

# Chapter I: Institutional Policies

Scientific and professional judgment and concern for the humane treatment of animals are required for the proper care of animals used in agricultural research and teaching (referred to in this guide as agricultural animal care and use). Because a variety of management systems and physical accommodations may be used for agricultural animals, an understanding of the husbandry needs of each species and of the particular requirements of agricultural research and teaching is essential for an effective institutional program of agricultural animal care and use (Stricklin and Mench, 1994; Granstrom, 2003). Critical components of such a program should include 1) clearly established lines of authority and responsibility; 2) an active Institutional Animal Care and Use Committee (IACUC); 3) procedures for self monitoring of the IACUC through semi-annual review of programs and facility oversight by the institutional officer; 4) appropriately maintained facilities for proper management, housing, and support of animals; 5) an adequate program of veterinary care; and 6) training and occupational health programs for individuals who work with the animals (ARENA/OLAW, 2002). This chapter is intended to aid in the development of institutional policies and programs for agricultural animal care and use.

## MONITORING THE CARE AND USE OF AGRICULTURAL ANIMALS

Each institution should establish an agricultural animal care and use program with clearly designated lines of authority in accordance with this guide and in compliance with applicable federal, state, and local laws, regulations, and policies.

The chief executive officer or responsible administrative official of the institution should appoint a committee, the IACUC, to monitor the care and use of agricultural animals in agricultural research and teaching activities. The IACUC should be composed of individuals who are qualified by experience or training to evaluate the programs and proposals under review and should include at least one individual from each of the following categories (no individual category should be over-represented):

- A scientist who has experience in agricultural research or teaching involving agricultural animals;
- An animal, dairy, or poultry scientist who has training and experience in the management of agricultural animals;
- A veterinarian who has training and experience in agricultural animal medicine and who is licensed or eligible to be licensed to practice veterinary medicine;
- A person whose primary concerns are in an area outside of science (e.g., a faculty member from a nonscience department, a staff member, a student, a member of the clergy, or an institutional administrator);
- A person who is not affiliated with the institution and who is not a family member of an individual affiliated with the institution. This public member is intended to provide representation for general community interests in the proper care and treatment of animals and should not be a person who uses animals in agricultural or biomedical research or teaching activities at the college or university level; and
- Other members as required by institutional needs and applicable laws, regulations, and policies.

Because of experience and training, however, one individual may adequately fulfill more than a single role on the IACUC, but the committee should not have fewer than 5 members. It is strongly recommended that this committee be one that also monitors the care and use of laboratory animals at the institution, providing that the special membership requirements outlined above are met. This recommendation can be fulfilled by several different types of committee structures, including a single institutional committee, unit committees (e.g., departmental, college, or program) that review agricultural as well as biomedical uses of animals. The overriding goal should be to facilitate centralized, uniform, and high-quality oversight of the institution's animal care program.

The IACUC should meet at regular intervals, as appropriate, to ensure that the use of agricultural animals in research and teaching programs is humane, appropriate, and in accordance with this guide. Meetings of the IACUC need not always be conducted in person. Electronic technology, including web-based or telecommunications, can allow the committee to function appropriately. Such communications must be held with a quorum of members in real time and provide the same interactive opportunities as a face-to-face meeting. It is preferred that the IACUC work with investigators to resolve issues while ensuring animal health. The IACUC is authorized to

- review and approve or disapprove protocols and other proposed activities, or proposed significant changes in activities, related to agricultural animal care and use in research and teaching;
- conduct, at least twice a year, an inspection of agricultural animal facilities and study areas and review of the overall agricultural animal care and use program, and to provide a written report to the responsible institutional official regarding the institution's compliance with this guide;
- investigate concerns, complaints, or reports of noncompliance involving agricultural animals at the facility;
- suspend an activity involving agricultural animals when it is not in compliance with approved protocols or written operating procedures (see section on Written Operating Procedures);
- make recommendations regarding the development and implementation of institutional policies and procedures to facilitate, support, and monitor the humane and appropriate use of animals in agricultural research and teaching as well as any other aspect of the agricultural animal care program; and
- perform other functions as may be required by institutional need and by applicable laws, regulations, and policies.

Other useful information about IACUC functions can be found in the *Institutional Animal Care and Use Committee Guidebook* (ARENA/OLAW, 2002), the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS, 2002), and Silverman et al. (2006).

## PROTOCOL REVIEW

The review of research and teaching activities using animals is one of the most important functions of the IACUC. Protocols describing these activities must be

reviewed before the initiation of the research or teaching activity to determine whether the proposed care and use of animals is appropriate and humane. Approval of the protocol may be granted, withheld pending modifications, or denied. The IACUC should perform a complete review at least once every three years, with additional continuing reviews if and when deemed necessary by the IACUC. The following topics should be considered in the preparation and review of animal care protocols:

- Objectives and significance of the research or teaching activity;
- Unnecessary duplication of previous studies;
- Availability or appropriateness of alternative procedures or models (e.g., less invasive procedures, cell or tissue culture, or computer simulations) for the proposed research or teaching activity. It should be noted, however, that hands-on training involving animals is a particularly important component of agricultural research and teaching;
- Aspects of the proposed experiment or demonstration having to do directly with animal care and use, including justification for the species and (or) strain of animal used; justification for the number of animals used; and a description of procedures that may cause discomfort, distress, or pain and of methods of alleviation including anesthesia, analgesia, tranquilizers, and nonpharmacologic means, as well as justification for any procedures that involve unalleviated pain, discomfort, or distress;
- Appropriateness of procedures and post-procedural care;
- Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful and stressful outcomes are anticipated;
- Unusual husbandry requirements (Note: describing a procedure as a “standard farm practice” may be acceptable if the institution's written operating procedure is being used or if the practice is needed to serve as an appropriate control);
- Aspects of animal husbandry not covered under written operating procedures (see section on Written Operating Procedures);
- Method of euthanasia or disposition of the animal; and
- Responsibilities, training, and qualifications of the researchers, teachers, students, and animal care personnel involved in the proposed activities.

The *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* (Appendix 1 of this guide) state

that “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.” Because IACUCs are not ordinarily constituted to function as scientific peer-review committees, the IACUC should be judicious in reviewing the merit of proposed research and teaching activities (Mann and Prentice, 2004). Institutions should consider developing other mechanisms for peer merit review of research projects that have not already been reviewed by outside agencies. Although qualified peer review of research and teaching is important to consider, such peer review does not eliminate the need for the IACUC to thoughtfully review animal use.

Institutions must develop policies for animal care and use related to research conducted off site as well as research using privately owned animals on and off site. The fact that research is conducted off site does not lessen the responsibility of the institution to assure appropriate and humane animal care and use.

IACUCs are encouraged to work with investigators to help them refine their protocols and proposed animal care and use practices.

The common acceptance and use in animal agriculture of a production system, management practice, or routine procedure does not reduce the responsibility of every animal user to follow applicable laws, regulations, and policies, including the standards outlined in this guide. Exceptions to some provisions, however, may be justifiable to obtain new knowledge or to demonstrate methods commonly used in commercial agricultural animal production. For example, applied research and teaching may require the use of production practices that are consistent with those currently in use in the appropriate industry even though those practices differ from those outlined in this guide; also, research and teaching dealing with infectious diseases, toxins, or products of biotechnology may require special facilities. Exceptions to this guide should be stated explicitly in research and teaching protocols and be reviewed and approved by the IACUC.

## **WRITTEN OPERATING PROCEDURES**

It is important to develop written policies or procedures for animal care and husbandry in the form of written operating procedures for each operating unit in the program. The IACUC must review and approve all written operating procedures involving the potential to cause pain or distress and should review all written operating procedures pertaining to animal care and husbandry. The written procedures must be filed in the appropriate administrative office and in locations accessible to those individuals involved in carrying out the designated procedures and must be monitored regularly by personnel designated by the institution.

There are certain commercial husbandry practices routinely carried out on agricultural animals that may cause temporary discomfort or pain. These standard agricultural practices (see Chapter 3 and Chapters 6 to 11) need not necessarily be described separately for each study, experiment, or demonstration, but are acceptable as written operating procedures provided that the practices 1) are warranted to sustain the long-term welfare of the animal and(or) the animal’s caretakers or handlers; 2) are performed by or under the direct supervision of capable, trained, and experienced personnel; and 3) are performed with precautions taken to reduce pain, stress, and infection. The written operating procedures for alleviating pain and distress should be reviewed and approved by the IACUC.

Husbandry procedures and production methods at agricultural research facilities should be revised as research demonstrates improvements. Research on improved methods and procedures is encouraged.

## **ANIMAL HEALTH CARE**

Adequate health care and records thereof must be provided for all agricultural animals used in research and teaching (see Chapter 2: Agricultural Animal Health Care). Institutional requirements will determine whether full-time, part-time, or consulting veterinary services are appropriate.

## **BIOSECURITY**

It is essential that the agricultural animal care staff maintain a high standard of biosecurity to protect the animals from pathogenic organisms that can be transferred by humans. For additional details on biosecurity issues, see Chapter 3: Husbandry, Housing, and Biosecurity.

## **PERSONNEL QUALIFICATIONS**

It is the responsibility of the institution to ensure that scientists, agricultural animal care staff, students, and other individuals who care for or use agricultural animals are qualified to do so through training or experience. Appropriate supervision should be provided to personnel until their competency is assured. Training programs should be tailored to institutional animal user needs but provide information about the humane care and use of agricultural animals, including, if applicable, 1) husbandry needs, proper handling, surgical procedures, and pre- and post-procedural care; 2) methods for minimizing the number of animals used and techniques for minimizing pain and distress, including the proper use of anesthetics, analgesics, tranquilizers, and nonpharmacologic methods; 3) methods for reporting deficiencies in the animal care program; 4) use of information services such as the Animal Welfare Informa-

tion Center at the National Agricultural Library (NRC, 1991; CFR, 1992); and 5) methods of euthanasia. Records of participation in training programs should be maintained and available for review as needed.

Employees who provide routine animal care should participate regularly in in-service education and training relevant to their responsibilities. Formal or on-the-job training opportunities should be made available to all technical and husbandry support staff, including those who are temporary or part-time employees. It is recommended that the training program include information provided by experts from a broad range of disciplines such as animal husbandry, behavior, nutrition, environmental physiology, experimental surgery, veterinary clinical and diagnostic medicine, agricultural engineering, and instrumentation, and others as deemed appropriate. A variety of reference materials is available for use in training programs (Kreger, 1995; Underwood, 2005).

In addition to having in-house training, it is desirable for agricultural animal care staff to be professionally trained or certified. Many states have colleges with accredited programs in veterinary technology (AVMA, 2007). Technician and technologist certification is available through the American Association for Laboratory Animal Science (AALAS), although that program primarily emphasizes the care and use of laboratory animals rather than agricultural animals. Animal scientists with educational credentials ranging from the baccalaureate to the doctorate who seek recognition of their expertise in the biology and production of agricultural animals can be certified by examination by the American Registry of Professional Animal Scientists (ARPAS).

## OCCUPATIONAL HEALTH

An occupational health and safety program must be established for individuals who work with agricultural animals. The program should be consistent with federal, state, and local regulations and will depend on the facilities, research activities, and hazards involved. The degree of participation of individuals in the program should be based on an assessment of risk by health and safety specialists involving consideration of the hazards posed by the animals and materials used; the duration, frequency, and intensity of exposure; the susceptibility of the personnel; and the history of occupational injury and illness in the particular workplace (Clark, 1993).

General guidelines for such programs have been published by the NRC (1997). The program for individuals working with agricultural animals may include a physical examination before placement, periodic medical evaluations for people in some job categories, surveillance to ensure protection from health hazards, and provisions for treating illness or injury. The program should also include an educational component to teach personnel about agricultural animal diseases and

zoonoses, physical hazards, personal hygiene, precautions to be taken by individuals who are at unusual risk (e.g., pregnant women), and other considerations as appropriate (e.g., safety precautions with chemicals, radiation, and other hazardous agents that are part of a particular experimental protocol).

An appropriate immunization schedule should be adopted. It is important that all agricultural animal caretakers be immunized against tetanus every 10 years based on the institution's risk assessment. Immunizations should be offered to people (before exposure) who handle animals and risk infection from certain infectious agents. Prophylactic vaccinations should also be considered when research is being conducted on infectious diseases for which effective vaccines are available.

Persons working with farm animals may develop allergies. The occupational safety and health program should identify high-risk areas with potential for allergy development. Persons with known allergies should be provided personal protective equipment or avoid exposure to animals.

Physical injuries constitute health hazards for individuals working with agricultural animals. Institutions should identify high-risk areas and tasks and should educate animal care personnel about methods for reducing risk. Injuries can be minimized by providing training in proper animal handling, lifting, and equipment use. Access to first aid and medical treatment should be readily available, and personnel should be trained and familiar with access procedures. Such access may include readily available and properly stocked first-aid kits. Cases of animal bites and scratches should be documented, and tetanus prophylaxis should be considered.

Caretakers working with agricultural animals in closed buildings may develop respiratory problems, including chronic and irreversible lung damage (Kirkhorn and Garry, 2000). Appropriate respiratory protection should be provided for these individuals.

Zoonoses can also be a serious risk. Personnel (including animal care staff, technicians, investigators, clinicians, students, maintenance workers, and security staff) who have contact with or an opportunity for contact with animals or their excreta, products, or tissues should be made aware of hazards that have been identified and that are determined to be a risk (Acha and Szyfres, 2001, 2003). Zoonotic disease in animal populations should be screened for or monitored regularly as appropriate. Table A-1 in Appendix 2 of this guide lists the most common zoonotic diseases found in agricultural animals and the means by which they are spread; refer to Chapter 2: Agricultural Animal Health Care for more information.

The noise level in some animal facilities may sometimes be high. When personnel are exposed to noise exceeding federal standards, appropriate protection programs should be implemented (CFR, 1995).

Work assignments and health records should be a part of an occupational health program. Records should be

kept of individual work assignments and should include the date and time of injuries or unusual illnesses. Supervisors should be instructed to fully inform personnel of potential health hazards, and personnel should be instructed to notify their supervisor if a zoonosis occurs.

## **SPECIAL CONSIDERATIONS**

### ***Hazardous Materials***

The use of certain hazardous biological, chemical, or physical materials necessitates compliance with applicable laws and regulations as well as compliance with guidelines issued by granting agencies and organizations. Institutions should have written policies governing experimentation with hazardous materials and should ensure that staff members conducting and supporting research projects involving hazardous materials are qualified to assess the dangers to animals and humans and are capable of selecting appropriate safeguards. Special facilities and equipment may be required for certain hazardous materials, and additional requirements exist for those biological materials or toxins deemed as select agents by federal law. Further information about recommended practices and procedures can be found in publications by CDC and NIH (2000, 2007), CFR (2005), and NRC (1997).

### ***Genetically Engineered and Cloned Animals***

As advancements in research drive the discovery and development of new technologies, specific considerations may need to be made for the care and use of agricultural animals in research and teaching. Institutions, researchers, and IACUCs should assure that assessment of animal care and use protocols reflects differences in various animal technologies. Guidelines for research involving genetically engineered (GE) animals or livestock clones do not differ materially from those that apply to conventional animals used in research except under special conditions. The published scientific literature has not established the need for unique guidelines. The general standards of care associated with GE or cloned agricultural animals should be the same as those applied to all agricultural animals in research unless the specific genetic modification requires an alteration in management within the research environment to specifically facilitate animal welfare.

In the future, institutions may wish to establish guidelines used in keeping with federal, state, and local government regulatory requirements. The animal biotechnology industry recently released guidelines for research and development with GE animals as a stewardship program for GE animals (Biotechnology Industry Organization, 2009). The BIO Guidance provides information for the development and implementation of stewardship programs for all institutions and research-

ers that plan to engage in research and development, and possible commercialization, of GE animals.

### ***Research Involving Genetic Engineering of Agricultural Animals***

Genetic engineering of agricultural animals is the direct manipulation of an organism's genes, including heritable and nonheritable recombinant DNA constructs. Genetic engineering is different from traditional breeding, in which the organism's genes are manipulated indirectly. The genetic engineering of agricultural animals has been extensively reviewed (National Research Council, 2002; Council on Agricultural Science and Technology, 2003, 2007, 2009; Wheeler, 2007). All GE animals in the United States are in research and development, with currently only one approved product from a GE agricultural animal in the United States. Animal welfare for GE animals used in research is regulated by law, regulations, and guidelines of the US Department of Agriculture (USDA) and the National Institutes of Health (NIH). For animals used in biomedical research, their needs for thermal comfort, humidity control, floor space, and husbandry practices should be based on the performance standards outlined in this Ag Guide. Animals in certain biomedical settings and with certain genetic backgrounds may have special requirements that should be understood so that animals are comfortable. The same performance standards that indicate adequate animal welfare in an agricultural setting will apply for animals in a biomedical setting. Welfare of animals used in biomedical research is currently regulated by law, regulations, and guidelines of the USDA and the NIH. Specific information can be obtained by reviewing the NIH guidelines for research involving recombinant DNA molecules (NIH, 2002) and the Animal Welfare Act regulations overseen by USDA. Furthermore, the US Food and Drug Administration (FDA) recently released guidance for industry that may be helpful in the conduct of research with GE animals (FDA, 2009).

### ***Research Involving Cloning of Agricultural Animals***

Animal cloning is an assisted reproductive technology (FDA, 2008) similar to artificial insemination, embryo transfer, and in vitro fertilization. The current technique used for animal cloning is somatic cell nuclear transfer (SCNT). In research, GE animals may be produced using SCNT. There are no published US guidelines for unique requirements regarding the care and use of animal clones in research. The care and use of animal clones in research does not differ from care provided for conventional animals to assure good animal welfare and animal well-being. In addition, because the progeny of animal clones are not clones, clearly progeny do not require special consideration.

## Disposition of Animal Clones

The disposition of animal clones may be of interest to animal agriculture, stakeholders in the food chain, and the US government because of issues involving the emergence of new policies by international country governments. Thus, it is recommended that institutions and researchers participate in the Livestock Industry Clone Registry whereby animal clones are registered in the database or registry. This Registry is part of the Supply Chain Management program developed by the livestock cloning companies in the United States to identify cattle and porcine clones in the United States. For more information about the registry, please see [www.livestockcloneregistry.com](http://www.livestockcloneregistry.com).

## Commercial Animal Cloning

In contrast to research with agricultural animal clones, commercial livestock cloning has been conducted in the United States for food purposes since the US Food and Drug Administration's 2008 conclusion that cloning and products of animal clones and progeny are safe. Information within their comprehensive scientific risk assessment might be useful in the future as agricultural animal clones are used in research (FDA, 2008). Furthermore, all commercially produced animal clones in the United States are registered in the aforementioned Livestock Industry Clone Registry.

Regardless of the animal technology, the IACUC should monitor the care and use of the agricultural animals in research and teaching activities and conduct careful review of protocols as noted earlier in Chapter 1 with respect to scientific protocols, public safety and animal welfare. Aspects of the review should include adequacy of methods to individually identify research animals and assure that the disposition of the research animals meets any federal, state and local government laws and regulations. Furthermore, institutions are required to meet federal, state and local laws and regulations regarding biosafety, biosecurity, and environmental issues in the conduct of research with animals derived from new technologies (see Chapter 3: Husbandry, Housing, and Biosecurity). International guidelines for GE animals either have not been initiated or are in various stages of development. Recently, the Codex Alimentarius (2008) adopted a new guideline for the conduct of food safety risk assessment for GE animals which might be helpful for institutions and researchers. As research with GE animals, animal clones, or animals derived using other technologies advances, institutions and researchers should keep abreast of new guidelines or policies being developed both domestically and internationally.

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