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LABORATORY ANIMAL WELFARE

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RELEASE OF ANIMAL WELFARE REPORT

On several occasions over the past two years, the National Institutes of Health (NIH) published notices about its plan to conduct site visits to awardee institutions to determine the adequacy of its present assurance system for promoting the proper care and use of animals in biomedical research. The Office of Extramural Research and Training (OERT) completed its formal assessment in late 1983. The results of a series of site visits to ten awardee institutions are presented in the accompanying report, **SITE VISITS TO ANIMAL CARE FACILITIES: A Report to the Director of the National Institutes of Health, March 1984.**

The report concludes that reliance on the present NIH policy of voluntary compliance with the provisions of the Animal Welfare Act and NIH policy outlined in the Guide for the Care and Use of Laboratory Animals is an effective way to foster the welfare of laboratory animals. At the same time, the site visits proved very informative and suggested ways by which the NIH might make its assurance process even more effective. One major recommendation is to expand and strengthen the Public Health Service (PHS) Policy on laboratory animals.

Although institutions and research investigators have the primary responsibility for the proper care and use of animals in PHS-funded projects, the Office for the Protection from Research Risks (OPRR), NIH, is responsible for the general administration and policy. No PHS awards involving animals or animal facilities are made unless an acceptable written assurance statement is on file with the OPRR, NIH.

During the past year, the OPRR has given the PHS policy careful review and is now prepared to make its latest (March 1984) draft revision, PUBLIC HEALTH SERVICE, POLICY ON HUMANE CARE AND USE OF ANIMALS BY AWARDEE INSTITUTIONS, available for comment by the biomedical community and the general public. The Policy reflects several changes in policy and procedures, some suggested as a result of the recent series of site visits.

Because of intense interest in these recent initiatives, we have decided to publish these related documents in a special edition of the NIH Guide for Grants and Contracts. The NIH, as a steward of public funds, has been mindful about public concerns about animal experimentation and continues to make vigorous efforts on behalf of animal welfare. This OERT site visit report and the draft revised PHS Policy are the products of activities directed toward ensuring the welfare of research animals.

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SITE VISITS TO ANIMAL CARE FACILITIES

A Report to the Director of the National Institutes of Health
March 1984

I. INTRODUCTION

This report summarizes the results of a series of site visits to ten randomly selected institutions that receive funds from the National Institutes of Health (NIH) for research projects involving animals. The objective of this survey was to determine whether these awardees' programs and facilities for the care and use of laboratory animals are consonant with their statements of assurance now on file with the NIH. Such information is indispensable for assessing the adequacy of administrative requirements and practices in this area on the part of both the NIH and the awardee community.

II. BACKGROUND

As a part of its overall mission to improve human health through biomedical research, the NIH recognizes its obligation to promote appropriate care and use of animals involved in research. It is the policy of the NIH that no research award be made unless a responsible official of the institution that proposes to use the animals has provided an acceptable written assurance to the Office for Protection from Research Risks (OPRR), NIH. The assurance commits the institution to comply with the Animal Welfare Act of 1966, as amended; other applicable laws and regulations; the NIH Principles for the Use of Animals, as stated in the Public Health Service (PHS) policy; and the Guide for the Care and Use of Laboratory Animals (hereafter referred to as the Guide).

In demonstrating conformance to this assurance, awardee institutions are required, according to the provisions of PHS policy, to appoint and maintain animal care committes with authority and responsibility to inspect animal facilities at least annually and to oversee the care and use of animals at that institution. As required by PHS policy, such local committees must be composed of at least five members with relevant scientific expertise, including at least one veterinarian. Under current policy, institutions must choose one of the following three options: (1) accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC); (2) self-accreditation indicating full compliance with the Guide; (3) self-accreditation indicating less than full compliance with the Guide and the efforts underway to remedy the deficiencies.

As a matter of policy, the NIH negotiates assurance statements carefully but makes no systematic effort to assess compliance unless concerns are raised by the following: (a) initial review groups--advisory panels composed of non-federal experts who are required to review proposals and applications for scientific merit and who are knowledgeable of the appropriateness of the species and numbers of animals required for a particular project; (b) NIH staff involved in reviewing requests for funds or administering actual awards; (c) authorized inspections such

as those performed by the United States Department of Agriculture (USDA); and/or (d) individuals or groups who submit evaluable allegations. In recent years, critics of NIH policies have questioned the adequacy of the assurance process, both in concept and in relation to specific instances of actual or apparent failure by awardee scientists or administrators to follow certain animal care practices. Because of the need to maintain public confidence in science and the individuals to whom federal funds are entrusted, the NIH decided to assess the adequacy of its traditional assurance system.

Under the leadership of the NIH Office of Extramural Research and Training (OERT), teams composed of Government and non-Government scientists conducted site visits to a stratified random sample of ten awardee institutions to gather information and impressions relevant to the following questions: Is the NIH's current assurance system adequate for promoting the proper care and use of animals involved in federally-funded biomedical research? If it is adequate, how it can be further improved? If it is not adequate, what alternatives should be considered?

Although the results of ten visits cannot provide a definitive assessment of the assurance system--there are more than 800 institutional assurances on file with the OPRR, NIH--the findings reported herein are not only a major step toward answering these questions but also an important interim aid to the NIH and the research-oriented institutions with which it deals.

III. METHODS

In order to carry out the proposed site visits, the NIH Director and the Institute, Bureau and Division (BID) Directors asked the NIH Deputy Director for Extramural Research and Training (DDERT). Dr. William F. Raub, to organize an internal advisory group made up of representatives of the various NIH components responsible for animal welfare. The committee was responsible for guiding the overall project. Dr. Raub appointed Dr. Louis R. Sibal of his Office to devise a protocol for conducting the visits and to act as the chairperson for the assessment teams. In January and February 1983, NIH officials tested the protocol by conducting visits to three AAALAC-accredited institutions near the Washington, DC area. The purpose of these visits was to determine whether the protocol would provide the information necessary for assessing the assurance system.

In February 1983, the NIH published a notice that the site visits would be made to a stratified, random sample of ten institutions that do not have accreditation from AAALAC but operate under approved assurances indicating full compliance with the Guide. The institutions were selected such that (a) one institution was chosen from each of the ten geographic regions of the Department of Health and Human Services (DHHS), and (b) the ten institutions were distributed among three categories of total annual NIH support as follows: more than $10 million (3), $5-10 million (3), and less than $5 million (4).

In June of 1983, the NIH published a notice of its intention to conduct site visits to the following institutions between June and September, 1983:

DHHS REGION	INSTITUTION/LOCATION
1	Brandeis University, Waltham, MA
2	New York University, New York, NY
3	Children's Hospital of Pittsburgh, Pittsburgh, PA
4	Bethune-Cookman College, Daytona Beach, FL
5	Northwestern University, Evanston, IL
6	University of Texas-Austin, Austin, TX
7	St. Louis University, St. Louis, MO
8	LDS Hospital, Salt Lake City, UT
9	Syntex Research Division, Palo Alto, CA
10	University of Washington*, Seattle, WA

In general, the protocol for the visits was designed to determine: (1) the administration's commitment to implementing the institutional policies governing research with experimental animals; (2) the animal care committee's role and responsibilities for oversight activities; (3) the investigator's understanding of proper animal care procedures; (4) the veterinarians' responsibilities for the management of laboratory animal facilities as well as animal care and use; and (5) the condition and design of the animal care facilities as an important element of good animal care.

Once the NIH approach to conducting the site visits had been refined, OERT obtained the services of a contractor (HCR, Washington, DC) to provide logistical aid for implementing the project. The NIH chairperson notified the appropriate institutional representative(s) at least one month before the scheduled visit and directed the contractor to collect and distribute background information from the institutions for site visit team members and arrange for reimbursement of the travel and subsistence expenses of the consultants.

Depending on the size of the institution and the complexity of its physical facilities, the teams were comprised of three to seven members led by the NIH chairperson. At a minimum, the site visit teams consisted of (a) a veterinarian, (b) a biological scientist currently working with animals and (c) an NIH scientist/administrator. Non-federal consultants were included with a view toward ensuring impartiality and enhancing expertise. Some consultants were selected because they had participated in or chaired NIH review committees (study sections) or institutional review committees (animal care committees), or because they had professional qualifications and experience in directing animal care programs. Most of the veterinarians had participated on AAALAC review

* At the time of selection, the NIH had not been notified of this institution's AAALAC accreditation.

teams. All of the site visitors had an ongoing interest in animal care and use; most were well-qualified by their training and experience in conducting research involving laboratory animals. In the interests of economy, consultants were often recruited from the geographic region of the institution to be visited; some were asked to serve on two visits, thereby reducing the total pool of persons required for the project.

In all but three instances, the site visits were performed in one day; two days were allotted for visits to larger institutions with multicentered animal care facilities. Prior to the visit the contractor sent each team member background information, which included the written statement of assurance on file with the OPRR, USDA inspection reports, handbooks, and minutes or reports of meetings of institutional officials and of animal care committees. The NIH chairperson conducted an on-site orientation session before each visit to ensure that team members understood the objective of the visit. At the completion of the visit, site visitors shared their assessments orally with institutional officials, indicating any major strengths and weaknesses of the animal care program.

IV. FINDINGS

The site visits were designed so that each institution's mechanisms for complying with its statement of assurance could be evaluated at every level of participation. In addition to inspecting facilities and questioning laboratory animal care personnel, the site visit teams asked institutional officials fundamental questions about how they organize and maintain oversight of animal research. Administrators and scientists with whom the site visitors spoke for the most part were supportive of the NIH's efforts to assess its assurance system and welcomed the opportunity to comment on their own programs. The comments from institutional officials and staffs were responsive and candid.

This section is subdivided into five parts summarizing the findings concerning administrative support, animal care committees, investigators, veterinary care and animal research facilities.

A. Administrative Support

One of the goals of the site visits was to evaluate the nature and extent of support given by administrative officials to laboratory animal programs. At each institution, the administration was usually represented by the most senior administrative official responsible for research conducted at the institution. This official was generally the person who signed the assurance document submitted to OPRR. Representation ranged from university vice-presidents and hospital administrators to deans or assistant deans of schools, as well as business and financial officials. Site visitors asked these officials to describe how oversight of animal facilities and research involving animals is maintained and how their current procedures ensure compliance with PHS policy and with the Guide.

At each institution visited, administrators demonstrated adequate understanding of and support for the operation of a laboratory animal program. Depending on the size of the institution, officials described organizations for maintaining centralized control over the care and use of

laboratory animals. Most officials actively participated in planning programs to provide animals and animal care essential to high-quality research and had designated at least one person as a director of laboratory animal care.

While a variety of oversight procedures were identified, programs for monitoring compliance were generally accomplished by:

- Establishing institutional policies governing research involving animals based on (a) specific knowledge of the needs of animals, (b) requirements for the research, and (c) conformance with Federal regulations and guidelines;

- Developing an organizational plan in which the animal care committee and animal care director are directly responsible to a senior administrative official;

- Establishing a strong central authority for (a) the procurement of animals, caging and/or housing systems, food and other supplies; (b) hiring of professional and technical support personnel, including employee training, education and health programs; and (c) veterinary services;

- Maintaining a central animal facility with financial accountability, usually with established user fees, per diem charges and other defined costs;

- Subsidizing the animal research program by (a) providing the salaries of professional and support staff; (b) purchasing capital equipment; and (c) maintaining, upgrading, renovating and constructing animal care facilities, laboratories and special procedures rooms.

In all but one of the ten institutions visited, administrators described some combination of these kinds of financial and programmatic procedures.

On many of the visits, administrative officials and staffs discussed the possibility of their institutions seeking AAALAC accreditation. The administrators acknowledged that this system of accreditation is accepted by the scientific community and by the concerned public.

On three occasions site visitors found that some laboratory animals were not actually housed at the awardee institution. Instead, they were maintained at a neighboring institution. While the actual research site might have been stated in the application or proposal, it was not recorded in the statement of assurance. The visitors had no cause to believe that the welfare of the animals was being compromised, but they were concerned that, lacking formal access to the other institution, it might be difficult for the awardee institution to exercise its oversight responsibilities.

B. Animal Care Committees

The site visitors spent a substantial amount of time with animal care committee members to determine the effectiveness of these bodies. The

membership of the committee was generally representative of the community of users of research animals. The chairperson reported directly to the senior institutional official, in most instances the individual signing the statement of assurance. With some exceptions, the chairperson was highly knowledgeable of animal welfare issues and respected as a good leader. In every case, at least one of the committee members was a veterinarian. A few institutions had appointed a lay person to serve on the committee. Meeting first with the chairperson and then with the entire committee, site visitors asked members about their role and their overall level of involvement and interaction with administrative officials, fellow scientists, veterinary staff and animal care personnel.

Committee members saw their role as ensuring that optimal conditions for research are maintained in animal facilities. Institutional committees generally described themselves as having assumed some or all of the following responsibilities:

- Working with administrators and veterinarians to oversee the operation of animal care facilities by (a) conducting periodic inspections of animal care facilities, (b) setting or approving per diem charges, (c) allocating space, (d) orienting new faculty/staff members on standard procedures of operation, and (e) developing guidelines for hiring, training and promoting animal care personnel;

- Reviewing at least some of the institution's research protocols involving laboratory animals for (a) appropriateness of numbers and species of animals used, and (b) the appropriateness of the procedures to be performed on living animals in relation to benefits gained from advancing scientific knowledge;

- Reviewing with special emphasis those procedures that may cause discomfort and/or pain to animals as well as methods used to alleviate any distress to animals such as suitable anesthesia or analgesia;

- Providing competent scientific advice to administrators on matters relating to (a) institutional animal welfare policies and practices; (b) animal welfare legislation, both local and national; and (c) biomedical research using experimental models other than vertebrate animals.

The site visitors found that the animal care committees were generally not as active as their charters (organizational descriptions) had depicted them: some of the stated responsibilities were not addressed on a regular basis; all or part of the review functions were often delegated to the veterinarian, chairperson, and/or administrative staff, or they were performed in a routine manner.

Further discussion brought out the fact that animal care committee members (and other scientists within the institution) sometimes placed too much reliance upon NIH scientific review groups to evaluate research involving laboratory animals. Institutional officials and staffs were aware that, according to PHS policy, consultants participating on NIH study

sections and on-site visits are expected not only to review research applications for scientific merit but also to evaluate experimental procedures involving laboratory animals.

For the most part, the site visitors were convinced that animal care committees recognized and took action to correct inappropriate experimental procedures involving laboratory animals and/or problems related to the operation of the animal care facilities, even if each issue did not always receive the benefit of group discussion. The reasons given for delegating the responsibility of protocol review and for management of the animal facility varied. In most instances, animal care committee members indicated that veterinarians were in the best position to evaluate protocols for deviations from appropriate practices and to monitor animal care, allowing the committee to concentrate on other issues.

The site visitors discussed the possibility of appointing an individual who is not a scientist and/or not affiliated with the institution to the committee. Two of the committees already included non-affiliated lay persons. These individuals had been selected because of their community standing, concern for animal welfare and their understanding of the need to use animals in biomedical research. Their participation on animal care committees was considered extremely useful because they provided different perspectives on issues dealing with animal care and use. Officials of institutions whose animal care committees did not include a lay member generally favored considering such an appointment.

C. Investigators

At each institution, the site teams spoke with faculty/staff scientists to evaluate their role in maintaining compliance with the Guide. In advance of each visit, OERT used the NIH data system to select a list of investigators from representative departments and areas of study. Investigators were asked to describe their own work, available veterinary care, recordkeeping, training, their interaction with the animal care committee, technicians and caretakers, and the quality of animal care provided at their facility.

For the most part, those interviewed understood the NIH assurance system and appeared to take compliance issues seriously. They were familiar with and supportive of the oversight procedures, such as the review of research proposals, allocation of space in the animal facilities, ordering and purchasing animals and supplies, and standard operating procedures in effect at their institutions.

These scientists were generally familiar with the activities of the animal care committee and understood its function. They routinely addressed concerns about the management of the facility, planning, costs and care to the committee. Some investigators related instances when they had been asked by committee members to provide more information for the review of their protocols. A few indicated that they had been advised to modify an experimental procedure involving animals. Most investigators were familiar with the Guide, even though they were not always thoroughly knowledgeable of its contents. Investigators working in central animal facilities generally used the wide variety of veterinary services available to them. They related

instances when they sought advice and/or assistance from the animal care director in developing animal models, designing equipment and/or caging, performing procedures, screening for disease and solving disease problems in their animal colonies.

Investigators working at sites remote from the central facilities seldom had access to staff technicians and caretakers; their contact with veterinarians and veterinary personnel was often limited to brief periods during routine inspections. In some institutions of higher education, undergraduate and post graduate students from the biological or behavioral sciences often performed procedures which, in the central facility, were performed by animal care personnel. These students worked under the direct supervision of a professional scientist. In discussing the reasons for continuing these practices in satellite laboratories, the scientists explained that: (a) the central facility was not readily accessible; (b) departmental laboratories were designed and maintained properly to meet the specific needs of a research program involving animals; or (c) the costs of the central animal facility were too high. However, investigators citing prohibitive costs did not always know how animal per diem rates and user fees were derived.

D. Veterinary Care

The site visit teams found that meetings with veterinarians were extremely helpful in assessing animal care practices at institutions large enough to support at least one full-time veterinarian. Present during most of the interviews and laboratory visits, the staff veterinarian was able to answer many questions about current institutional policies and future plans. Frank discussions among veterinarians and members of the site visit teams often helped to correct any misconceptions about animal care programs.

The role of the veterinarian depended on the size and scope of the scientific program at the institution but almost invariably was a pivotal one in the oversight of biomedical research involving animals. In addition to providing service to the institution's animal facility, some veterinarians had departmental appointments with teaching assignments and research activities. Most had developed comprehensive centralized animal care services. In the larger institutions, a well-trained support staff purchased animals, feed, caging and other supplies and maintained financial accountability through effective information and recordkeeping systems. Some veterinarians were delegated full responsibility for conducting the primary review of proposed research protocols involving animals. As noted previously, animal care committees relied heavily on the advice and professional judgment of the veterinarian in reviewing experimental protocols, especially with respect to conformance to PHS policy and the Guide.

Veterinarians or their staffs usually maintained a close working relationship with investigators and assisted them on such matters as animal husbandry, animal biology, animal disease and experimental surgery. Veterinarians interacted with the administrators, animal care committee members and staff scientists in meeting their responsibilities. Scientists at most of the sites credited the veterinarian(s) with improving the conditions for animal

research at their institution. However, a few appeared to be limited in their effectiveness because they were overburdened by numerous administrative responsibilities or were not provided sufficient support staff to cover large, diffuse facilities.

Veterinarians at smaller institutions worked under a contract or on a fee-for-service basis. Depending on the complexity of the programs, they routinely inspected animal care facilities, participated in animal care committee meetings and advised institutional scientists on matters relating to the general health of laboratory animals and on the appropriateness of experimental procedures involving animals, provided preventive care as appropriate, and attended sick animals.

E. Animal Facilities

The site visitors inspected the premises where animals are bred, maintained and treated. Even when the facilities were extensive, team members were able to assess most of the areas within central and satellite laboratories, including storage, cage sanitation, special procedures and surgical rooms. Based on their professional experience and judgment, they evaluated the general condition of the physical plant, observed the quality of animal husbandry, recordkeeping, caging, and sanitation and appraised the overall health of the laboratory animals. During the visits, the members questioned veterinarians, technicians and caretakers about standard and emergency operating procedures of the animal facility.

In inspecting the environment of the laboratory animals, the site visit team found no conditions that might violate the Guide at the ten institutions. Other than for minor deficiencies in the physical plants, the centralized facilities were usually adequate to excellent. Even in the older facilities, the animal areas were clean and well-organized, with little or no overcrowding. There was proper concern for access to food and water. Animals were comfortably caged and appeared healthy.

Because the site visitors learned that certain procedures involving animals were performed in satellite facilities in some institutions, they made special effort to visit as many of them as practicable. In a few instances, they were invited by scientists to observe experiments in progress. Visits to satellite facilities, which are defined in this report as any building, room, area, or vehicle designed to confine, transport, maintain, treat or use animals not within the central facility, were not usually announced in advance and took place during the general evaluation of the institution's central facilities. Conditions in some satellite animal facilities were inadequate. Although they represented only a small percentage of animal care space, the satellite facilities were more likely to be crowded, with less control over environmental conditions, e.g., heat, light. Veterinary services and monitoring of the animals housed outside the central facility tended to be less than comprehensive.

In general, laboratory animal technicians and caretakers working in central facilities have been trained in programs offered by the American Association of Laboratory Animal Science. Technicians in most institutions were encouraged to seek advanced training and certification for promotions to more responsible, higher-paying positions.

V. CONCLUSIONS

Although there are necessary operational differences in the laboratory animal care programs among the ten sites selected for this study, it is clear that all institutions share a common concern--that the care and use of laboratory animals be in accord with good science and that the welfare of the animals be considered. We conclude:

1. Reliance upon voluntary compliance with PHS policy and recommendations in the Guide is a realistic approach to fostering proper care and use of laboratory animals in biomedical research. There is no reason to believe that regular NIH inspections are needed or would be more effective than the traditional assurance process.

2. The present assurance system should be strengthened by modifying the current PHS policy on animal welfare to promote more conscientious involvement by both the NIH and its awardee institutions.

These conclusions are based on the following findings:

- o No incidents of animal abuse were observed.

- o In general, senior administrative officials had accepted responsibility for the appropriate care and use of animals involved in PHS-funded projects by supporting effective animal care programs. Most of these officials: (a) possessed adequate knowledge of Federal animal welfare requirements; (b) provided financial support by subsidizing animal care personnel and animal care facilities; and (c) created strong centralized authority by linking an animal care director (veterinarian) and the animal care committee to the overall management plan.

- o In general, the institutional animal care committees met periodically to provide the senior administrative officials with advice and guidance on matters dealing with the proper care and use of animals in biomedical research. Although the committees differed widely in their procedures and responsibilities, most were chaired by a highly knowledgeable leader and served by competent member scientists who were representative of the research community within the institution. Given these capabilities, the site visitors were disappointed to find that the animal care committees frequently seemed less than fully assertive in exercising their responsibilities. Some suggestions for increasing the impact of these committees are addressed among the recommendations of this report.

- o At all institutions, most investigators interviewed understood or at least were familiar with institutional policies and procedures, and the PHS policy and Guide. Most demonstrated their willingness to work within the Federal and institutional animal care systems by: (a) submitting research protocols involving animals to institutional officials, the veterinarian, animal care committee chairperson and members, especially for procedures

that might cause pain or discomfort to experimental animals or require anesthesia or analgesia; (b) cooperating with periodic inspections of satellite facilities by the attending veterinarian and/or members of the animal care committee; and (c) heeding the advice of NIH scientific review groups with respect to the adequacy of the care and use of laboratory animals in biomedical research.

- At all institutions, a full- or part-time attending veterinarian had been appointed. In most cases, the attending veterinarian possessed advanced training in laboratory animal medicine. Senior administrative officials, scientists, and animal care committee members were heavily dependent on the knowledge and leadership of this individual for advising on matters of animal care, future planning, public service relations and keeping the facilities and programs at the institution in compliance with the Guide. The responsibilities of the animal care director varied among the institutions but often included: (a) operation of laboratory animal care program; (b) operation of the animal care facilities, especially the central facility if it existed; (c) oversight and concurrence on experimental procedures involving animals; and (d) monitoring of animal health both in central and satellite facilities.

- Most of the animal care directors provided dedicated and effective leadership of their animal care programs to the extent that they were given authority by the administration and were not overburdened with routine duties and responsibilities.

- In all of the institutions, the physical plant of the central animal facility was adequate to excellent; however, where satellite facilities existed, deficiencies were common and problems seemed more likely to occur.

VI. RECOMMENDATIONS

Notwithstanding the overall conclusions described above, the site visits proved instructive with respect to ways that the NIH and its awardees could make the system of voluntary compliance even more effective. These are as follows:

- The NIH should undertake a program for helping institutional officials, scientists and animal care directors (veterinarians) understand fully their responsibilities in implementing the PHS Policy on the Care and Use of Laboratory Animals. More specifically, institutional officials should know in detail what constitutes a successful program of laboratory animal care and how to structure one that ensures control over all animal care activities, especially those conducted in satellite facilities and at neighboring institutions.

- The PHS Policy on the Care and Use of Laboratory Animals should be expanded to include more specific information regarding responsibilities of the institution that receives funds for research involving the use of animals. These responsibilities

should be clearly described and incorporated in new animal welfare assurance statements to be negotiated with the OPRR, NIH. The OPRR should negotiate these assurances carefully and promptly. The information contained in the assurance document should be examined and updated periodically.

- The PHS policy should be further modified to define more precisely the responsibilities of the awardee institutions, particularly the role of the animal care committee. It is imperative that the experience and expertise of the members of such committees be used to conduct full and effective reviews of proposals involving research with animals. The appointment of a non-scientist and an individual unaffiliated with the institution should be given serious consideration.

- The NIH should consider conducting or sponsoring a survey to assess whether the number of veterinarians trained in laboratory animal science is sufficient to meet the needs of institutions conducting biomedical research involving animals.

- The NIH should conduct further assessment of the assurance process: in particular, the NIH should visit additional awardee institutions receiving total annual support of less than $5 million. The sample size should be increased because this category has the largest number of institutions with assurance statements on file with the OPRR.

PREAMBLE - PROPOSED PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF ANIMALS BY AWARDEE INSTITUTIONS

The Public Health Service (PHS) is proposing to amend the PHS Extramural Animal Welfare Policy as specified in DHEW Grants Administration Manual Chapter 1-43, "Animal Welfare." This notice summarizes the proposed changes and includes the proposed policy, on which public comment is encouraged. Written comments on the proposed policy should be received on or before July 15, 1984 if they are to be given full consideration. Please send comments to the following:

Carol Young
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31 - Room 4B09
Bethesda, Maryland 20205

In addition, PHS intends to hold three open hearings to give the public an opportunity to make oral comments on the proposed policy. The times and places of the hearings will be announced at a later date.

I. BACKGROUND

Responsibility for the humane care and use of animals involved in activities supported by grants or contracts from the PHS rests primarily with the institutions receiving the award. In order to provide for the adequate discharge of this responsibility, the PHS requires that institutions receiving awards for projects that involve animals provide an Animal Welfare Assurance, as specified in the PHS Animal Welfare Policy. A National Institutes of Health (NIH) policy was instituted in 1971, and the revision which went into effect in 1979 was broadened to include all PHS components. The Office for Protection from Research Risks (OPRR), NIH has continuing responsibility for implementing the PHS Policy.

As part of the PHS ongoing review and assessment of its programs and policies, and in response to recommendations from the Office of Extramural Research and Training (OERT), NIH, to the Director, NIH, the PHS has determined that the existing policy should be revised in order to strengthen the assurance mechanism on which the policy is based. The PHS believes that a revised policy should (1) require that institutions designate clear lines of authority and responsibility for those involved in animal care and use issues, (2) more clearly define the role and responsibilities of Animal Research Committees (ARC) (formerly Animal Care Committees), (3) require that assurances provide more specific information regarding an institution's program for the conduct of experiments involving animals, and (4) require ARCs to review and approve the proposed use of animals in individual grants and contracts to ensure compliance with the institution's assurance.

II. SPECIFIC PROPOSED CHANGES:

A. Animal Welfare Assurances

The proposed policy requires that the assurance be signed by a responsible institutional official who bears final responsibility for the institution's entire program of animal care and use. This individual must be a high-level institutional administrator who has the authority to make a commitment on behalf of the institution that the requirements of the policy will be met. This individual will also be responsible for certifying that the ARC has reviewed and approved individual grants and contracts. The proposal also requires that the institution designate in its assurance a veterinarian (or veterinarians) qualified in laboratory animal medicine who will be responsible for supervising the care, use, housing and feeding of all animals. The PHS believes that appropriate veterinary care must include a comprehensive program involving many aspects (nutrition, examinations, sanitation, feed, TB tests, etc.), and should be administered by a veterinarian with experience and expertise in laboratory animal medicine.

The present policy requires all institutions to state that they are "committed to comply with the Principles for the Use of Animals (Principles), the Guide for the Care and Use of Laboratory Animals (Guide), the provisions of the Animal Welfare Act, and other applicable laws and regulations." The language in the proposed policy is stronger because it requires all institutions to "accept the Principles as mandatory" and to state that the institution has "implemented the requirements of the Guide and is committed to implementing the recommendations of the Guide." Since the Principles are intended to ensure that research involving animals is conducted in a humane manner and in appropriate facilities, the PHS believes that institutions must accept them as mandatory requirements. Similarly, since the Guide contains few absolute requirements and many recommendations, institutions should provide assurance that they have implemented the requirements and are committed to implementing the recommendations contained in the Guide. The Principles remain virtually unchanged in the proposed policy because the PHS is discussing with other Federal agencies the possibility of developing federal-wide principles for the care and use of laboratory animals. In the event that such principles are developed, they may be inserted in the policy at a later date.

The present policy provides three options for institutions with Animal Welfare Assurances. The proposed policy offers two options: (1) full accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC) or (2) self-assessment by the institution of its animal program and facilities. Institutions covered by Option 2 will be required to submit with the assurance, and annually thereafter, a report to OPRR. The proposed policy details specific information which must be included in these reports. The information in the reports is intended to provide OPRR with sufficient information to assess the institution's implementation of the recommendations in the Guide, and the institution's progress towards remedying any deficiencies. The proposed policy also states that institutions covered by Option 2 may be selected at random for site visits by PHS staff and advisors to assess the adequacy of compliance with their assurance.

Institutions that are fully accredited by AAALAC and therefore covered by Option 1 would not be required to submit annual reports to OPRR and would not be subject to random site visits by PHS, although they may be visited if questions are raised regarding the institution's compliance with the policy.

B. Animal Research Committees

The proposed policy requires that institutions establish an ARC and contains specific requirements for the membership of the ARC. The present policy requires that the committee have at least five members and at least one doctor of veterinary medicine. The proposal states that the committee include at least five members, but in addition, specifically requires that the committee include an individual unaffiliated with the institution, the attending veterinarian with appropriate qualifying expertise in laboratory animal medicine, a practicing scientist experienced in laboratory animal medicine, and a member whose primary vocation is in a nonscientific area.

C. Functions of the Animal Research Committee

The PHS believes that an active ARC is an essential element of a good institutional animal care and use program, and therefore the proposed revision includes substantially more detail than the current policy on the appropriate role and responsibilities of the ARC. The ARC must have oversight responsibility for an institution's animal program, including the conduct of research supported by specific grants and contracts. The ARC is also given the authority to terminate a research activity if it determines that the activity cannot be brought into compliance with the policy.

Another substantive addition in the proposed policy is the requirement that the ARC review and approve the care and use of animals as set forth in applications and proposals. The proposal specifies five categories of animal use in research which must be reviewed and approved by a majority of the members of the ARC. Animal use in research which does not fall into the five categories must also be reviewed, but the review may be conducted by the ARC chairperson, or by a qualified ARC member designated by the chairperson. The purpose of the ARC review of research applications and proposals is to ensure that the described care and use of animals are in compliance with the policy and the institution's assurance, not to review for "scientific merit."

The proposed policy also specifies that no award will be made by PHS unless the responsible institutional official has verified that the care and use of animals in the proposed research has received the appropriate ARC review and approval.

D. Information Required in Applications and Proposals Submitted to PHS. The proposed policy states that applications and proposals must contain a complete description of the proposed use of the animals. This is intended to incorporate requirements already imposed on applicants and is not intended to place additional burdens on applicants.

E. Recordkeeping

To ensure that institutions maintain appropriate records, the proposal contains specific recordkeeping requirements. In the event that PHS conducts a site visit at an institution, the records would assist the PHS in determining the effectiveness of an institution's animal program, and of the assurance mechanism in general.

F. Waiver

The proposed policy states that an institution may request a waiver of a provision or provisions of the policy. However, no waiver would be granted unless sufficient justification is provided to OPRR and approved in advance and in writing. In any event, such waivers would be granted only in exceptional circumstances.

PROPOSED

PUBLIC HEALTH SERVICE

POLICY ON HUMANE CARE AND USE OF ANIMALS

BY AWARDEE INSTITUTIONS

I. INTRODUCTION

It is the policy of the Public Health Service (PHS) that before an institution receives a PHS award involving the use of animals the institution shall submit an Animal Welfare Assurance, acceptable to the PHS[1], stating that the institution will meet the requirements detailed below in Part I and that the institution (a) accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles), (b) has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and (c) is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations. Institutions and research investigators have primary responsibility for the humane care and use of animals involved in PHS-funded projects. Where the proposed work involves animals, no award will be made to an institution unless a responsible official of the institution has submitted, on behalf of the institution, an Animal Welfare Assurance acceptable to the PHS. Similarly, no award will be made to an individual unless that individual is affiliated with an institution which holds an accepted Animal Welfare Assurance.

This policy is applicable to recipients of any PHS support for research, training, testing or other activities involving the use of animals, whether performed by the awardee institution or by any other institution. The PHS requires administrators and investigators of foreign institutions receiving PHS funds for research involving the use of animals to follow only the PHS Principles for the Care and Use of Laboratory Animals.

II. DEFINITIONS

A. Animal

Any live, vertebrate animal used or intended for use in research, experimentation, testing, training or related purposes. The current Guide (see definition below) does not include recommendations on facilities for cold-blooded animals; however, the Principles for the Care and Use of Laboratory

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[1] Assurances shall be submitted to the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), Department of Health and Human Services (DHHS). Bethesda, Maryland 20205.

Animals (see definition below) and this policy apply to all live vertebrates.

B. Animal Facility

Any building, room, area or vehicle designed or used to confine, transport, maintain or use animals, including satellite facilities. A satellite facility is any facility in which animals are housed for more than 24 hours outside the central facility.

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. Assurance

Animal Welfare Assurance, the documentation on file wit (or submitted when requested by) the OPRR, 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 institution, organization or agency (including Federal, state or local government agencies) in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States.

G. Principles

Principles for the Care and Use of Laboratory Animals (see below).

H. Responsible Institutional Official

An individual who bears final responsibility for the entire program of animal care and use at the institution, and who has the authority to sign the institution's assurance and to make a commitment on behalf of the institution that the requirements of the PHS policy will be met.

III. PRINCIPLES FOR THE CARE AND USE OF LABORATORY ANIMALS

A. 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.

B. The Research

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

2. 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.

3. 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.

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

5. 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.

6. 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.

7. 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.

8. 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 ensure immediate death in accordance with procedures approved by an institutional committee.

C. The Facilities

1. 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. 78-23 (reprinted in 1980 DHEW 80-23), or succeeding editions or as otherwise required by the U.S. Department of Agriculture regulations established under the terms of the Animal Welfare Act (P.L. 89-544) as amended.

D. Transportation

1. 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 picked up and delivered, uncrated, and placed in acceptable permanent facilities promptly.

IV. IMPLEMENTATION BY AWARDEES

Before an institution is eligible to receive PHS support for projects in which animals are to be involved, the institution must submit to the Office for Protection from Research Risks (OPRR), Office of the Director, National Institutes of Health, an Animal Welfare Assurance acceptable to OPRR, stating that the institution will meet the requirements detailed in this policy and that the institution

- accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles),
- has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and
- is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations.

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.

A. Animal Welfare Assurance

The Animal Welfare Assurance (assurance) shall be typed on the institution's letterhead and signed by a responsible institutional official who has the authority to make a commitment on behalf of the institution and who bears final responsibility for the entire program of animal care and use at the institution. OPRR will provide the applicant institution with necessary definitions, instructions, and an example of an acceptable assurance. Subsequent to the institution's submission of an assurance, OPRR will notify the institution as to the acceptability of the assurance. No project proposing to use animals will be supported, and no active PHS project will be permitted to continue, in the absence of an acceptable assurance. Significant changes in the status of an existing assurance, departures from information submitted in an annual report (see Option 2), or problems encountered in implementing this policy shall be reported immediately to OPRR. After reviewing changes or problems, OPRR may require renegotiation of the assurance or other appropriate actions. In any case each institution must submit a new and complete assurance to OPRR at least every 5 years.

1. Program for Animal Care and Use

The assurance must contain a description of the institution's program for animal care and use, designating:

a. appropriate lines of authority and responsibility for administering the program and ensuring compliance with this policy; and

b. the veterinarian(s) qualified in laboratory animal medicine who will be responsible for supervising the housing, feeding, and care and use of all animals.

2. Institutional Status

The assurance must include a statement indicating that the institution has adopted one of the following options:

Option 1 - The institution is fully accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) or other accrediting body recognized by PHS2 and (a) accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles), (b) has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and (c) is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations.

An institution may not adopt Option 1 unless the institution has received full accreditation, by AAALAC or other accrediting body recognized by PHS, for all of its programs and facilities, including satellite facilities. An institution that has received provisional or probationary accreditation, or whose accreditation is revoked or is currently being withheld for any of its facilities, including satellite facilities, must select Option 2.

Option 2 - The institution has conducted a self-assessment (as described in the institution's assurance and annual reports) and the institution (a) accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles), (b) has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and (c) is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations.

Institutions covered by Option 2 must submit with the assurance and thereafter annually a report to OPRR. These reports will become a part of the assurance. Failure to submit an annual report may result in withdrawal by OPRR of the acceptance of the assurance.

Each report shall contain, at a minimum:

(a) a description of the nature and extent of the institution's adherence to the Principles and to the requirements and recommendations contained in the Guide;

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2 As of March 1984, the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

(b) a description of deficiencies, if any, in the institution's adherence to the requirements and recommendations contained in the Guide;

(c) a plan of action, including a specified time frame, for correcting deficiencies described in "(b)" above;

(d) progress towards remedying deficiencies previously described in "(b)" above; and

(e) the Animal Research Committee's recommendations for changes or improvements as forwarded to the responsible institutional official and other appropriate institutional officials (see B. Functions of the Animal Research Committee).

Upon consideration of the annual report and the institution's implementation of its assurance OPRR may impose specific restrictions or requirements pertaining to the care and use of laboratory animals.

3. Animal Research Committee (ARC)

Each institution shall appoint an Animal Research Committee (ARC), sufficiently qualified through the experience and expertise of its members to maintain oversight of the institution's animal program, facilities and procedures, and to provide complete and adequate review of research activities involving animals conducted by the institution.

The assurance must include the names, position titles and credentials of the ARC members, the ARC chairperson, and the responsible institutional official (see definitions). The membership of the ARC shall include:

a. at least five members;

b. at least one Doctor of Veterinary Medicine who is responsible for supervising the housing, feeding, and care and use of all animals at the institution, and who has appropriate qualifying expertise in laboratory animal medicine (demonstrated either by certification from the American College of Laboratory Animal Medicine, or by other evidence of expertise determined by OPRR to be satisfactory);

c. at least one practicing scientist experienced in research involving animals;

d. at least one member whose primary vocation is in a nonscientific area; and

e. at least one individual who is not otherwise affiliated with the institution and is not a member of the immediate family of a person who is affiliated with the institution.

Changes in the membership of the ARC must be reported promptly to OPRR.

B. Functions of the Animal Research Committee

The Animal Research Committee (ARC) will be the principal advisory group on humane care and use of animals to the institution and to researchers who use animals. The ARC is the appropriate body for resolving concerns involving the care and use of animals brought to the attention of the committee by veterinarians, researchers, animal caretakers or others. As necessary, the ARC will recommend to the responsible institutional official and other appropriate institutional officials, changes and improvements regarding the institution's animal program or facilities. Annual reports to OPRR (required under Option 2 only) must include any committee recommendations as forwarded to the responsible institutional official.

The ARC or the ARC Doctor(s) of Veterinary Medicine in conjunction with the ARC must be prepared to alter or to suspend a research activity whenever either of them determines that the activity is not in compliance with this policy. The ARC has responsibility to terminate the research activity if it determines that the activity cannot be brought into compliance with this policy.

In the conduct of its duties, the ARC at a minimum shall:

1. review annually the institution's program for humane animal care and use;

2. inspect annually all of the institution's animal facilities, including satellite facilities;

3. review and approve the care and use of animals as set forth in applications or proposals when PHS funds are requested (see C. Review of PHS Research Applications and Proposals);

4. review and approve proposed changes in ongoing research funded by PHS which introduce significant concerns regarding the use of the animals involved, or when animal studies were not originally proposed and approved by the ARC; and

5. when requested by PHS, review specific animal welfare issues identified during the PHS review process.

C. Review of PHS Research Applications and Proposals

Review and approval of the care and use of animals as set forth in all applications or proposals is required. However, unless one of the categories listed below pertains, the review may be conducted by the chairperson of the ARC, or another member of the ARC designated by the chairperson and qualified to conduct the review.

The care and use of animals as set forth in applications and proposals must be reviewed at a convened meeting of at least a majority of the full membership of the ARC and must be approved by a majority of the full membership whenever a research activity would:

1. include the use of nonroutine or harmful invasive procedures; or

2. include prolonged restraint; or

3. require the use of animals that have a serious natural or experimental disease and which would be maintained in that state for an extended period of time; or

4. propose methods of euthanasia that differ from those recommended by the American Veterinary Medicine Association (AVMA) Panel on Euthanasia[3]; or

5. involve any animal procedure or use which is stipulated by the ARC or by OPRR as requiring ARC review and approval.

The ARC shall approve the application or proposal only when the care and use of animals has been reviewed and found to comply with this policy and with the conditions of the institution's assurance. The ARC may not have a member participate in the ARC's review or approval of a project in which the member has a conflicting interest (e.g., the principal investigator for the project), except to provide information requested by the ARC.

An ARC may invite ad hoc technical consultants with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the ARC. These ad hoc consultants may not vote with the ARC.

Verification of approval by the ARC shall be indicated by the signature of the responsible institutional official on the face page of the application or proposal. OPRR will ask institutions that do not have an acceptable assurance on file to submit verification of approval after the institution has complied with an OPRR request to submit an assurance and establish an ARC (see D. Information Required in Applications and Proposals Submitted to PHS).

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 laboratory animals shall contain the following information:

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[3]Journal of the American Veterinary Medical Association (JAVMA), 1978, Vol. 173, No. 1, pp. 59-72.

a. identification of the species and 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. if euthanasia is to be involved, a description of the method to be used.

2. Institutions Which Have an Acceptable Assurance

Applications and proposals involving animals from institutions with an acceptable assurance on file with OPRR shall contain verification of approval by the ARC, indicated by the signature of the responsible institutional official on the face page of the application or proposal. PHS will consider applications or proposals incomplete if they lack verification of approval. If verification of approval is not received at the time of submission to PHS of a grant application or contract proposal, the application or proposal may be returned to the institution.

3. Institutions Which Do Not Have an Acceptable Assurance

Applications and proposals involving animals from institutions that do not have an acceptable assurance on file with OPRR shall contain a declaration that the institution will establish an ARC and submit an assurance upon request by OPRR. After such assurance has been accepted by OPRR, the ARC (or appropriate ARC member) shall review and approve the care and use of animals in the research. The responsible institutional official must submit, by letter, verification of approval of the proposed care and use of animals in the research by the ARC before an award will be made.

E. Recordkeeping.

The awardee institution shall maintain:

1. an Animal Welfare Assurance approved by the PHS;

2. minutes of ARC meetings, including records of attendance, activities of the committee, and committee deliberations;

3. records of applications, proposals and proposed changes in ongoing research reviewed and approved or disapproved;

4. records of ARC recommendations as forwarded to the responsible institutional official; and

5. records of accreditating body determinations.

All records shall be maintained for at least 3 years. Records that directly relate to applications, proposals, and proposed changes in ongoing research reviewed and approved by the ARC shall be maintained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

V. IMPLEMENTATION BY PHS

A. Responsibilities of the OPRR.

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

1. request and approve Animal Welfare Assurances and related reports;

2. distribute to executive secretaries of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions that have filed an acceptable Animal Welfare Assurance;

3. advise awarding units and awardee institutions concerning the implementation of this policy; and

4. evaluate allegations of noncompliance with this policy.

B. Responsibilities of PHS Awarding Units

PHS awarding units may not make an award for a project involving animals unless the institution submitting the application or proposal is on the list of institutions that have an acceptable assurance on file with OPRR, and the responsible institutional official has provided verification of approval by the ARC. 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, accepted by OPRR, and the responsible institutional official has provided verification of approval, by the ARC, of the care and use of animals as set forth in the application or proposal.

No initial, competing continuation, or recompeting award will be made if the application or proposal does not satisfy the terms of this policy.

C. Conduct of Special Reviews/Site Visits

Each awardee institution is subject to a special review, which may include a site visit, when questions are raised regarding its compliance with this policy. Institutions covered by Option 2 may be selected at random for site

visits by PHS staff and advisors to assess the adequacy of compliance with their assurance, but institutions that are covered by Option 1 will not be subject to such random site visits.

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 advance and in writing by OPRR. In any event, such waivers will be granted only in exceptional circumstances.

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