Institutional and IACUC Responsibilities for Animal Care and Use Education and Training Programs

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Abstract

Training and instruction of personnel are important components of animal care and use programs because they help to ensure the health and welfare of the animals and the integrity of the research or testing results. Training also helps to promote the consideration of alternatives, recognition of animal pain and distress, appropriate use of pain-relieving agents, aseptic technique, pre- and post-procedural care, and personnel health and safety. While individuals who provide the care for or conduct research or testing in laboratory animals should take personal responsibility for ensuring that they have the skills to perform their duties, the institution is ultimately responsible for ensuring their competency. The institution is also responsible for providing the training or instruction that is required by federal legislation, regulations, and policies. The institutional animal care and use committee (IACUC) is responsible for ensuring, as part of their review of research activities, that the personnel are capable of performing the procedures described. The IACUC must also assess the institution's training program as part of their semiannual animal care and use program review and make recommendations regarding training to the institutional official. This article provides a comprehensive overview of the US regulatory mandates for training and personnel qualification.

Key Words: animal care; continuing education; IACUC; laboratory animals; personnel qualifications; regulatory requirements; training

Historical Overview

The earliest records of animal experimentation date back to the fourth and third centuries BC, when Aristotle used dissection to demonstrate internal differences among animals. However, nearly two millennia passed before significant advances were made in understanding the relationship between anatomy and physiology, and it was not until the mid-1800s that animal diseases were studied to enhance understanding of human disease and pathology (Loew and Cohen 2002).

Despite the scientific advances made through the use of animals in research, certain segments of society, particularly in England, opposed such use of animals. In 1876, the Cruelty to Animals Act was enacted in the United Kingdom, which required the government to license individual scientists who used animals in research. This licensing was intended to address the public's concerns and to ensure that only qualified individuals conducted research in animals.

Nearly a century later, in 1966, the United States passed the first legislation governing the use of animals in research—the Laboratory Animal Welfare Act (PL 89-544 1966). This law was intended to ensure that animals used in research were provided humane care and treatment, and it authorized the US Department of Agriculture (USDA[1]) to develop and enforce regulations and minimum animal care standards (Anderson 2002). In 1970, the Laboratory Animal Welfare Act was amended and renamed as the Animal Welfare Act (PL 91-579 1970), which was amended again in 1976 (PL 94-279 1976).

USDA Training Requirements

It was not until the Food Security Act of 1985 (PL 99-198 1985), also known as the Improved Standards for Laboratory Animals Act, was enacted that USDA-registered research facilities were required to establish an institutional animal care and use committee (IACUC[1]) with specific roles, composition, and responsibilities. It was also the first time that training was addressed, by requiring that "each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility as required by the Secretary." The legislation also included the formation of an

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[1]Abbreviations used in this article: AAALAC, Association for Assessment and Accreditation of Laboratory Animal Care International; DOD, Department of Defense; EPA, Environmental Protection Agency; FDA, Food and Drug Administration; GLPs, good laboratory practices; *Guide, Guide for the Care and Use of Laboratory Animals;* IACUC, institutional animal care and use committee; ICLAS, International Council for Laboratory Animal Science; IO, institutional official; NIH, National Institutes of Health; OLAW, Office of Laboratory Animal Welfare; PHS, Public Health Service; PHS Policy, *Public Health Service Policy on Humane Care and Use of Laboratory Animals*; USDA, United States Department of Agriculture; VMO, veterinary medical officer.

information service at the National Agricultural Library to assist in employee training. The regulations developed by the USDA to enact the 1985 amendments were published in 1989 and remain unchanged to date with respect to the institutional and IACUC responsibility for personnel training.

The USDA regulations require the IACUC to review activities involving animals and, as part of that review, to determine that personnel conducting the procedures are appropriately trained and qualified (9 CFR 2.31; CFR 1989, 2006). In addition, the research facility is responsible for ensuring that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility is to be fulfilled in part through the provision of training and instruction for those personnel. The training and instruction must include guidance in humane methods of animal maintenance and experimentation, including the following: "i) the basic needs of each species of animal; ii) proper handling and care for the various species of animals used by the facility; iii) proper pre-procedural and post-procedural care of animals; and iv) aseptic surgical methods and procedures."

Training and instruction must also include the "concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress and the proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility." In addition, the institution must provide instruction on the "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, IACUC member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act."

Employees must also be instructed regarding the utilization of services (e.g., National Agricultural Library, National Library of Medicine) that are available to provide the following information: "1) on appropriate methods of animal care and use; 2) on alternatives to the use of live animals in research; 3) that could prevent unintended and unnecessary duplication of research involving animals; and 4) regarding the intent and requirements of the Act" (9 CFR 2.32; CFR 1989).

Although these regulations have remained constant since they were first published in 1989, the USDA has issued several policies that provide additional guidance on certain aspects of the regulations related to training. Policy #12, *Consideration of Alternatives to Painful/Distressful Procedures*, elaborates on the requirement that scientists consider alternatives that would minimize animal pain and distress and the documentation required to assure the IACUC that due consideration was given (USDA 2002).

In March 2006, the USDA issued a revision to Policy #15, *IACUC Membership*, adding that IACUC members must be qualified to assess the research facility's animal program, facilities, and procedures. The research facility is responsible for ensuring their qualifications, and this responsibility is to be fulfilled, in part, through the provision of training and instruction on the provisions of the Animal Welfare Act, protocol review, and facility inspections. Each member should be given a copy of the USDA regulations, the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy[1]), the *Guide for the Care and Use of Laboratory Animals* (*Guide*[1]) (NRC 1996), institutional policies, and protocol form.

The USDA also provides guidance regarding assessment of personnel qualifications to their veterinary medical officers (VMOs[1]) who conduct research facility inspections (USDA 2001, 2006). The VMOs are instructed to evaluate the appropriateness of the number of employees who provide animal care and their responsibilities, training, and experience. VMO review of the incidence of injuries to personnel and animals is recommended as an indicator of adequate training. The USDA also requires that research facilities adequately document the qualifications and training of personnel, which may include maintaining their curriculum vitae or resumes, diplomas or certificates from educational institutions, records of attendance at institutional training programs or formal meetings, or completion of continuing education programs. In addition, the USDA encourages VMOs to use professional judgment when assessing the adequacy of a facility's training program.

Public Health Service (PHS[1]) Policy Training Requirements

One month before the Improved Standards for Laboratory Animals Act was passed into legislation, the Health Research Extension Act of 1985 (PL 99-158 1985), also known as the "Animals in Research" act, was enacted. This law, which applies to the PHS, directs the Secretary of Health and Human Services, through the Director of the National Institutes of Health (NIH[1]), to establish guidelines for institutions conducting activities supported by PHS funds for the proper care and treatment of animals used in biomedical and behavioral research, to require animal care committees, and to mandate certain assurances, including the training of personnel. Institutions must provide assurance that "scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant [institution] have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress."

In response to this legislation, the PHS published the PHS Policy in 1986, with several subsequent amendments (PHS 2002). The PHS Policy endorses and helps to implement and supplement the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (IRAC Principles), which

were developed by the Interagency Research Animal Committee and published in 1985 (Table 1) (IRAC 1985). It also requires institutions to use the *Guide* (NRC 1996) as a basis for developing and implementing their animal care and use program.

The *Guide* states that the institution should provide animal care personnel with formal or on-the-job training to ensure effective program implementation and humane animal care and use. The scope and complexity of the required training will depend on the type and size of the institution, the administrative structure for providing adequate animal care, the physical plant, the number and species of animals being maintained, and the nature of the research, testing, and educational activities. Personnel caring for or using animals should participate in continuing education activities, and institutions should sponsor discussion and training programs and provide reference materials that are relevant to their respective job responsibilities. The *Guide* also cites the laws that require institutions to provide appropriate orientation, reference materials, and, if necessary, specific training for IACUC members to enable them to understand and evaluate the issues presented to the committee.

Institutions must also provide personnel with information and procedures for working with potentially hazardous materials, including chemical, microbiological, and physical hazards. Instruction and personal protective equipment should also be provided by the institution to help ensure personal hygiene and safety. The IACUC should consider all of the components of the animal care program's occupational health and safety program, including training of personnel, as part of their semiannual program review and facility inspections (NRC 1997).

Each institution must provide a written assurance to the Office of Laboratory Animal Welfare (OLAW[1]), Office of Extramural Research, Office of the Director, NIH, documenting that it is in compliance with the PHS Policy and the *Guide*. The assurance statement, signed by the institutional official (IO[1]), must include a synopsis of the training or instruction that is offered to scientists, animal technicians, and other personnel involved in animal care, treatment, or use. This training or instruction must include the humane practice of animal care and use in addition to research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress.

Table 1 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

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

I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all anmals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their inservice training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

Like the USDA Animal Welfare Regulations, PHS Policy also requires the IACUC, as part of their review of research projects, to determine whether the personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained to perform those procedures. In addition, the IACUC is responsible for evaluating the program for humane care and use of animals at least once every 6 months, including the training and instruction that are provided. The IACUC is required to report their evaluations and make recommendations to the IO regarding any aspect of the program, including personnel training. OLAW is responsible for determining the adequacy of the institution's proposed program for animal care and use.

From time to time, OLAW publishes articles and issues notices and guidance that provide clarification regarding the PHS policy. Such publications (e.g., Potkay et al. 1995) acknowledge that the scope, depth, and frequency of institutional training programs will vary depending on the size and nature of the institution, staffing, number of species and individual animals maintained, and the kinds of research conducted. Published OLAW notices and guidance may be found on the OLAW website (http://grants.nih.gov/grants/olaw/olaw.htm).

The OLAW website also provides access to training materials for working with nonhuman primates and dogs, survival rodent surgery, and basic biomethodology for laboratory mice. Also available is the OLAW brochure "What Investigators Need to Know about the Use of Animals" (OLAW 2006), which summarizes the PHS Policy requirements (OLAW 1985) and includes reference to personnel qualifications. In addition, OLAW sponsors a number of training courses throughout the United States, often in collaboration with academic institutions or associations dedicated to training. These programs and registration information are also available on the OLAW website.

Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC[1]) Training Requirements

AAALAC is a private, nonprofit organization that promotes the humane treatment of animals in science through a voluntary program of accreditation for institutions that conduct research, testing, or teaching. Although AAALAC uses the *Guide* (NRC 1996) as the primary reference for assessing animal care and use programs, a number of other applicable resources are used. A complete list of these publications can be found on the AAALAC website (http://www.aaalac.org/accreditation/resources.cfm).

Institutions that apply for AAALAC accreditation must provide a detailed written program description that includes information on personnel qualifications and training based on the recommendations of the *Guide*. Institutions must provide the credentials, training, and continuing education of the animal resources staff, including the certification of animal care technicians, and describe the training programs provided for research staff regarding the humane and scientifically acceptable use of animals in research. Training for specific procedures must also be provided, including training on the use of hazardous agents in animals, occupational health, surgery, anesthesia, and euthanasia.

Training Requirements for Good Laboratory Practices (GLPs[1])

In the early 1980s, GLPs were established for preclinical animal studies submitted to the Food and Drug Administration (FDA[1]) or the Environmental Protection Agency (EPA[1]) in support of product approval. The Good Laboratory Practice for Nonclinical Laboratory Studies was promulgated by the FDA under the Federal Food, Drug, and Cosmetic Act (FDA 2004). The EPA GLPs are enforced under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA 1996) and the Toxic Substances Control Act (TSCA 1976). The GLPs have identical training and recordkeeping requirements, which include the following: (1) "Each individual engaged in the conduct of or responsible [sic] for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions"; and (2) "Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study" (21 CFR, Chapter 1, Subchapter A, part 58, Subpart B, Sec. 58.29 [FDA] and 40 CFR Chapter 1, Subpart B, Sec.160.29 [EPA]) (CFR 1997a,b). The GLPs also require written standard operating procedures and minimal standards for animal care, animal care facilities, and animal supply facilities.

Department of Defense Training (DOD[1]) Requirements

Although research conducted or funded by the DOD must comply with the Animal Welfare Act and the accompanying Animal Welfare Regulations, the *Guide*, and the U.S. Government Principles for Animal Use, the DOD also issued documents in 1995 that pertain to the training of individuals responsible for animal care and use—Directive Number 3216.1, "Use of Laboratory Animals in DoD Programs" (DOD 1995b) and DOD Policy for Compliance with Federal Regulations (DOD 1995a). The Directive, which applies to intramural and extramural animal research and training conducted by DOD, increases and clarifies the requirements for IACUC membership and the training requirements for IACUC members and personnel who are associated with animal use programs. The nonaffiliated IACUC member(s) and alternates must be provided a minimum of 4 hours of training on their regulatory responsibilities and protocol review processes and 4 additional

hours of training related to humane care and ethical issues associated with animal use.

Institutional Responsibilities

Institutions must meet the minimal requirements stipulated by applicable laws, regulations, and policies; however, an institution may choose to establish more extensive training programs for personnel to ensure the humane care and use of animals, to support their scientific mission, and to optimize the management of the animal care and use program. Although the institution is ultimately responsible for ensuring that personnel are appropriately trained, it must rely on the IACUC's oversight and hold the research, veterinary, and animal care staff members accountable for ensuring that their training is adequate.

In addition to providing the mandatory training, the institution may provide practical guidance on facility entry and gowning procedures, personnel traffic flow within the facility, animal transportation within the research laboratory, and equipment and material storage and disposal. The institution should also provide instruction on disaster management in the event of utility malfunctions, natural disasters, and animal escapes. Institutions may also instruct employees on how to screen potential employees for animal activism and the institution's crisis management plan, including how to respond to suspicious phone calls or break-ins and how to manage threats.

Some institutions require training for any employees or visitors who enter the animal facilities, including members of the institution's maintenance, engineering, security, and housekeeping staff or vendors who deliver materials to the facility. Although these individuals are not directly responsible for animal care or use, it should help to minimize concerns about the activities they observe within the animal facility by informing them of the institution's commitment to animal welfare, the benefits of animal research to both human and animal health, and the oversight provided to ensure humane and scientifically responsible research.

IACUC Responsibilities

As stated above, the federal laws, regulations, and policies require the IACUC to determine that personnel are appropriately trained and qualified to provide animal care or conduct animal research. The IACUC is also responsible for assessing, as part of semiannual program review, the adequacy of the training and instruction provided by the institution. The IACUC should monitor its own semiannual program and facility evaluation reports, USDA inspection reports, and/or AAALAC site visit findings to identify areas of ongoing or repeated deficiencies. The IACUC can also evaluate the effectiveness of training by reviewing the results of tests administered as part of the institution's training courses, observing individual performances and auditing compliance with standard operating procedures and approved research protocols. These assessments will help the IACUC to identify issues that could be prevented by enhancements in the training programs. Recommendations for improvements in the training programs should be submitted in the semiannual reports to the IO.

The IACUC may also describe the benefits of training, and therefore help to justify the investment of institutional resources, in their semiannual reports. In addition, the IACUC may publicly recognize technicians who have achieved American Association of Laboratory Animal Science (AALAS) certification or may sponsor attendance at external continuing education opportunities to help reinforce the importance of ongoing education in animal care and use.

International Considerations

Outside the United States, the content of training programs is often similar to that outlined in *Education and Training in the Care and Use of Laboratory Animals*: *A Guide for Developing Institutional Programs* (NRC 1991) and includes both theoretical and practical components. The specific requirements for training and institutional responsibilities for ensuring the qualifications of personnel vary according to country-specific legislation. The Council of Europe recognizes an accreditation system for training that was begun by the Federation of European Laboratory Animal Science Associations (FELASA) in January 2003. This program defines four categories of competence for persons who (1) care for animals, (2) conduct animal experiments, (3) are responsible for directing animal research, and (4) are laboratory animal specialists. The European perspective on education and training in the context of laboratory animal research is also provided elsewhere in this issue (van Zutphen 2007).

The Canadian Council on Animal Care (CCAC) requires institutional animal care committees to track theoretical and practical training provided to personnel and to ensure the competency of the staff. In November 2005, the International Council for Laboratory Animal Science (ICLAS[1]) appointed a committee with representatives from the United States, Europe, Canada, New Zealand, Japan, Israel, and Brazil to define guiding principles for training that will facilitate the movement of investigators and research between countries (M. Brown, Chair, Harmonization of Training Guidelines Committee, personal communication, 2006). Additional information may be found on the ICLAS website (http://www.iclas.org/index.htm).

Conclusion

Although general training topics are prescribed by federal regulations and policies, as described above, institutions may need to provide additional personnel training and in-

struction to meet their specific research, teaching, or testing requirements. The scope and intensity of the training will vary depending on the animal species to be used, the research procedures to be performed, equipment that is available, and the initial skill sets of the employees.

An effective training program will not only support quality science but will also promote humane animal care and use. In addition, it should contribute to more effective and efficient animal care operations and help to avoid costly mistakes and lost time. The IACUC, which is responsible for ensuring that personnel are capable of performing their animal-related tasks, must also identify potential training deficits as part of their semiannual program review and make recommendations to the IO for enhancements to the training program. This ongoing process of evaluating personnel qualifications and training program effectiveness should ultimately optimize all aspects of the institution's animal care and use program.

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