

Chapter 15

# Institutional and Self-Regulation of Animal Use

*The public fears and distrusts science. Regulation-any regulation—may in the end make them fear it less. But scientists themselves have a duty, I believe, not just to argue their own case but to argue it in a manner acceptable to society as a whole. . . . [Fear] must be allayed if at all by scientists and doctors themselves, making their own case and making it intelligibly in public.*

Baroness Mary Warnock  
Girton College, Cambridge  
*Br. Med. J.* 291: 187-190, 1985

*What's happening in Washington is a red herring. The issue of the use of animals in research won't be resolved on Capitol Hill. The real action is right here on your front door step.*

William M. Samuels  
American Physiological Society  
Address given at the University of South Florida Medical Center  
March 21, 1984

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# Institutional and Self-Regulation of Animal Use

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The most important check on the proper treatment of animals is the conscience of the individual investigator (23). A person's view about animal welfare is influenced by many forces; some of the most formidable include exposure to professional peers, mentors, and formal course work on animal care or the ethics of animal experimentation.

Beyond individual conscience, the most visible means of self-regulation is institutional committee review of animal care and use. The use of animals is also overseen by the peer review of scien-

tific colleagues and others outside of the research facility—an important part of the grants administration process.

In addition, most scientists are members of one or more professional associations, some of which have codes of ethics for research with animal subjects. These statements of principles can serve to inspire ethical behavior and alert researchers to ethical issues raised by their work. Codes can sometimes provide advice on specific cases and sanctions for violations (reviewed in ref. 21).

## REVIEW OF ANIMAL CARE AND USE

All research supported by the Public Health Service (PHS), including that of the National Institutes of Health (NIH), is subject to the provisions of the PHS *Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions* (revision effective Dec. 31, 1985) (44). Each institution so funded must submit an acceptable assurance to NIH's Office for Protection from Research Risks (OPRR) that commits the facility to active promotion of compliance with the policy and the NIH *Guide for the Care and Use of Laboratory Animals* (42).

The NIH peer-review system can be construed as external rather than self-regulation (46). Site visits to determine compliance can occur, and funding can be terminated for lack of compliance with contractual assurances, as happened in the *Taub* case (see ch. 14). In the broadest sense, however, NIH is fully dependent on grant recipients for effective policing of its provisions.

The enactment in 1985 of Public Law 99-158 (see ch. 13) provided statutory authority and recognition for some provisions of the PHS policy, requiring, for example, all entities conducting research with PHS funds to organize and operate institutional animal care and use committees. Also in

1985, amendments to the Animal Welfare Act (see ch. 13) extended the mandate for institutional committee oversight to research facilities covered by the Animal Welfare Act and to Federal research facilities.

### *NIH Assurance Review*

To test the operation of written assurances of compliance with the PHS policy regarding humane care and treatment of experimental animals by investigators in the field, and perhaps in response to congressional and public pressure, the NIH Office of Extramural Research and Training in 1983 conducted site visits to 10 grantee facilities (43). These institutions were chosen from a stratified sample of the more than 800 awardees with general assurances on file at the NIH Office for Protection from Research Risks.

The 10 institutions were distributed among those receiving more than \$10 million in annual support from NIH (3 institutions), between \$5 million and \$10 million (3 institutions), and less than \$5 million (4 institutions). The sample was further defined by selecting institutions from each of those categories with valid written assurances on file

but lacking accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC). Awardee institutions were notified of the prospective visits by publication of the selection criteria and the site names (43), and the NIH chairperson notified the appropriate institutional representative(s) at least 1 month prior to the scheduled visit.

Site-visit team size depended on the size of the institution and the complexity of its physical facilities. At a minimum, teams consisted of a veterinarian, a biological scientist engaged in research using animals, and an NIH scientist/administrator. In addition, non-Federal consultants were included "with a view towards ensuring impartiality and enhancing expertise" (43). Between June and September 1983, the 10 site visits were conducted to receive information and impressions in order to answer the following questions:

- **Is 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 can it be further improved?
- If it is not adequate, what alternatives should be considered?

The NIH site visits were generally criticized within the animal welfare community on three grounds:

- 10 institutions may not represent a sizable enough sample to generate sufficiently representative data on which to base policy;
- the 1-month advance notification to the institutions to be visited may have skewed the findings; and
- too few smaller institutions were visited, since the majority of NIH-funded recipients fall into the unaccredited, less-than-\$5-million category.

Despite these potential shortcomings, information generated by the 10 site visits led NIH to draw conclusions and make recommendations about the PHS policy regarding laboratory-animal welfare,

In early 1984, NIH reported on the site visits (43). Based on the finding of these visits, two general conclusions were reached:

- Reliance upon voluntary compliance with PHS policy and recommendations in the NIH 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.

- The present assurance system should be strengthened by modifying the 1979 PHS policy on animal welfare to promote more conscientious involvement by both NIH and its awardee institutions.

In addition, the report stated that "no incidents of animal abuse were observed" (43).

From the findings of the site-visit teams, a series of recommendations concerning the adequacy of the current policy and its enforcement were made. The site-visit report recommended that NIH:

- undertake a program for helping institutional officials, scientists, and responsible veterinarians "understand fully their responsibilities" for policy implementation;
- expand the policy to include "(more specific information regarding responsibilities of the institution that receives funds for research involving the use of animals, " including new and more specific assurances to be negotiated with institutions receiving funds "carefully and promptly";
- modify the policy to define more precisely institutional responsibilities, "particularly the role of the animal welfare committee," to which the appointment of a nonscientist and a person unaffiliated with the institution should be given serious consideration;
- conduct or sponsor 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; and
- conduct further assessments of the assurance process, including visiting more awardee institutions receiving total annual support of less than \$5 million, since that category of institutions is the largest with assurance statements on file (43).

In response to the above recommendations and criticisms, five additional institutions receiving less than \$5 million were visited in 1984. Using the same

protocol as before, visits were made to a stratified sample of institutions without AAALAC accreditation during the months of July and August 1984. The site-visit teams consisted of a representative of the NIH Office of Extramural Research and Training, a scientist or administrator from OPRR, and two non-Federal consultants (a veterinarian experienced in laboratory-animal medicine and a biomedical scientist currently conducting research requiring laboratory animals) (44).

The conclusions following these additional visits are almost identical to the earlier ones. The teams noted that the small institutions were capable of both meeting the responsibilities of the 1979 PHS policy and assuming additional responsibilities in response to changes made in the 1985 PHS policy. The site visitors did find, however, that these institutions needed to improve the advisory and oversight roles of their institutional animal care and use committees (IACUCs) and upgrade their veterinary oversight (44).

### ***Public Health Service Policy***

In mid-1985, the Department of Health and Human Services (DHHS) released its new PHS ***Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions (44)*** to replace the 1979 PHS ***Extramural Animal Welfare Policy (41)***. (For the full text of the new policy, see app. C.) This new policy is a result of the proposed PHS policy (43), the conclusions from the 15 site visits to animal care facilities by NIH, and 340 written and oral comments on the proposed policy. It took effect December 31, 1985, for all potential grantees of PHS wishing to use animals in experimentation.

This policy has many of the same features as the 1979 version. It applies to all PHS-supported activities involving animals in the United States. Animal is defined as “any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.” 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. The policy relies on the NIH ***Guide for the Care and Use of Labora-***

***tory Animals*** for the standards for animal care and treatment. Finally, the PHS policy is based on a set of overall principles governing animal experimentation. The 1979 policy was based on 12 principles on the use of animals. The new policy implements and supplements the “Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training” (50 FR 20864) prepared by the U.S. Interagency Research Animal Committee (see ch. 13, box A). The principles contained in these two documents are very similar.

Two major requirements form the core of the PHS policy—the institutional animal welfare assurance to NIH and an institutional animal care and use committee. Each institution wishing to obtain PHS funding for a research project involving animals must have on file with NIH’s Office for Protection from Research Risks a written assurance setting forth compliance with this policy. The assurance must describe in detail the institution’s program for the care and use of animals in PHS-supported activities including:

- a list of every branch and major component of the institution;
- the lines of authority and responsibility for administering the program (each institution must identify an official who is ultimately responsible for the institution’s animal program);
- the qualifications, authority, and responsibility of the veterinarian who will participate in the program;
- the membership list of the IACUC;
- the procedures that the IACUC will follow to implement this policy;
- the health-care practices for personnel who work with laboratory animals or their facilities; and
- 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.

In addition, each assurance must categorize the evaluation of its program and facilities as either accredited by AAALAC or as evaluated by the institution itself. The second category requires that the IACUC assess its own program every year and maintain records on the nature and extent of the institution’s adherence to the NIH ***Guide*** and the PHS policy. This report must also contain justifi-

cations for any departures from the policy. Deficiencies in an institution's program or facilities must be reported to NIH and the institution must adhere to an approved time frame for correction of the deficiencies.

The animal care and use committee required by the new PHS policy is specifically structured to consist of at least five members including:

. . . one Doctor of Veterinary Medicine with training or experience in laboratory animal medicine, one practicing scientist experienced in research involving animals, one member whose primary concerns are in a nonscientific area, and one individual who is not affiliated with the institution in anyway other than as a member of the IACUC.

New duties of this committee include reviewing the institution's program for animal care and use and inspecting the facilities (including satellites) at least annually. The policy also authorizes the IACUC to suspend any activity involving animals that is found to not be in compliance with the policy.

A new power of the IACUC is to "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." The policy gives a detailed plan for the administrative structure to handle this task, along with certain specific animal care requirements that must be met by each proposal (e.g., minimization of discomfort of animals). Each application or proposal submitted to PHS must verify that the IACUC has approved those sections of the proposal related to the care and use of laboratory animals. It should be submitted along with the application but may be sent directly to the executive secretary of the initial review group within 60 days of the original submission. Figure 15-1 is the example NIH provides of an acceptable verification letter for a proposal. 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 PHS policy is implemented by the NIH's Office for Protection from Research Risks, which is responsible for approving, disapproving, or withdrawing approval of institutional assurances. It

also has the power to evaluate allegations of non-compliance with the policy and to conduct site visits to selected institutions to check for proper implementation of the policy.

The new PHS policy differs from the 1979 version in the following ways:

- Institutions are required to designate clear lines of authority and responsibility for those involved in animal care and use in PHS-supported projects, including an institutional officer responsible for the entire program.
- The role and responsibilities of the IACUC have been upgraded. The requirements of specific types of committee members (e.g., a member unaffiliated with the institution or a member in a nonscientific area) are new, as is the policy that these committees review and approve those sections of research applications for PHS funding that relate to the care and use of animals before they are actually funded.
- If an institution is not AAALAC-accredited, stringent standards for self-assurances apply and more information about animal facilities must be made available to NIH.
- Following the policy is mandatory, as opposed to the earlier "commitment to comply."
- Recordkeeping requirements for institutions are explicitly addressed. Records of IACUC meeting deliberations, assurance forms, accrediting body determinations, and so forth must be maintained for 3 years and made accessible for inspection to PHS officials.
- OPRR has power to "evaluate allegations of noncompliance with the policy [and]. . . conduct site visits to selected institutions."

In general, the Public Health Service now has a much more structured animal welfare policy that specifically designates what individual institutions must do in order to achieve satisfactory compliance. The old policy had many of the same structures (e.g., institutional committees and assurances) but in a form that allowed different degrees of institutional animal care and treatment responsibility. The new policy defines a minimum standard animal care and use policy for an institution that wishes to obtain PHS funding. In 1979, OPRR released a sample assurance that was two pages long and only required a few specifics from the insti-

Figure 15.1—Example of Acceptable Verification for Grant Submission to NIH

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[Date]

Division of Research Grants  
National Institutes of Health  
5333 Westbard Avenue  
Westwood Building, Room 240  
Bethesda, Maryland 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:

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

[Signature]  
[Title]

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SOURCE: Adapted from US. Department of Health and Human Services, Public Health Service, National Institutes of Health, "Laboratory Animal Welfare," *NIH Guide for Grants and Contracts* 14(8): June 25, 1985.

tution. The new sample assurance, released in 1985, is seven pages long, including two tables (one on membership of the **IACUC** and one summarizing the institution's individual animal facilities, their

square footage, the species within, and the average daily inventory of species), and requires specific detailed data on the institution's animal welfare program.

## REVIEW BY COMMITTEE

Recourse to committees to sort through a thicket of value questions occasioned by advances in biomedicine, and in particular biomedical research, is not unique to the area of research with animals. For example, there has been a recent explosion of interest in the formation of hospital ethics committees to develop policies and consult in individual cases. According to one newspaper account, "quietly and without fanfare, hundreds of American hospitals are organizing internal ethics committees that are coming to play crucial roles . . . involving life and death decisions for thousands of patients" (24).

Concern in this country about the objects of research—and the link between animal and human subjects—has been evident for decades. A recently

published historical account describes nontherapeutic research into the cause of syphilis conducted at the beginning of the century and reviews the reaction to the use of orphans and hospital patients who had not given their consent. The result was a nearly 20-year campaign against "human vivisection" conducted by antivivisectionists who saw the use of human beings without their consent in nontherapeutic research as the logical outcome of a science built on animal suffering: "To whomsoever, in the cause of Science, the agony of a dying rabbit is of no consequence, it is likely that the old or worthless man which in the cause of learning may well be sacrificed" (22). A number of State and Federal legislative initiatives proposed 60 to 70 years ago regarding animal research were amended to regulate "human vivisection" as well.

Some egregious violations of human rights in the name of medical research occurred earlier in this century. The experiments conducted on prisoners of war during World War II that were revealed at Nuremberg are the most notorious and well-known examples; the trials resulted in a code of ethics to guide future research. Haunted by the specter of patently unethical and scientifically unsound research conducted by Nazi physicians, some commentators began to complain that it was not only in wartime that the rights of human subjects had been overlooked. In an influential series of articles by an American physician (12) and a British physiologist (28), hundreds of experiments published in major medical journals were reviewed, revealing many instances in which research subjects were abused or misinformed. In addition, there was concern that certain segments of the population—blacks, the poor, women, or the elderly—were bearing a disproportionate share of the burden of being research subjects.

In response to such revelations about the exploitation of vulnerable populations, a number of in-

stitutional review boards (IRBs) were setup in the mid-1960s under Federal regulations to oversee research with human subjects. Of all the committees formed to respond to value questions raised by medical practice and biomedical and behavioral research, IRBs have the most obvious parallels to animal care and use committees. Many of the questions raised now about committees on animals—whether they can both protect animal subjects and abet the scientific enterprise, whether they function to minimize pain and suffering in experiments, or are mere window dressings for public relations purposes—have been addressed in 15 years of experience with committees on human subjects. This experience includes not only the establishment of IRBs within institutions and oversight of the process through the general assurance process monitored by OPRR (31), but also frequent conferences, a spate of academic literature, and the publication of a journal devoted exclusively to the human-subjects review process, which includes case studies reviewing problematic protocols.

## ANIMAL CARE AND USE COMMITTEES

### *Roles and Responsibilities*

One commentator has summarized the potential functions for animal care and use committees as (26):

- to ensure compliance with local, State, and Federal laws and regulations on animal care and use;
- to inspect animal care facilities;
- to review protocols for animal welfare issues;
- to assess the qualifications of investigators;
- to oversee student use of animals;
- to advise on institutional needs, costs of animals, and animal procurement policies;
- to control allocation of animals within the institution;
- to act as a resource on animal welfare issues and to educate the university community and the community at large on animal welfare issues; and
- to serve as a community complaint forum.

Each IACUC may be mandated to perform all or some of the above responsibilities. Some committees oversee the care of all the research animals housed in an institution. This may include ensuring compliance with local, State, and Federal regulations; inspecting facilities; and advising on matters of care and feeding, design of facilities, and resource allocation. Some of the most difficult problems in this regard have been encountered in large institutions with farflung, decentralized facilities that may house only a few animals for use by individual researchers or small groups of students. Small, satellite facilities can present problems in ventilation, sanitation, care, and oversight during weekends and holidays (25). Some universities have countered this problem by centralizing a procurement system, so that the purchase of an animal by a researcher anywhere in the university triggers oversight mechanisms (32). At a minimum, the IACUC must comply with the PHS policy committee requirements,

According to NIH, approximately 26 percent of existing animal care and use committees review research protocols (25). Under the new PHS policy, all IACUCS will be required to approve all sections of each research protocol that involves animals. Some committees have established a system of expedited review where only protocols that raise questions regarding pain and suffering are considered by the full committee. More innocuous projects are reviewed perfunctorily by smaller subcommittees. Rating scales have been established for expedited reviews. One suggestion of such a scale has five categories, detailing a range of degree of harm inflicted on animals. This proposal, already in place in some form in a number of institutions, is designed to provide a calculus so that “ethical risks” can be weighed against “(the benefit in terms of improvement of animal or human health or other societal good)” (27). Other committees have a bifurcated review, with parallel processes for considering animal care and ethical issues (32).

In a broad sense, animal welfare concerns are by definition inextricably intertwined with scientific issues. The threshold question of the validity of an animal model approach and the possible availability of alternatives is followed closely by questions of the efficiency of animal use. Is the smallest number of animals of an appropriate species being used? Would a more sophisticated statistical methodology assure this is the case? Are genetic variables manipulated to the extent necessary? Will the data generated by the experiment be understood and of use to other scientists? Does the research answer an important question and has the researcher made sure it does not unintentionally duplicate already published work? Is the researcher qualified to undertake the project? These are among the questions that raise twin concerns of scientific and ethical appropriateness.

The dual nature of the scientific and care review issues were the focus of remarks by one committee proponent (20):

Concern for the reduction or elimination of pain is inseparable from consideration of the potential scientific value or the benefits to humankind to be derived from the work. . . . Decisions about, for example, the species and number of animals to be used, or the necessity for particular inva-

sive procedures, simply cannot be made intelligently without reference to the scientific value of the work; or without an understanding of the scientific discipline represented in the proposal. Research of inferior quality should not be done on any species, regardless of how humanely it is done. Concern for humane treatment of animals is not only consistent with good science, but augments its quality by assuring us of well-maintained and nourished animals that are behaviorally comfortable.

Many people feel that the IACUC is not qualified to judge the science or “(scientific merit)” of an experiment. Yet, it maybe impossible to discuss animal care and use issues without some discussion of the science involved. How does an IACUC draw the line between discussing and approving the animal care and use issues and the scientific merit, feasibility, and potential scientific gain of a particular experiment? Depending on the membership of a particular committee or the institution itself, science issues may or may not be addressed in the approval process. This may lead to an inconsistent system: A proposal that might be modified in one IACUC could be approved in a different committee depending on whether only animal care and use issues were addressed.

In addition to the above functions, animal care and use committees can also play an educational role. The process by which investigators justify their research can be an educational one and the committee can also be used to teach the research community as a whole. The availability of alternatives, ways to avoid unintentional duplication, and amelioration of pain are all subjects the committee can discuss. Some committees also monitor animal welfare legislation and advise institutional officials about pending State and Federal initiatives.

### ***Financial and Procedural Issues***

A number of questions about how committees operate involve “housekeeping” details that, as a practical matter, may be as important as substantive concerns. The operation of the committee in terms of recordkeeping and voting has important implications. Whether it operates on a consensus or majority vote may determine how much influence unaffiliated members have. In addition, some committees have provisions for investigators to

appeal adverse findings; the rights of investigators in this regard, as well as the legal posture of the committee (and individual members), are still open to question. Other concerns include the committee's ability to monitor current research and to establish procedures ensuring that its advice is followed.

There is a paucity of data on operating costs for animal care and use committees for several reasons. Service on committees is part of the general responsibilities of salaried faculty or institutional officials. Additional overhead costs of office space, support staff, and recordkeeping are also often factored into general budgets. One cost estimate comes from Colorado State University, where the animal research committee costs about \$24,000 per year to run, which was 0.43 percent of the university's biomedical research budget (35). In smaller institutions, requirements for more active committees would likely be a great administrative and financial burden, especially with a review process entailing prospective review of all protocols submitted for funding.

The parallel between the institutional review boards and IACUCs is the strongest when discussing procedural matters. The lessons learned by individual institutions in setting up, funding, finding administrative staff support, and structuring IRBs can help IACUCs avoid similar problems.

### ***Membership***

Much of the debate about the value of animal care and use committees has focused on who should be on them. One commentator, writing about the use of hospital ethics committees to advise on decisions about seriously ill newborns, maintained (10):

... when it comes to matters of life and death, our society prefers procedure to substance. Instead of asking, "What is the right thing to do?" we ask, "Who should decide?" The attractiveness of such committees probably derives in large measure from their potential for transmuting a hard question (Who shall live?) into a more tractable one (Who shall sit on the committee?).

For animal care and use committees, however, the question may not be quite so tractable after all.

### **Practicing Research Scientists**

Until the recent changes in the PHS policy, which now requires a diverse group of individuals on the IACUC, many institutional committees consisted primarily of practicing research scientists involved with animal research. Their contribution to an IACUC is important because of their knowledge on animal models, research protocols and procedures, and the use of animals in research. These members make sure that the views of the major users of animals are represented. At the same time, they have a conflict of interest with some of the goals of the IACUC since their jobs and livelihood are involved with research on animals. Ensuring their objectivity, therefore, is important.

### **Veterinarians**

Having a veterinarian on the committee is essential since in many cases that person is responsible for the institution's animals. The PHS policy requires that each IACUC have one Doctor of Veterinary Medicine with training or experience in laboratory-animal science and medicine. The veterinarian must implement the institution's animal care and use program on a daily basis. The role of this person on an IACUC is to be the professional-level link between the committee and the daily operation of the institutional program.

Veterinarians for institutions doing animal research have come from all fields of veterinary medicine. In the late 1950s, veterinarians began to enter the specialty known as laboratory-animal medicine. To date, approximately 700 full-time veterinarians are certified in this field (out of a total of about 45,000 nationwide). The two organizations accrediting practitioners of laboratory-animal medicine are the American Society of Laboratory Animal Practitioners and the American College of Laboratory Animal Medicine. These veterinarians, along with any others with experience in laboratory-animal science and medicine, fulfill the PHS requirement on IACUC membership. For small institutions with only a few projects with animals, it can be difficult and costly to obtain a part-time laboratory-animal veterinarian as there are so few of them.

### **Unaffiliated Members**

Most proposals for institutional animal review committees require that one or more persons not affiliated with the research entity (e.g., members of the local community) be included. This would be someone who is primarily responsible for representing community concerns regarding the welfare of animal subjects. This person can bring objectivity to the committee because there is no financial tie between the person and the institution and therefore no conflict of interest. The PHS policy requires one such unaffiliated member. (This person might also fill the nonscientific spot described below, but need not.) An unaffiliated member could well be a research scientist at a different institution.

The unaffiliated members who have generated the most controversy are representatives of the animal welfare and animal rights community. Scientists have feared that the involvement of such people might delay or derail research projects. There have also been concerns about confidentiality and unwarranted disclosure of research ideas in progress, a fear exacerbated in the commercial setting. On the other hand, not unlike individuals with strongly held views opposing capital punishment (who may be challenged during the jury selection process for a capital case), some animal welfare advocates have refused to cooperate with these committees at all.

This leads to another problem: How to certify the bona fides of such a committee member? Is membership in a local humane society sufficient or must it be a particular activist group? Some institutions may have difficulty finding members of the general community, let alone animal welfare advocates, who are willing to expend the considerable time necessary to participate in the process. Animal welfare proponents have complained that the fact they are generally not remunerated for such activities (whereas other committee members maybe devoting salaried time to the committee) tends to greatly discourage their participation. (This has generally not been a problem in the human subjects area, however.) Paying unaffiliated members, which some schemes have proposed, would present a “Catch 22” situation: Payment would “affiliate” them with the institution and therefore disqualify them. Even with all these pos-

sible problems, many committees have been very successful at opening their deliberations to unaffiliated members.

### **Nonscientific Members**

The presence of nonscientifically trained people on the IACUC has rankled some scientists; others have speculated that the need to translate research questions for nonspecialists “may well necessitate [the investigator’s] use of a new vocabulary and new patterns of thought, especially if he is compelled to provide moral justifications for his use of animals” (34,37). Against the wishes of many scientists, the PHS policy requires that one member of the IACUC be from a nonscientific area.

Although nonscientific members are often spoken of as lay members, often they are simply professionals with different backgrounds. Lawyers, members of the clergy, and philosophers with training in bioethics have all been suggested as able to bring relevant outlooks to bear. On occasion, committees may also rely on specialists on an ad hoc basis to review particular projects. A professional statistician, for example, might be consulted in a determination of the appropriate number of animals to be used in a particular protocol.

### **Animal Care Staff**

Many committees include an animal technician or a member of the technical staff who provide the daily service, health care, and personal care of the laboratory animals. Animal technicians, well trained in animal health care, animal maintenance, and facility design, can represent the view of the animal care facility on the committee. Animal care committees with technical staff find these members helpful with issues of protocol review (including whether the protocol can be done within the facility), space allocation, and management issues. On some committees, animal technicians act as full voting members of the IACUC; in others, they act as ad hoc advisory members without voting privileges.

### **Institutional Representatives**

Representatives of the institutional administration are often members of animal care and use committees because of the insights they may have

into the overall management of the institution, including the financial constraints under which it operates. Management personnel can often provide information on the physical plant that may bear on care and husbandry issues. For the committees to have clout, it is necessary to have a representative of the office of the president, dean, or provost.

### ***Monitoring the Monitors***

**How** can the successful functioning of animal care and use committees be determined? Some of the committee functions just described translate into fairly accessible benchmarks. The composition of the committees, the number of protocols reviewed, and the types of experiments given full review are all factors that can be examined. Yet even this relatively "hard" data can belie more elu-

sive factors at work. For example, as in the area of human subjects review, often the process by which a committee approves a protocol is one of negotiation, during which an investigator may justify or change the number of animals, or species, or methods of experimental manipulation—a process that would not be reflected in a "yes" or "no" vote.

Since the review process itself is one that is difficult to study, site visits have been relied on to examine committee functioning. In addition to examining minutes of meetings, the composition of the committee, and number and types of protocols approved, site visits can afford the opportunity to interview scientists, committee members, and institutional officials and, perhaps, to sit in on a committee meeting.

## **THE AAALAC PROCESS**

The American Association for Accreditation of Laboratory Animal Care is a voluntary organization that accredits institutions that conduct animal research. According to the group (2):

... [the association] was organized in 1965 to conduct a voluntary program for the accreditation of laboratory animal care facilities and programs. The accreditation program is concerned with encouraging high standards for the care and use of laboratory animals including appropriate veterinary care, controlling variables that might adversely affect animal research, and protecting the health of animal research workers.

AAALAC is governed by a Board of Trustees composed of representatives of 27 professional organizations in education and research, including the American Association for Laboratory Animal Science, American Veterinary Medical Association, Pharmaceutical Manufacturers Association, and American Association for the Advancement of Science. A 16-member Council on Accreditation is appointed by the board to make recommendations. All the Council members have D.V.M. or Ph.D. degrees and are actively involved in laboratory-animal medicine or biomedical science. As of 1985, a total of 483 institutions had received AAALAC

accreditation (see app. D) (3). Table 15-1 summarizes the types of facilities that have received accreditation.

To become AAALAC-accredited, a facility must pay a nonrefundable application fee prior to the

**Table 15.1.—Distribution of AAALAC-Accredited Facilities by Category**

Type of facility	Percent of total
Veterans' Administration medical centers . . .	15
Commercial laboratories . . . . .	14
Medical schools . . . . .	13
Pharmaceutical manufacturers . . . . .	9
Nonprofit research laboratories . . . . .	9
Government laboratories . . . . .	8
Hospitals . . . . .	8
Universities (facilities serving an entire campus) . . . . .	6
Combined facilities for health schools . . . . .	4
Dental schools . . . . .	4
Laboratory animal breeders . . . . .	3
Colleges of pharmacy . . . . .	3
Veterinary schools . . . . .	1
Colleges of biological science . . . . .	1
Colleges of arts . . . . .	1
Universities (programs serving only a portion of a campus) . . . . .	1
College of engineering . . . . .	1
<b>Total . . . . .</b>	<b>100</b>

SOURCE: American Association for Accreditation of Laboratory Animal Care, *AAALAC Activities Report*, vol. 13, New Lenox, IL, Apr. 1, 1985.

first site visit. Current application fees range from \$1,050 to \$1,650, depending on the size of the facility, and annual fees range from \$600 to \$900. AAALAC uses the NIH **Guide for the Care and Use of Laboratory Animals** as its primary standard for evaluating facilities and programs. In addition, the association recommends these sources about laboratory animal care:

- “Report of the AVMA Panel on Euthanasia” (19) and subsequent revisions.
- **NIH Guidelines for the Laboratory Use of Chemical Carcinogens** (45).
- **Biological Safety Manual for Research Involving Oncogenic Viruses** (40).
- **Classification of Etiologic Agents on the Basis of Hazard** (39) and subsequent revisions.
- Laboratory animal management and standards documents developed by committees of the Institute of Laboratory Animal Resources (3).

The accreditation procedure involves 11 steps. First, an application is requested from AAALAC. The completed application for accreditation is returned to AAALAC, which reviews it and determines whether the applicant is eligible to seek accreditation. After the application fee is paid, the Chairman of the AAALAC Council on Accreditation selects the site-visit team. Normally, this consists of one member of the council and one consultant. The institution is notified of the date and time of the visit and the names of the site visitors and is asked to have assembled materials ready. The site-visit team inspects the laboratory-animal

care facility and evaluates all aspects of the animal care program with respect to AAALAC standards. Copies of the report are forwarded to two members of the council, who evaluate it for completeness and clarity. The final site visit report is then reviewed by the council during its next scheduled council meeting, and the accreditation status of the applicant is determined. The Board of Trustees confirms the action of the council. Finally, the applicant institution is provided with a letter summarizing the conclusions of the council (3).

After the initial site visit, an institution can be awarded full accreditation, provisional accreditation, or accreditation can be withheld. For accredited institutions, AAALAC reinspects facilities once every 3 years and can either decide to continue accreditation, provide a probationary accreditation while deficiencies are corrected, or revoke accreditation. Sixty-six percent (483 out of 731) of the institutions applying for accreditation since 1965 have received it.

Although AAALAC is a private, voluntary organization, its decisions carry great weight because the PHS recognizes AAALAC accreditation as a demonstration of institutional compliance with PHS policies. Moreover, the NIH **Guide for the Care and Use of Laboratory Animals** is the benchmark AAALAC uses in assessing the adequacy of laboratory facilities, sanitation, veterinary care, animal husbandry, and such basic but important details such as cage size. Approximately 25 percent of the close to 1,000 institutions with approved assurances on file with NIH are AAALAC-accredited.

## POLICIES OF SCIENTIFIC AND PROFESSIONAL SOCIETIES

A number of scientific societies and professional organizations associated with science and research have generated policies on the standards of conduct expected of their members in the care or use of animals. Some of these are simple statements of support for research use and for humane care of research animals in accordance with Federal and State laws and the NIH **Guide**. For example, the American Association for Laboratory Animal Science (AALAS), an organization that emphasizes improved animal care and personnel training (13), has issued a four-paragraph statement of this na-

ture (1). It states, in part: “The AALAS is committed to the principles of humane care and treatment of laboratory animals and endorses membership compliance with established scientific and legal standards .”

The AALAS policy statement also contains some of the strong language that has only recently begun to appear in statements of scientific and professional organizations:

Many of the factors that affect both animal and human life can only be studied in intact animal

systems by systematically manipulating specific research variables. Given an incomplete knowledge of biological systems, it is inconceivable that animal experimentation can be replaced, in the foreseeable future, by mechanical models or other incomplete biological systems.

Several organizations have developed more comprehensive policies. These statements of principle have tended to evolve from early concern with solely humane animal care to a concentration on the humane care and use of animals.

Ethical standards and policies may be developed in a variety of ways. Some are prepared by committees or boards composed of members from different areas of research within a given discipline (e.g., American Psychological Association), from many countries (e.g., International Association for the Study of Pain), from several disciplines (e.g., Federation of American Societies for Experimental Biology), from the faculties and communities associated with a university (e.g., University of Southern California), or from within industry (e.g., Smith Kline & French Laboratories). Guidelines may also be issued by a professional society as part of the requirements for publication of research reports in a society's journal (e.g., Society for the Study of Reproduction).

The comprehensive statements of well-established organizations are examined here to provide insight into both the development and the promulgation of policies affecting large numbers of research investigators and their experimental subjects. The guidelines of the societies and associations reviewed by OTA share certain common elements, in that they all support or require:

- humane care and use of animals in accordance with relevant laws and the NIH guidelines;
- use of minimum numbers of animals of an appropriate species;
- limitations of the time and/or degree of allowable pain or discomfort during chronic experiments;
- use of proper types and amounts of analgesics or anesthetics or of euthanasia to prevent or terminate excessive pain during acute experiments; and
- assurance that all animal experiments are conducted by or under the supervision of qualified personnel.

Beyond these common elements, most policy statements contain principles tailored to the specific research interests of each organization's members. The Animal Care Guidelines of the Animal Behavior Society, for example, offer instruction on the observation of natural populations (9):

Observation of free-living animals in their natural habitat may involve disruption, particularly if feeding, trapping, or marking is involved. While field studies may further scientific knowledge and advance awareness of human responsibility towards animal life, the investigator should always weigh any potential gain in knowledge against the adverse consequences of disruption for the animals used as subjects and also for other animals in the ecosystem.

### ***American Psychological Association***

The American Psychological Association (APA) was founded in 1892 to advance the understanding of basic behavioral principles and to contribute to the improvement of human health and welfare. Today, there are approximately 61,700 members of the APA in research, education, and clinical practice. Policies adopted in 1979, entitled ***Principles for the Care and Use of Animals***, were designed to be posted in all facilities and included several additions to the common elements listed previously. They read, in part (5):

All research conducted by members of the American Psychological Association or published in its journals must conform to these Principles.

Investigators are strongly urged to consult with the Committee on Animal Research and Experimentation at any stage preparatory to or during a research project for advice about the appropriateness of research procedures or ethical issues related to experiments involving animals.

Apparent violations of these Principles shall be reported immediately to the facility supervisor whose signature appears below.

All persons in each laboratory, classroom, or applied facility shall indicate by signature and date . . . that they have read these Principles.

Although the issues of ethics and responsibility were briefly addressed in the **1979 Principles**, the **APA** soon felt that a more complete statement was needed. The principles were extensively revised

and issued in 1985 as the *Guidelines for Ethical Conduct in the Care and Use of Animals (6)*.

The most comprehensive document of its type, the APA *Guidelines* is a detailed statement covering all aspects of animal care and use—personnel, facilities, acquisition of animals, care and housing, experimental design and procedures, field research, educational use of animals, and disposition and disposal of animals. The importance of the use of sound ethical judgment is reiterated throughout, and the new guidelines are to be signed by a supervisor and an administrative official and posted wherever animals are maintained or used.

The APA statement is distinguished by both the number and diversity of its requirements. In addition to supporting the principles previously mentioned, it states that “considerations limited to the time, convenience, or expense of a procedure do not justify violations of any of the principles.” When violations are not resolved at the local level, they “should be referred to the APA Committee on Ethics, which is empowered to impose sanctions.” The possible nature of such sanctions remains undefined.

The APA Guidelines state: “Psychologists should ensure that all individuals who use animals under their supervision receive explicit instruction in experimental methods and in the care, maintenance, and handling of the species being studied. “ All research should be justifiable, with “a reasonable expectation” that the research will:

- increase knowledge of the processes underlying the evolution, development, control, or biological significance of behavior;
- increase understanding of the species under study in the research; or
- provide results that benefit the health or welfare of humans or other animals.

These contributions “should be of sufficient potential significance as to outweigh any harm or distress to the animals used.” Moreover, “when appropriate, animals intended for use in the laboratory should be bred for that purpose.”

The APA stands virtually alone among scientific societies in offering guidance in the educational use of animals:

When animals are used solely for educational rather than research purposes, the consideration of possible benefits accruing from their use vs. the cost in terms of animal distress should take into account the fact that some procedures which can be justified for research purposes cannot be justified for educational purposes.

The *Guidelines* further urge that alternatives to the use of animals be investigated and that alternatives to euthanasia, such as animal sharing and return of wild-trapped animals in the field, be considered. Following euthanasia, “no animal shall be discarded until its death is verified.” Investigators are invited to seek assistance from the APA on relevant issues, and a list of references on the ethics of animal research is mentioned as available. The association supports the formation of institutional animal care and use committees (including representatives from the local community) to assist in the resolution of questions within individual institutions, but it recognizes that “laws and regulations notwithstanding, an animal’s immediate protection depends upon the scientist’s own conscience.”

### *American Physiological Society*

The minutes of the 1913 meeting of the Council of the American Physiological Society (APS) contain the first written statement by a U.S. scientific society in support of the prevention of cruelty to research animals. Although it did not receive much attention at that time, the statement later led to the development of the NIH *Guide (33)*. The present APS policy statement, revised in 1980 as *Guiding Principles in the Care and Use of Animals (30)*, is sent to each member to be signed and posted.

In addition to the principles they have in common with other societies, the APS *Guiding Principles* require that “animal experiments are to be undertaken only for the purpose of advancing knowledge” and that “consideration should be given to the appropriateness of experimental procedures.”

“Only animals that are lawfully acquired shall be used, ”and, when muscle relaxants or paralytics are employed, ‘(they should not be used alone for surgical restraint, rout] in conjunction with drugs known to produce adequate analgesia.” In 1984, this provision concerning relaxants and paralytic

became the object of a proposed revision, stating that they:

... must only be used after administration of a general anesthetic, adequate to cause unconsciousness, so that when the muscle relaxant is given, the animal is already unconscious. The animal must then be kept unconscious until complete recovery from paralysis occurs. The only exception to this guideline would be in unusual cases where the use of an anesthetic would defeat the purpose of experiment and data cannot be obtained by any other humane procedure.

The revision was proposed in 1984 by the APS Animal Care and Experimentation Committee and is presently under consideration by APS members for comment on its impact on the design of their research.

### ***Federation of American Societies for Experimental Biology***

The Federation of American Societies for Experimental Biology (FASEB) is composed of six constituent societies (APS, the American Society of Biological Chemists, the American Society for Pharmacology and Experimental Therapeutics, the American Society of Pathologists, the American Institute of Nutritionists, and the American Association of Immunologists) and one affiliated society (the American Society for Cell Biology). As such, FASEB represents more than 28,000 research investigators and clinicians.

The organization adopted a policy on animal experimentation in 1913 that in 1984 it reaffirmed, while endorsing the APS Guiding Principles and issuing a policy statement on the appropriate use of animals for scientific experimentation and education (16). The latter document urges "(appropriate safeguards to preclude inadvertent use of pet animals," supports the "wide application of accreditation procedures for animal experimental facilities)" and resolves "that continuing collection of appropriate data on the conditions and number of animals used in scientific research and education is necessary for development of legislative or administrative remedies in the field. "

### ***International Association for the Study of Pain***

The International Association for the Study of Pain publishes the journal *Pain*, which first appeared in 1975. In its first issue, the journal expressed its "(one proper duty; to pursue knowledge for the alleviation of suffering in man and animals without any deviation in which we justify the passive observation or intentional production of suffering)" (48). *Pain* refuses "to publish any reports where the animal was unable to indicate or arrest the onset of suffering" (48). In 1980, the association's Committee for Research and Ethical Issues published ***Ethical Standards for Investigations of Experimental Pain in Animals (15)***. These urge the acceptance of "a general attitude in which the animal is regarded not as an object for exploitation, but as a living individual" and offer a list of guidelines "concerned with the importance of the investigation, the severity and the duration of the pain." The statement speaks to the need for justification and review by colleagues, ethologists, and laypersons. In addition, it:

- states that "if possible, the investigator should try the pain stimulus on himself";
- urges careful assessment of the animal's "deviation from normal behavior" during the experiment;
- requires that by escape or avoidance, the animal "be able to control the effects of acute experimental pain" and be treated for chronic pain or "allowed to self-administer analgesic agents or procedures, as long as this will not interfere with the aim of the investigation"; and
- urges researchers to "choose a species which is as low as possible in the phylogenetic order."

In 1983, the committee ***issued Ethical Guidelines for Investigations of Experimental Pain in Conscious Animals (50)***, containing two salient revisions from the 1980 document. First, when submitting a manuscript to *Pain*, authors are "required to show" that they have followed the ethical guidelines that are published in every issue. Second,

“studies of pain in animals paralyzed with a neuromuscular blocking agent should not be performed without a general anesthetic or an appropriate surgical procedure that eliminates sensory awareness.”

### ***Society for Neuroscience***

After more than 2 years of revision, review, and commentary by members of the Society for Neuroscience (17), an Ad Hoc Committee on Animals in Research published its *Guidelines for the Use of Animals in Neuroscience Research* in 1984 (14). In addition to the requirements in common with other societies, these *Guidelines* place particular emphasis on good experimental design and state that “advances in experimental methods, more efficient use of animals, within-subject designs, and modern statistical techniques all provide possible ways to minimize the numbers of animals used in research.”

The *Guidelines* show particular concern about prolonged immobilization or restraint, suggesting that “reasonable periods of rest and readjustment should be included in the experimental schedule unless these would be absolutely inconsistent with valid scientific objectives.” It is noteworthy that although the policy statement was formulated to deal with research using warm-blooded vertebrates, it includes a statement concerning invertebrates:

As a general principle. . . ethical issues involved in the use of any species, whether vertebrate or invertebrate, are best considered in relation to the complexity of that species’ nervous system and its apparent awareness of the environment, rather than physical appearance or evolutionary proximity to humans.

In this inclusion of invertebrates into its *Guidelines*, the Society for Neuroscience is unique among scientific organizations. This policy likely reflects an enhanced awareness in neurobiology of the degree of sophistication exhibited by some invertebrate nervous systems.

### ***Society for the Study of Reproduction***

The Society for the Study of Reproduction (SSR) publishes its *Guiding Principles for the Care and Use of Research Animals* in each issue of its journal, *Biology of Reproduction*, as part of the instructions to authors. Investigators are urged to give consideration to, among other things, “the use of in vitro models.”

An investigator wishing to present data at the annual meeting of the SSR must first make a declaration regarding the use of animals in generating those data. The researcher is required to attest with his or her signature (see fig. 15-2) that the research described in the abstract is in strict accord with the guiding principles for experimental procedures endorsed by the society. Written affirmations of this nature are becoming increasingly common among scientific societies; the American Physiological Society, the Society for Neuroscience, and the International Association for the Study of Pain are among the groups with prerequisites of signed statements of humane treatment of experimental subjects for abstract presentations.

### ***American College of Physicians***

In a 1983 position paper entitled *Animal Research*, the American College of Physicians (ACP) stated that “scientists and animal welfare advocates share a belief that safeguards are necessary to ensure humane treatment of animals used in scientific research and testing” and that other issues needing to be addressed include “development of alternative testing methods” and “mechanisms to ensure that. . . treatment, care, and experimental methods limit animal pain and suffering.”

ACP suggests that appropriate safeguards “may require the establishment of procedures not unlike human subjects protection review” and “recognizes the importance of standards that promote the conduct of quality research and ensure the humane care of healthy animals for research activities” (4).

**Figure 15-2.- Declaration Required for the Presentation of Data at the Annual Meeting of the Society for the Study of Reproduction, July 1985**

Abstract for

SOCIETY FOR THE  
STUDY OF  
REPRODUCTION

I have read and understand the Society's Guiding Principles for the Care and Humane Treatment of Research Animals and affirm that the research described in the above abstract is in strict accord with these principles.

Presenter's signature \_\_\_\_\_

Telephone No. (Area Code) \_\_\_\_\_ No. \_\_\_\_\_

SOURCE: Society for the Study of Reproduction, Champaign, IL.

***American Pharmaceutical  
Association***

In 1981, the Policy Committee on Scientific Affairs of the American Pharmaceutical Association offered a number of recommendations on the use of animals in drug research (36). These included:

- provision for adequate regulation, controls, and enforcement directed toward the procurement, transportation, housing, care, and treatment of animals;
- encouragement of further development of alternative methods; and
- opposition of legislation penalizing properly controlled and conducted animal research and testing.

In what stands as one of the most strongly worded statements of support for the use of alternative methods from any scientific organization, the policy committee also observed that:

... the use of animals for research, testing, control and production purposes is all inherently quite expensive when compared to other procedures, such as microbiological, chemical, instrumentation and tissue culture. Moreover, both the speed and accuracy of analytical tests and the yields of biological production are much superior when these alternate methods can be employed in place of animal procedures. As a result, there has been a continuing shift away from the use of animals and in favor of alternate procedures

as the latter have been developed and have been demonstrated to be acceptable substitutes.

***American Veterinary Medical  
Association***

In 1982, the American Veterinary Medical Association (AVMA) approved the ***AVMA Animal Welfare Guiding Principles (7)***, which states that veterinarians must consider certain ethical, philosophical, and moral values relating to the welfare of animals. Among these considerations are the encouragement of humane care and proper stewardship, implementation of relevant laws and regulations, support of research to illuminate animal welfare issues, and identification of individuals qualified to speak to these issues as a continuing education resource. In 1983, ***an AVMA Animal Welfare Positions*** report recommended the voluntary establishment of standards of excellence for animal care and use (8). This report includes a number of recommendations on animal welfare issues outside of research use, such as ownership of exotic animals, declawing of domestic cats, and ear-trimming and tail-docking of dogs.

***Association of American  
Veterinary Medical Colleges***

In ***A Policy on Standards and Procedures Related to the Use and Care of Animals in Veterinary Medical Education and Research***, the Association of

American Veterinary Medical Colleges recommended use of the **NIH Guide** and pursuit of AAALAC accreditation by all its member institutions (11). It also supports education in ethical considerations, use of alternatives where feasible, and

continual monitoring of animal use and policies. It urges that “administrators . . . voluntarily establish standards of excellence for animal care and use programs rather than relying upon external enforcement agencies.”

## STATEMENTS OF INSTITUTIONAL POLICY

In addition to scientific and professional societies, several universities have formulated policies regarding animal use in research and education. Three such statements are reviewed here for purposes of illustration.

### *University of Southern California*

In 1984, the University of Southern California published *Policies Governing the Use of Live Vertebrate Animals*, which contains a “Code of Ethics for the Use of Animals in Research and Teaching” adopted by the university’s Animal Ethics Review Board. The code contains guidelines on avoidance of unnecessary pain or distress, searching for alternatives for all LD<sub>50</sub> studies, prohibition of prolonged physical restraint or deprivation studies, the use of euthanasia and anesthesia, and consideration of alternatives to animal use. It further states that “this University shall expect each Investigator to consider alternatives to the use of animals in research or teaching before presenting a protocol for the use of live animals. The signed protocol should contain a statement to that effect.” All protocols must be approved by the Animal Ethics Review Board. Principles governing the use of live animals for teaching are similar to those for research animals (47).

### *University of Wisconsin*

The University of Wisconsin system began requiring in 1981 that all animals used for teaching and research on all of its campuses be used and cared for according to the **NIH Guide**, regardless of the species or source of funds used to conduct the teaching or research. The university at that time took a second extraordinary step and required the certification of all investigators, technicians, graduate students, or staff who supervise, use, or care for animals. On the main campus in Madi-

son, for example, approximately 1,400 persons have been certified to date through instruction and examination (49).

### **Wisconsin Regional Primate Research Center**

In 1982, the Director of the Wisconsin Regional Primate Research Center (WRPRC) published a *Policy Statement on Principles for the Ethical Uses of Animals at the Wisconsin Regional Primate Research Center (18)*. This statement deals with the issues of respect for animals, care, choice of alternatives, use of animals in education, personnel training, appointment of animal rights advocates to oversight groups, and the use of good ethical judgment in evaluating the significance of proposed research. It is official WRPRC policy that “all animals under its control are recognized as creatures of great intrinsic value, remarkable complexity, and inherent dignity.”

In a section of the Policy dealing with the unique value of nonhuman animals as models, researchers are charged to make the following choices when designing experiments:

- When the research question can be meaningfully pursued using nonanimal or in vitro models, the researcher must choose these alternatives.
- When animal experimentation is required, the researcher must seek the least traumatic techniques feasible, minimize the intensity and duration of any distress, and minimize the number of subjects.
- Nonhuman primates should be used only in projects for which they are the most suitable animal model.

All research at the WRPRC must have a “reasonable expectation that the experiment will contribute significantly to knowledge that may even-

tually lead to improvements in the health and welfare of humans or nonhuman animals” and the expected benefits must “clearly outweigh any pain and suffering experienced by the . . . animals.” Consideration of time or expense alone may never justify violation of the principles. Sanctions for violation of the Policy include dismissal in accordance with due process and university regulations.

### ***School of Veterinary Medicine, Purdue University***

Purdue University’s School of Veterinary Medicine drafted a Policy Statement *on the Utilization of Animals* in 1985 (38). The statement makes clear

that the school “cannot fulfill its teaching, research, and service missions without the utilization of animals.” Purdue’s policy spells out the sources of animals for veterinary medical research and education:

Animals must be legally acquired, and properly housed, fed, cleaned, and cared for to insure their comfort and well-being.

The instructional programs require that preventive medicine, curative medicine, and surgery be practiced in a sequence involving, first, animals owned and maintained by the School and second, animals owned by the general populace who seek professional health services.

## **STATEMENTS OF CORPORATE POLICY**

Industrial testing and research laboratories often have standard operating procedures in writing regarding animal care and use. One of the most comprehensive policy statements on animal welfare comes from the Research and Development Division of Smith Kline&French Laboratories of Philadelphia, PA. In its *Policies and Procedures for the Conservation and Humane Treatment of Experimental Animals*, Smith Kline & French adopted the following initiatives (29):

- Animal studies of a seemingly unwarranted nature, but that are required to meet regulations set by external agencies, will be reported to the Director of Laboratory Animal Science.

- Animal tests required by regulatory authorities in certain countries, but generally not by others, will be reported to the Director of Laboratory Animal Science,
- In vitro test methods developed to replace in vivo studies are to be documented so that other areas may consider potential applications.
- Mistreatment of animals is a serious violation of policy and may be grounds for dismissal.
- A series of Animal Welfare Achievement Awards will recognize and encourage a maximum effort toward conserving animals and developing in vitro techniques.

## **SUMMARY AND CONCLUSIONS**

In mid-1985, the Public Health Service of the Department of Health and Human Services released a new policy on humane care and use of laboratory animals for all awardee institutions. The policy requires self-regulation of animal welfare by all institutions using animals in research and obtaining PHS funds. It is based on a PHS 1979 policy

and on information obtained during 15 site visits by NIH to awardee institutions with general assurances on file with NIH. The new policy is more stringent and structured than the old one. It revolves around the institutional assurance to NIH and the institutional animal care and use committee. To obtain assured status with NIH, an institu-

tion must either be AAALAC-accredited or fulfill the steps outlined in the policy for self-assurance status.

In 1985, Congress gave the force of Federal law to some of the provisions of the PHS policy and, in separate action, mandated the establishment of institutional animal care and use committees at all research facilities covered by the Animal Welfare Act as well as at Federal facilities (see ch. 13). Taken together, the new PHS policy and Federal statutes bring the overwhelming majority of animal users in the United States under the oversight of institutional animal care and use committees.

Researchers who use animals, their institutional colleagues, their peers in science, laboratory-animal veterinarians, and local community members are today viewed as the appropriate arbiters of what constitutes acceptable care and use of animals. The PHS policy charges these individuals with membership on institutional animal care and use committees at each site where animals are involved in PHS-funded research. Each IACUC shall have broad oversight authority of the animal welfare program at the institution and approve all portions of research protocols involving animals for proper animal care and treatment.

The functions of animal care and use committees may include:

- ensuring compliance with local, State, and Federal laws and regulations on animal care and use;
- inspecting animal care facilities;
- reviewing protocols for animal welfare issues;
- assessing the qualifications of investigators;
- overseeing student use of animals;
- advising on institutional needs, costs of animals, and animal procurement policies;
- controlling allocation of animals within the institution;
- serving as a resource on animal welfare issues and as an educator of the university community and the community at large on animal welfare issues; and
- acting as a community complaint forum.

The concept of review by committee is not unique to the use of animals in experimentation. In fact, institutional review boards and human-subjects committees have overseen research using humans for a decade or more. Current thinking

about animal care and use committees is modeled after experience with IRBs.

A voluntary private organization, the American Association for Accreditation of Laboratory Animal Care, functions as a respected agent of certification of an individual laboratory's standards of care. As of April 1985, a total of 483 institutions using animals had received AAALAC accreditation after passing an inspection based on the NIH Guide *for the Care and Use of Laboratory Animals*.

Several scientific and professional societies, universities, and corporations have promulgated statements of policy concerning their members' and employees' standards of conduct in the care and/or use of animals. An organization's policy statement usually reflects its characteristic interests. Some policies are brief enough to cover only one column of a page, while others (e.g., American Psychological Association) take many pages and go into great detail. These policies generally require:

- humane care and use of animals,
  - . use of a minimum number of animals,
- alleviation of pain and suffering, and
  - . supervision of animal use by qualified personnel.

At least eight of the organizations and institutions whose policies were reviewed by OTA support the concept of animal care and use committees. Twelve of the fifteen organizations reviewed specifically support or require consideration of the use of alternatives to animals in research, and three specify the maximum use of available statistical methodology.

Several statements of policy require signed statements attesting to humane animal care prior to the publication and/or presentation of papers. Only three policy statements, those of the American Psychological Association, the Wisconsin Regional Primate Research Center, and Smith Kline & French Laboratories, directly mention any sanctions against violators of their guidelines. As a rule, there are neither enforcement provisions accompanying the stated policies and principles of scientific and professional societies nor any apparent penalties for the violation of these policies. For these reasons, the practical significance of certain of these statements of principle is open to question.

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