development of the revised PHS Policy.

The most significant changes in the revised policy are:

- a. The policy requires that each institution receiving PHS funds for research involving animals submit detailed information in an Animal Welfare Assurance regarding the institution's program for the care and use of animals.
- b. Awardee institutions will be required to identify an institutional official who is ultimately responsible for the institution's program for the care and use of animals, and a veterinarian qualified in laboratory animal medicine who will participate in the program. Institutions will also be required to designate clear lines of authority and responsibility for those involved in animal care and use in PHS-supported activities.
- c. The policy clearly defines the role and responsibilities of institutional animal care and use committees and will enhance the involvement of such committees in all aspects of PHS-supported research at institutions. The policy requires that institutional animal care and use committees include an individual unaffiliated with the institution, a veterinarian who has program responsibilities and who has training or experience in laboratory animal science and medicine, a practicing scientist experienced in research involving animals, and a member whose concerns are in a nonscientific area.
- d. The policy requires institutional animal care and use committees to review and approve those sections of applications for PHS funds that relate to the care and use of animals before PHS funds may be awarded.
- e. Institutions that are not accredited by the American Association for the Accreditation of Laboratory Animal Care will be required to conduct a self-assessment of the institution's program, based on the Guide for the Care and Use of Laboratory Animals. Significant deficiencies in the institution's program must be identified and the institution must adhere to an approved plan and schedule for correction of the deficiencies.

The policy shall become effective December 31, 1985. Instructions regarding implementation follow the text of the policy.

- (2) Sample Animal Welfare Assurance. The Office for Protection from Research Risks (OPRR), NIH, which is responsible for the general administration and coordination of the PHS Policy has developed a sample assurance to assist PHS awardee institutions in developing an assurance in accordance with the revised policy. Institutions that are presently conducting PHS-supported research in accordance with an approved Animal Welfare Assurance may continue to do so in accordance with the conditions of that assurance. However, these institutions are encouraged to implement the revised policy as soon as it is feasible to do so, and must submit a new assurance to OPRR in accordance with the revised policy by January 1, 1986. Institutions are expected to begin operating under their new assurance as of January 1, 1986.
- (3) U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. At the request of the Office of Science and Technology Policy, the Interagency Research Animal Committee (IRAC) developed these Principles based on the Principles incorporated in the 1979 PHS Extramural Animal Welfare Policy and a similar statement adopted by the Council for International Organizations of Medical Science in 1984. IRAC is comprised of representatives from Federal agencies that conduct, support or regulate the use of animals in testing, research and training. Nine Federal agencies have adopted the U.S. Government Principles, including the Department of Health and Human Services, of which PHS is a component. The revised PHS Policy is intended to implement and supplement these U.S. Government Principles.
- (4) Site Visits to Animal Care Facilities: An Addendum. As part of the NIH evaluation of the adequacy of the Animal Welfare Assurance system, NIH conducted a series of ten site visits in 1983. The results of those site visits were published in the April 5, 1984, Special Edition of the NIH Guide for Grants and Contracts. The report contained in this publication is an addendum to the original report and summarizes the results of a series of five additional site visits to institutions that received less than \$5 million in NIH funds during Fiscal Year 1984. These additional site visits were conducted because this category represents the largest number of institutions that have Animal Welfare Assurances. In light of the revised PHS Policy, NIH was particularly interested in how institutions in this funding category would implement stronger requirements for the care and use of laboratory animals. The addendum concludes that these institutions are capable of meeting the requirements of the revised PHS Policy, and includes recommendations that the NIH assist institutions in implementing the revised PHS Policy.

NOTE: The Institute of Laboratory Animal Resources of the National Research Council, National Academy of Sciences, has completed the revision of the Guide for the Care and Use of Laboratory Animals, (Guide). The PHS Policy requires that institutions use the Guide as a basis for developing and implementing an institutional animal care and use program. Therefore, the full text of the revised Guide is published as a Supplement to this Special Edition and will be mailed to all institutions that currently have an Animal Welfare Assurance.

The revised Guide will be published as a booklet in the coming months. Publication of the text in a Supplement to this Special Edition is an interim measure to ensure that institutions receive the new Guide as soon as possible. Copies of the Supplement containing the Guide may be requested from Dr. John Holman, Division of Research Resources, NIH, Building 31, Room 5B59, Bethesda, Maryland 20205.

PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE
OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS

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PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE
OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS

I. Introduction

It is the policy of the Public Health Service (PHS) to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training and biological testing activities (hereinafter referred to as activities) supported by the PHS. The PHS endorses the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training" developed by the Interagency Research Animal Committee (IRAC). This policy is intended to implement and supplement those Principles.

II. Applicability

This policy is applicable to all PHS-supported activities involving animals, whether the activities are performed at an awardee institution or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this policy, or provide evidence to the PHS that acceptable standards for the humane care and use of the animals in PHS-supported activities will be met. No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this policy for PHS-supported activities, or unless the individual makes other arrangements with the PHS. This policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.

III. Definitions

A. Animal

Any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.

B. Animal Facility

Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

C. Animal Welfare Act

Public Law 89-544, 1966, as amended, (P.L. 91-579 and P.L. 94-279) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the Code of Federal

Regulations (CFR), Title 9, Subchapter A, Parts 1, 2, 3 and 4, and are administered by the U.S. Department of Agriculture.

D. Animal Welfare Assurance or Assurance

The documentation from an awardee or a prospective awardee institution assuring institutional compliance with this policy.

E. Guide

Guide for the Care and Use of Laboratory Animals, DHEW, NIH Pub. No. 78-23, 1978 edition or succeeding revised editions.

F. Institution

Any public or private organization, business, or agency (including components of Federal, state and local governments).

G. Institutional Official

An individual who has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this policy will be met.

H. Public Health Service

The Public Health Service includes the Alcohol, Drug Abuse, and Mental Health Administration, the Centers for Disease Control, the Food and Drug Administration, the Health Resources and Services Administration, and the National Institutes of Health.

I. Quorum

A majority of the members of the Institutional Animal Care and Use Committee.

IV. Implementation by Awardee Institutions

A. Animal Welfare Assurance

No activity involving animals will be supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with this policy for PHS-supported activities. Assurances shall be submitted to the Office for Protection from Research Risks (OPRR), Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 4B09, Bethesda, Maryland 20205. The Assurance shall be typed on the institution's letterhead and signed by an institutional official. OPRR will provide the applicant institution with necessary instructions and an example of an acceptable Assurance. All Assurances submitted to the PHS in accordance with this policy will be evaluated by OPRR to determine the adequacy of the institution's proposed program for the care and use of animals in PHS-supported activities. On the basis of this evaluation OPRR may approve or disapprove the Assurance, or negotiate an approvable Assurance with the

institution. Approval of an Assurance will be for a specified period of time (no longer than five years) after which time the institution must submit a new Assurance to OPRR. OPRR may limit the period during which any particular approved Assurance shall remain effective or otherwise condition, restrict, or withdraw approval. Without an applicable PHS approved Assurance no PHS-supported activity involving animals at the institution will be permitted to continue.

1. Institutional Program for Animal Care and Use

The Assurance shall fully describe the institution's program for the care and use of animals in PHS-supported activities. The PHS requires institutions to use the Guide for the Care and Use of Laboratory Animals (Guide) as a basis for developing and implementing an institutional program for activities involving animals. The program description must include the following:

- a. a list of every branch and major component of the institution, as well as a list of every branch and major component of any other institution which is to be included under the Assurance;
- b. the lines of authority and responsibility for administering the program and ensuring compliance with this policy;
- c. the qualifications, authority and responsibility of the veterinarian(s) who will participate in the program;
- d. the membership list of the Institutional Animal Care and Use Committee(s)^{1/} (IACUC) established in accordance with the requirements set forth in IV.A.3.;
- e. the procedures which the IACUC will follow to fulfill the requirements set forth in IV.B.;
- f. the health program for personnel who work in laboratory animal facilities or have frequent contact with animals;

^{1/} The name Institutional Animal Care and Use Committee (IACUC) as used in this policy is intended as a generic term for a committee whose function is to ensure that the care and use of animals in PHS-supported activities is appropriate and humane in accordance with this policy. However, each institution may identify the committee by whatever name it chooses. Membership and responsibilities of the IACUC are set forth in IV.A.3. and IV.B.

- g. the gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and
- h. any other pertinent information requested by OPRR.

2. Institutional Status

Each institution must assure that its program and facilities are in one of the following categories:

Category 1 - Accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or other accrediting body recognized by PHS.^{2/}

Category 2 - Evaluated by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once each year. The IACUC shall use the Guide for the Care and Use of Laboratory Animals as a basis for evaluating the institution's program and facilities. A report of the IACUC evaluation shall be submitted to the institutional official and updated on an annual basis.^{3/} The initial report shall be submitted to OPRR with the Assurance. Annual reports of the IACUC evaluation shall be maintained by the institution and made available to OPRR upon request. The report must contain a description of the nature and extent of the institution's adherence to the Guide and this policy.^{4/} The report must identify specifically any departures from provisions of the Guide and this policy, and state the reasons for each departure. If

^{2/} As of the issuance date of this policy the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

^{3/} The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to conduct or assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

^{4/} If some of the institution's facilities are accredited by AAALAC or other accrediting body recognized by PHS, the report should identify those facilities and need not contain any further information about evaluation of those facilities.

program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule for correcting each deficiency. The report must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, in the judgment of the IACUC and the institutional official, is or may be a threat to the health or safety of the animals. Failure of the IACUC to conduct an annual evaluation and submit the required report to the institutional official may result in PHS withdrawal of its approval of the Assurance.

3. Institutional Animal Care and Use Committee

- a. Each institution shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution's animal program, facilities and procedures.
- b. The Assurance must include the names, position titles and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:
 - (1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the institution;
 - (2) one practicing scientist experienced in research involving animals;
 - (3) one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and
 - (4) one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.
- c. An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b.(1)-(4) may fulfill more than one requirement. However, no committee may consist of less than five members.

B. Functions of the Institutional Animal Care and Use Committee

As an agent of the institution the IACUC shall, with respect to PHS-supported activities:

1. review at least annually the institution's program for humane care and use of animals;
2. inspect at least annually all of the institution's animal facilities, including satellite facilities;

3. review concerns involving the care and use of animals at the institution;
4. make recommendations to the institutional official regarding any aspect of the institution's animal program, facilities or personnel training;
5. review and approve, require modifications in (to secure approval) or withhold approval of those sections of PHS applications or proposals related to the care and use of animals as specified in IV.C.;
6. review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and
7. be authorized to suspend an activity involving animals in accord with specifications set forth in IV.C.6.

C. Review of PHS Applications and Proposals

1. In order to approve applications and proposals or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those sections related to the care and use of animals and determine that the proposed activities are in accord with this policy. In making this determination, the IACUC shall confirm that the activity will be conducted in accord with the Animal Welfare Act insofar as it applies to the activity, and that the activity is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the activity conforms with the institution's Assurance and meets the following requirements:
 - a. Procedures with animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.
 - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly sacrificed at the end of the procedure or, if appropriate, during the procedure.
 - d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling and use of the species being maintained or studied.
 - e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - g. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia,^{5/} unless a deviation is justified for scientific reasons in writing by the investigator.
2. Prior to the review, each IACUC member shall be provided with a list of applications and proposals to be reviewed. Those sections of applications and proposals that relate to the care and use of animals shall be available to all IACUC members, and any member of the IACUC may upon request obtain full committee review of those sections. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those sections and have the authority to approve, require modifications in (to secure approval) or request full committee review of those sections. If full committee review is requested, approval of those sections may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an application or proposal in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
3. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an application or proposal or vote with the IACUC.
4. The IACUC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an application or proposal, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
5. The IACUC shall conduct continuing review of applications and proposals covered by this policy at appropriate intervals as determined by the IACUC, but not less than once every three years.

^{5/} Journal of the American Veterinary Medical Association (JAVMA), 1978, Vol. 173, No. 1, pp. 59-72, or succeeding revised editions.

6. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.l.a.-g. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
7. If the IACUC suspends an activity involving animals, the institutional official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action and report that action with a full explanation to OPRR.
8. Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the IACUC.

D. Information Required in Applications and Proposals Submitted to PHS

1. All Institutions

Applications and proposals submitted to PHS that involve the care and use of animals shall contain the following information:

- a. identification of the species and approximate number of animals to be used;
 - b. rationale for involving animals, and for the appropriateness of the species and numbers to be used;
 - c. a complete description of the proposed use of the animals;
 - d. assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
 - e. a description of any euthanasia method to be used.
2. Institutions That Have an Approved Assurance

Applications or proposals covered by this policy from institutions which have an approved Assurance on file with OPRR shall include verification of approval by the IACUC of those sections related to the

care and use of animals. With the authorization of PHS, such verification may be filed at a time not to exceed 60 days after submission of applications or proposals.^{6/}

If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification shall state the modifications, if any, required by the IACUC. The verification shall be signed by an individual authorized by the institution, but need not be signed by the institutional official who signed the Assurance.

3. Institutions That Do Not Have an Approved Assurance

Applications and proposals involving animals from institutions that do not have an approved Assurance on file with OPRR shall contain a declaration that the institution will establish an IACUC and submit an Assurance upon request by OPRR. After OPRR has requested the Assurance, the institution shall establish an IACUC as required by IV.A.3. and the IACUC shall review those sections of the application or proposal as required by IV.C. The institution shall then submit to OPRR the Assurance and verification of IACUC approval. The verification shall state the modifications, if any, required by the IACUC. The verification shall be signed by an individual authorized by the institution, but need not be signed by the institutional official who signed the Assurance.

E. Recordkeeping

1. The awardee institution shall maintain:

- a. an Assurance approved by the PHS;
- b. minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;
- c. records of applications, proposals and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
- d. records of any IACUC reports and recommendations as forwarded to the institutional official; and
- e. records of accrediting body determinations.

2. All records shall be maintained for at least three years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall

^{6/} Until further notice, PHS hereby authorizes all institutions with approved Assurances to file verification of IACUC approval either along with the application or proposal or within 60 days of submission of the application or proposal. From time to time PHS will reevaluate this blanket authorization. Any decision to withdraw this authorization will take place only after ample opportunity is provided for comment by the public.

be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

F. Reporting Requirements

1. On or before each anniversary of approval of its Assurance, the institution shall report in writing to OPRR:
 - a. any change in the institution's program or facilities which would place the institution in a different category than specified in its Assurance (see IV.A.2.);
 - b. any change in the description of the institution's program for animal care and use as required by IV.A.1.a.-h.;
 - c. any changes in IACUC membership; and
 - d. if the institution's program and facilities are in Category 2 (see IV.A.2.), verification that the IACUC has conducted an annual evaluation of the institution's program and facilities and submitted the evaluation to the institutional official.
2. Institutions that have no changes to report as specified in IV.F.1. a.-c. shall submit a letter to OPRR stating that there are no changes.
3. Institutions shall provide OPRR promptly with a full explanation of the circumstances and actions taken with respect to:
 - a. any serious or continuing noncompliance with this policy;
 - b. any serious deviation from the provisions of the Guide; or
 - c. any suspension of an activity by the IACUC.

V. Implementation by PHS

A. Responsibilities of OPRR.

OPRR is responsible for the general administration and coordination of this policy and will:

1. request and negotiate, approve or disapprove, and, as necessary, withdraw approval of Assurances;
2. distribute to executive secretaries of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions that have an approved Assurance;
3. advise awarding units and awardee institutions concerning the implementation of this policy;

4. evaluate allegations of noncompliance with this policy;
5. have the authority to review and approve or disapprove waivers to this policy (see V.D.); and
6. conduct site visits to selected institutions.

B. Responsibilities of PHS Awarding Units

PHS awarding units may not make an award for an activity involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance on file with OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities. If an institution is not listed, the awarding unit will ask OPRR to negotiate an Assurance with the institution before an award is made. No award shall be made until the Assurance has been submitted by the institution, approved by OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities.

C. Conduct of Special Reviews/Site Visits

Each awardee institution is subject to review at anytime by PHS staff and advisors, which may include a site visit, in order to assess the adequacy of the institution's compliance with this policy.

D. Waiver

Institutions may request a waiver of a provision or provisions of this policy by submitting a request to OPRR. No waiver will be granted unless sufficient justification is provided and the waiver is approved in writing by OPRR.

INSTRUCTIONS FOR IMPLEMENTATION OF THE REVISED PHS POLICY

The revised PHS Policy for the Humane Care and Use of Laboratory Animals will become effective December 31, 1985. Institutions which currently have an approved Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR) must submit to OPRR by January 1, 1986, a revised Assurance developed in accordance with the new policy. These institutions are encouraged to begin implementing the revised policy as soon as possible and are expected to begin operating under their new Assurance as of January 1, 1986.

Applications and proposals submitted to the PHS after January 1, 1986, must meet the requirements of the revised PHS Policy. Section IV.D.1. of the revised policy requires all applications and proposals to contain specific information regarding the proposed use of laboratory animals. Applications and proposals received after January 1, 1986, that do not contain the information required in Section IV.D.1. will be considered incomplete and may be deferred for a later review. (The information required by Section IV.D.1. of the revised policy should appear in the appropriate section of each grant application form, for example, Section 2.F. of the PHS Grant Application Form 398.)

Institutions That Have an Approved Assurance

Applications and proposals submitted to the PHS after January 1, 1986, must contain verification that the institutional animal care and use committee (IACUC) has approved those sections of the application or proposal related to the care and use of laboratory animals. PHS prefers that verification of IACUC approval be submitted along with the application or proposal, however, it may be submitted within 60 days of submission of the application or proposal. If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification must state any modifications required by the IACUC.

In the near future, PHS will institute a standardized method for institutional submission of IACUC approval. In the interim, verification of IACUC approval must be submitted via a letter from the institution to PHS. The letter must be signed either by the institutional official who signed the institution's Animal Welfare Assurance, or by another individual authorized by the institution to provide verification of IACUC approval.

The following example may be used in preparing such letters of verification.

EXAMPLE OF ACCEPTABLE VERIFICATION

Date

Division of Research Grants*
National Institutes of Health
5333 Westbard Avenue
Westwood Bldg., Room 240
Bethesda, MD 20205

Dear Sir:

The following application submitted to the Public Health Service was reviewed and approved by this institution's Animal Care and Use Committee on (insert date of approval) :

Title of application:
Name of Principal Investigator:
Name of Institution:

This institution has an Animal Welfare Assurance on file with the Office for Protection from Research Risks. The Assurance number is _____. (Insert old assurance number until a new assurance number is assigned.)

As a condition of approval, this institution's Animal Care and Use Committee required the following modifications to the above referenced application:**

(Signature)
(Title)

* This address should be used for submission with grant applications. If verification is submitted subsequent to the submission of the application, it should be addressed to the Executive Secretary of the initial review group designated on the card returned to the institution acknowledging receipt of the application. For contract proposals, verification should be addressed to the contract officer.

** This information is required when the modifications are not reflected in the original grant application or contract proposal.

Institutions That Do Not Have an Approved Assurance

Institutions that do not have an approved Animal Welfare Assurance on file with OPRR must submit, with the application or proposal, a declaration that the institution will establish an Institutional Animal Care and Use Committee and submit an Assurance upon request by OPRR. The following letter is an example of an acceptable declaration:

EXAMPLE OF ACCEPTABLE DECLARATION

	Date
Division of Research Grants* National Institutes of Health 5333 Westbard Avenue Westwood Bldg., Room 240 Bethesda, MD 20205	
Dear Sir:	
This institution does not have an Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR) to cover the following application:	
Title of application: Name of Principal Investigator: Name of Institution:	
This institution will establish an Institutional Animal Care and Use Committee, have the application reviewed by the IACUC and submit an Animal Welfare Assurance, upon request, to OPRR.	
	(Signed by institutional official) (Title)

* For contract proposals, this letter should be addressed to the contract officer.

If an award is likely to be made, OPRR will then request that the institution submit an Assurance. The institution's Animal Care and Use Committee (IACUC) must review those sections of the application or proposal related to the care and use of animals and submit the Assurance and verification of IACUC approval to OPRR. The Example of an Acceptable Verification Letter (see previous section on Institutions That Have an Approved Assurance) may be followed in submitting verification of IACUC approval.

Sample Animal Welfare Assurance

Attached is a sample Animal Welfare Assurance prepared by the Office for Protection from Research Risks to assist awardee institutions in developing an assurance in accord with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (revised June 1985). This sample includes all of the necessary elements for compliance with the PHS Policy. There are several areas in an assurance which require that the institution provide specific information regarding procedures, policies and responsibilities and qualifications of personnel of the institution. The Animal Welfare Assurance will need to be tailored to meet the administrative and research requirements for each institution. This sample assurance document provides suggestions and examples of the kind of information that is to be provided by the institution in accordance with the PHS Policy. The sample refers to an Institutional Animal Care and Use Committee (IACUC), a generic name for the institutional committee established in accord with the PHS Policy to fulfill the functions outlined in the policy. In preparing its assurance document, each institution should consistently use whatever name it has assigned to that committee. More than one IACUC may be established to meet the needs of an institution. The assurance must identify each IACUC established by the institution.

This sample is intended as an aid to your institution in developing an Animal Welfare Assurance. Close adherence to the format will facilitate the review process. Questions should be directed to the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20205, (301) 496-7005.

INSTITUTIONAL LETTERHEAD

(Name of Institution)

Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions

(Name of Institution), hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, hereinafter referred to as PHS Policy.

I. Applicability

This assurance is applicable to all research, research training, and biological testing activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-supported activity by this institution. "Institution" includes the following branches and major components of **(name of institution) (list every branch and major component covered by this assurance)**. (If applicable), "Institution" also includes the following branches and major components of **(name(s) of other institution(s) to be included under this assurance) (list every branch and major component of other institution(s) to be covered by this assurance)**.

II. Institutional Policy

- A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This institution is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.
- C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this assurance. As partial fulfillment of this responsibility this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with this policy are:

(Describe or diagram the organization of the administration and staff, including the Institutional Animal Care and Use Committee, the institutional official and the veterinarian.)

- B. The qualifications, authority and responsibility of the veterinarian(s) who will participate in the program include:

(Indicate professional or academic degrees and the number of years of pertinent training or experience in laboratory animal medicine. Describe the veterinarians functions and responsibilities insofar as they relate to implementing recommendations in the Guide for the Care and Use of Laboratory Animals.)

- C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the compositional requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the names, position titles and earned degrees or other credentials of the IACUC chairperson and members.
- D. The IACUC will:
1. Review at least annually the institution's program for humane care and use of animals.
 2. Inspect at least annually all of the institution's animal facilities, including satellite facilities.
 3. Review concerns involving the care and use of animals at the institution.
 4. Make written recommendations to **(insert name or title of institutional official signing assurance)** regarding any aspect of the institution's animal program, facilities, or personnel training.
 5. Review and approve, require modifications in (to secure approval) or withhold approval of those sections of applications or proposals to PHS related to the care and use of animals as set forth in the PHS Policy at IV.C.
 6. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C.
 7. Notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4.
 8. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6.
- E. The procedures which the IACUC will follow to fulfill the requirements set forth in the PHS Policy at IV.B. are:

(Describe how the IACUC will fulfill each of the functions set forth in the PHS Policy at IV.B. Include how often the IACUC will meet, how often it will inspect facilities, and how the inspections will take place. Describe the procedures the IACUC will follow to address any concerns, and how recommendations will be developed and forwarded to the institutional official. The channels for receiving applications and proposals, and for reporting the results of IACUC review of applications and proposals should be addressed.)

F. The individual(s) authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is (insert name of individual).

G. The health program for personnel who work in laboratory animal facilities or have frequent contact with animals is:

(Describe the institution's occupational health program, including the frequency of tuberculosis tests, if any, requirements for medical examinations, etc. The institution may submit a memorandum or pamphlet (if one exists) which informs animal care and use staff of institutional policies regarding health screening or tests.)

H. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory, by species, of animals in each facility is: **(This information may be provided in an attached chart.)**

IV. Institutional Status

As specified in the PHS Policy at IV.A.2. as Category 1, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by the American Association for Accreditation of Laboratory Animal Care.

- OR -

As specified in the PHS Policy at IV.A.2 as Category 2, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once each year. The IACUC has and will continue to use the Guide as a basis for evaluating the institution's programs and facilities. The report of the IACUC evaluation has been submitted to **(insert name or title of institutional official signing assurance)** and a copy of the report is attached. The report contains a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide are identified specifically and reasons for each departure are stated. Where program or facility deficiencies are noted, the report contains a reasonable and specific plan and schedule for correcting each deficiency. The report distinguishes significant deficiencies from minor deficiencies. Annual reports of the IACUC evaluation will be maintained by this institution and made available to OPRR upon request.

V. Recordkeeping

- A. This institution will maintain for at least three years:
 1. A copy of this assurance as approved by PHS.
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee and committee deliberations.
 3. Records of applications, proposals and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
 4. Records of any IACUC reports and recommendations as forwarded to **(insert name or title of institutional official signing assurance)**.
 5. Records of accrediting body determinations.
- B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. On or before each anniversary of approval of this assurance, this institution will report in writing to the Office for Protection from Research Risks (OPRR):
 1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this assurance, or any changes in IACUC membership. If there are no changes to report, this institution will submit a letter to OPRR stating that there are no changes.
 2. **(To be included only in assurance submitted by institutions whose program and facilities are not fully accredited by the American Association for the Accreditation of Laboratory Animal Care).** Verification that the IACUC has conducted an annual evaluation of the institution's program and facilities and submitted the evaluation to **(insert name or title of institutional official signing assurance)**.
- B. This institution will provide the OPRR promptly with a full explanation of the circumstances and actions taken with respect to:
 1. Any serious or continuing noncompliance with the PHS Policy.
 2. Any serious deviations from the provisions of the Guide.
 3. Any suspension of an activity by the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: _____

Title: _____

Address: _____

Phone: _____

Signature: _____ Date: _____

B. PHS Approving Official

Name: _____

Title: _____

Address: _____

Phone: _____

Signature: _____ Date: _____

C. Effective date of assurance: _____

D. Expiration date of assurance: _____

U.S. Interagency Research Animal Committee

PRINCIPLES FOR THE UTILIZATION AND CARE OF VERTEBRATE ANIMALS USED IN TESTING, RESEARCH AND TRAINING

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible institutional official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.¹
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or

¹ For guidance throughout these Principles the reader is referred to the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal research committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

SITE VISITS TO ANIMAL CARE FACILITIES: AN ADDENDUM

I. INTRODUCTION AND BACKGROUND

Following publication of the Report: SITE VISITS TO ANIMAL CARE FACILITIES, A Report to the Director of the National Institutes of Health, March 1984, the National Institutes of Health (NIH) conducted a further assessment of its Animal Welfare Assurance System. Only institutions receiving total support of less than \$5 million in funds from the NIH in Fiscal Year 1984 (FY '84) were visited in the second series because this category had the largest number of institutions filing Assurance Statements with the NIH Office for the Protection from Research Risks (OPRR) and was least well sampled in the first series. Additionally, in light of proposed changes in the Public Health Service (PHS) Animal Welfare Policy emphasizing more explicit procedures and more active animal care committees, the NIH was particularly interested in observing how institutions with a relatively modest-sized program of biomedical research approach their commitments to ensure the appropriate care and use of laboratory animals. This report, prepared as an addendum to the original report, summarizes the results of a series of site visits to five (5) institutions.

II. METHODS

To carry out the proposed site visits, a stratified, random sample of five institutions that do not have accreditation from the American Association for Accreditation of Laboratory Animal Care (AAALAC) but operate under approved assurances indicating full compliance with PHS policy were selected. One institution receiving less than \$5 million in FY '84 was chosen from each of the ten geographic regions of the Department of Health and Human Services. The ten institutions were randomly ordered and the following institutions in each of the first five regions were selected for site visits:

<u>DHHS REGION</u>	<u>INSTITUTION/LOCATION</u>
5	OAKLAND UNIVERSITY, ROCHESTER, MI.
3	NORFOLK STATE UNIVERSITY, NORFOLK, VA.
10	OREGON STATE UNIVERSITY, CORVALLIS, OR.
7	RHODE ISLAND HOSPITAL, PROVIDENCE, RI.
8	RICE UNIVERSITY, HOUSTON, TX.

The protocol for these visits was the same as the one used for the first ten visits. It was designed to evaluate an institution's mechanisms for complying with its Statement of Assurance at every level of participation: administrative organization and commitment; responsibilities and activities of the animal care committee; investigators' understanding and practice of animal care procedures; veterinary oversight; and condition and design of animal facilities. In all instances, the site visits were performed in one day during the months of July and August 1984 and followed an agenda similar to the one used for the first ten visits. The site visit teams were composed of four members. To maintain continuity, all of the

visits were chaired by Dr. Louis R. Sibal of the NIH Office of Extramural Research and Training and included a scientist or administrator from the OPRR and two non-federal consultants—a veterinarian experienced in laboratory animal medicine and a biomedical scientist currently conducting research requiring laboratory animals.

Finally, the descriptions of the oversight procedures are deliberately brief in this report to avoid unnecessary overlap and duplication with the Report issued in March 1984. All findings, conclusions and recommendations are reported in general terms so that they may be applied to the diverse scientific institutions supported by the NIH.

III. FINDINGS

In general, institutional administrators, scientists and animal care personnel with whom the site visitors spoke were supportive of NIH's assessment efforts. They cooperated by providing relevant documents such as United States Department of Agriculture inspection reports and animal care committee minutes prior to and during the visits and responded candidly to questions about the PHS policy and the NIH assurance process in relation to their animal care programs or research interests. This section is divided into five parts and summarized as follows:

A. Administrative Support

Objective: To evaluate the nature and extent of support provided by administrative officials to institutional laboratory animal programs.

Senior administrative officials at each of the five institutions were knowledgeable of the animal programs for which they were responsible. Their interest in animal welfare issues seemed heightened by the recent emphasis on animal welfare legislation, antivivisectionist activities and the previous site visits undertaken by the NIH. They described institutional oversight systems with relatively simple organizational structures. Most officials relied heavily upon the leadership and dedication of one or two individuals, usually the animal care committee chairman, the veterinarian or a senior scientist, and upon informal contacts with other scientists and technicians working with laboratory animals.

Two of the institutions were planning to expand their biomedical research programs by adding faculty and/or by making significant capital investments in new facilities and equipment. In these cases, the administrators were strongly supportive of developing more extensive animal care programs and had taken steps to formalize oversight procedures, distributing the responsibility for protocol review and facilities management to other officials or to the animal care committee. The proposed PHS policy, which would vest more responsibility in the local animal care committee, appears to have been an important impetus for such actions. One institution had established a strong central authority for managing its animal care programs. The others maintained loosely structured but functional systems.

B. Animal Care Committees

Objective: To assess the quality of oversight of the institution's animal care program.

In general, the site visitors found that animal care committees met most of present policy requirements. The committees were composed of appropriate representatives of the user community, usually one or more practicing scientists, a veterinarian and an institutional official. In those institutions where the biomedical research program was small in size and scope the veterinarian, usually hired on a consulting basis, was neither specially trained in laboratory animal medicine nor fully responsible for housing, feeding and care of the animals. All but one of the committees met at least annually to inspect animal research facilities and review the institutions' programs for animal care and use. The proposed PHS policy requirement that animal care committees include a lay member had already been addressed by three of the committees. Because these nonscientists by definition were not part of the user community, committee activity was usually more formalized to accommodate their participation. Committees which had not yet appointed lay members were not opposed to doing so.

The committee members were concerned and knowledgeable individuals, but their responsibilities were not well defined. Each committee acted in an advisory capacity to the institutional official and represented the needs and concerns of laboratory animal users at that institution. However, the concerns were often budgetary, dealing with such problems as the increased costs of doing research, purchasing new equipment and making capital improvements. Allocating space, providing guidelines for operating animal facilities and setting per diem charges for animal maintenance were usually the responsibility of the chairperson, the veterinarian or the administrator.

Proposed changes in the PHS policy caused some of the institutions to redefine the duties of their animal care committees. Three of the committees had already developed standard procedures for the review of all applications and proposals involving animals submitted to the NIH by the institutional investigators. Even though most institutional officials seemed willing to upgrade committee activities to include the review of experimental protocols involving animals, they felt that this task was primarily the responsibility of NIH study sections.

C. INVESTIGATORS

Objective: To determine the degree of interaction between investigators and officials and/or personnel associated with the animal care program.

Most investigators interviewed at each institution were generally familiar with both the NIH assurance system and their institution's policies and procedures for laboratory animal research. Because of the relatively small scale of these programs, these investigators often assumed the responsibility for ordering animals, purchasing supplies and equipment, maintaining the animals and the training of technicians and caretakers usually recruited from the student body. They were familiar with the activities of the animal care committee; in fact, in some smaller institutions the same investigators were members of the animal care committee.

Few investigators had complaints about the quality of care provided for their animals. However, upon further questioning, some investigators said that they had not been provided sufficient advice from a veterinarian in the planning and

execution of their experiments. Some expressed the desire for facilities with more sophisticated animal holding areas to avoid problems associated with poor environmental control and naturally-occurring diseases--factors that might affect the quality of their experimental results.

D. VETERINARY CARE.

Objective: To assess the availability and degree of involvement of qualified veterinarians in institutional animal care programs.

For the current series of visits, only one of the five veterinarians interviewed played a major role in the institution's animal care program (e.g. hiring and training personnel, selecting animal suppliers, advising on experimental procedures including the administration of anesthetics and analgesics, maintaining the animal care facility). The remaining institutions acquired the services of consulting veterinarians often on a part-time basis; their responsibilities were generally limited to such activities as participating in the animal care committee meetings, inspecting animal facilities, and handling special problems or animal medical emergencies as necessary. Four institutions employed veterinarians who had pertinent experience in laboratory animal medicine; however, only two veterinarians were qualified by formal training. One institution had not formally secured the services of a veterinarian.

In general, the small number of investigators using animals, the use of noninvasive experimental procedures and the acute nature of most of the projects did not require a great deal of veterinary guidance. The lack of ready access to a well-trained veterinarian did not seem to jeopardize the general health and well-being of the experimental animals. However, the site visitors noted that marginal or limited veterinary expertise placed severe constraints on the nature and scope of the projects that could be carried out satisfactorily.

E. ANIMAL FACILITIES

Objective: To inspect the physical plant and determine the quality of animal care provided by the institution.

Because the space designated for animal care was not extensive, the site visitors inspected every area where animals were maintained and treated at the five institutions visited. Four had centralized laboratories, one had three additional satellite laboratories; the other institution maintained three separate laboratories. In general, the animals were well-housed in facilities having good sanitation. Light, environmental and security controls were simple but adequate. The teams found little or no evidence of overcrowding or sickness; some facilities were underused, having relatively few animal users.

Three of the facilities had been renovated within the past two years. They were designed appropriately with reasonable space allocations for animals and moderate degrees of containment; however, specialized laboratories for such activities as surgery or experimental manipulation of animals were not common. Based on the nature of the research activities at most of the institutions--short term, acute studies--the animal facilities were adequate for the limited numbers and species of animals used. In two instances, the site visitors examined the renovation plans that had been under consideration for several years. In one case, however, it was evident that renovations were very

recent; animal care rooms had just been freshly cleaned and painted, suggesting that the special attention given to the premises was intended to impress the site visitors. Even with improvements, existing deficiencies made this institution's current program only marginally acceptable.

III. CONCLUSIONS AND RECOMMENDATIONS

A. CONCLUSIONS

The programs for the care and use of laboratory animals at the five institutional sites selected for this study met or exceeded the minimum standards set forth in the current PHS policy. Although the sample size is still very small--nine institutions in this funding category were visited in two years--the findings reported herein help to answer questions relevant to institutions that are less oriented to the conduct of biomedical research but still receive support--in some cases substantial--from the NIH. We conclude:

1. Institutions receiving less than \$5 million per year in NIH research funds are capable of meeting the responsibilities imposed by the PHS policy. Therefore, reliance on voluntary compliance remains a realistic approach to promoting the proper care and use of laboratory animals in biomedical research.
2. Institutions within this same group are capable of assuming additional responsibilities in response to proposed changes in the PHS policy.

These conclusions are based on the following findings:

- o No incidents of animal abuse were observed.
- o Most institutional officials provided adequate leadership and responded to the needs of institutional animal care programs. Communication problems were few because of the opportunities for frequent contacts among the institutional administrators, investigators and animal care personnel.
- o Some institutional animal care committees were recently reorganized for the purpose of assuming additional responsibilities required by the proposed PHS policy; three institutions' rosters included lay members. Institutional committees were potentially capable of reviewing protocols with respect to the adequacy of the care and use of laboratory animals in research projects. Compared to those institutions in higher funding categories, fewer complaints were registered about the burden of these reviews. However, despite these capabilities, the site visitors found that most of the committees needed to improve their advisory or oversight roles.
- o With some exceptions, the lack of adequate veterinary oversight in some of the institutions forced investigators to become self-reliant; however, when available, most consulting veterinarians provided helpful guidance.
- o The areas designated as animal care facilities were adequate to excellent. However, most would not have been appropriate for long-term maintenance or specialized treatment of animals.

B. RECOMMENDATIONS

1. The NIH should continue assessing the adequacy of its traditional assurance system by visiting additional awardee institutions. When formulating further site visits plans, the institutions should be selected randomly using different stratification criteria than the first two series to ensure more nearly uniform sampling of the universe of settings in which NIH-funded animal experimentation is conducted.
2. The NIH should consider a plan for helping institutions obtain appropriate veterinary care and advice.
3. The NIH should undertake a program for helping institutions understand fully their responsibilities in implementing a successful program of laboratory animal care.