

Defining the Animal Care and Use Program

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An effective Animal Care and Use Program is critical to an institution's ability to ensure that animal research is conducted humanely and follows all applicable regulations and guidelines; however, no straightforward definition of the fundamentals of such a Program now exists. The author provides a global view of the key programmatic components, which can be used to improve existing programs or implement new programs.

Institutions and individuals using animals for research, teaching, and/or testing must acknowledge and accept both legal and ethical responsibility for the animals under their care, as specified in the Animal Welfare Act¹ (AWA) and associated Animal Welfare Regulations² (AWRs) and Public Health Service *Policy on Humane Care and Use of Laboratory Animals*³ (PHS Policy). Institutions can meet this responsibility for animal well-being by establishing an effective Animal Care and Use Program (henceforth referred to as the Program), encompassing all physical, procedural, medical, and human resources required to ensure that animals are cared for and used "in ways judged to be scientifically, technically, and humanely appropriate"⁴. Federal regulations and policies require us to achieve specific outcomes related to each of several program components (see later), and we can achieve these outcomes through the application of performance standards described in the *Guide for the Care and Use of Laboratory Animals* (*Guide*). "Performance standards define an outcome in detail and provide criteria for assessing that outcome, but do not limit the methods by which to achieve that outcome"⁵. Thus it becomes the responsibility of each institution to establish and maintain a Program that meets all performance standards. Doing so formalizes the best practices already followed by most animal users, and provides a tool for education both within and outside of the institution.

A second level of program evaluation exists that is external to the institution. The United States Department of Agriculture (USDA) enforces the AWA. A Veterinary Medical Officer visits and evaluates each institution at least yearly. The AWA covers all warm-blooded animals with the exception of birds, rats of the

genus *Rattus*, and mice of the genus *Mus* that are bred for use in research. Nor does the AWA cover agricultural animals used in food, fiber, or agricultural research. The Office of Laboratory Animal Welfare, (OLAW), which is part of the PHS, requires any institution that conducts or supports PHS-funded activities involving animals to file an assurance statement committing the institution to follow the PHS Policy and the *Guide*. The Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) is a voluntary accreditation organization that evaluates institutional Animal Care and Use Programs according to standards described in the *Guide*. Institutions undergo review every 3 years. External evaluation ensures institutional compliance with regulations and guidelines, and also can serve to guide Program improvement.

When considering the concept of the Program, recall that a program consists of component parts linked together in certain ways. An effective Program will possess adequate components, appropriate linkages, and a means to evaluate Program functions on a continuing basis, thus providing an assurance that we assume responsibility for maintaining the well-being of the animals under our care.

PROGRAM COMPONENTS

The following Program description divides the Program into several component parts: (i) program integration; (ii) physical plant; (iii) animal environment, housing, and management; (iv) personnel qualifications and training; (v) occupational health and safety (OHS) program; (vi) veterinary medical care; (vii) Institutional Animal Care and Use Committee (IACUC); (viii) Institutional Official (IO); (ix) support of the institutional mission. The *Guide*

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includes (iv), (v), (vii), and (viii) under a single category of institutional responsibilities, but that is a less useful classification, because all Program components ultimately are the responsibility of the institution. Each section includes specific performance criteria extracted from the *Guide*.

Program integration

For the Program to be effective, all Program components must function well together. Development and maintenance of a cohesive Program requires the following:

- A cadre of individuals with a comprehensive understanding of the Program who can evaluate Program adequacy throughout the institution;
- Strong and well-informed administrative coordination of efforts;
- Effective and timely communication among Program administration, veterinarians, Principal Investigators (PIs), IACUCs, and the IO so that each of these groups can carry out its designated responsibilities;
- Sufficient financial, physical, procedural, and human resources to meet Program objectives;
- An institutional culture of compliance.

The institution must develop methods to monitor program integration to ensure that it remains adequate and appropriate. The institution must establish procedures to identify, communicate, and correct all deficiencies.

Physical plant

“A well-planned, well-designed, well-constructed, and properly maintained facility is an important element of good animal care and use, and it facilitates efficient, economical, and safe operation⁶.”

The physical plant constitutes one of the most obvious components of the Program. As suggested earlier, the *Guide* establishes performance standards in the areas of facility planning, design, construction, and maintenance. There are expectations that appropriate areas will be available for each of the following:

- Animal housing, care, and materials sanitation;
- Receipt, quarantine, and separation of animals;
- Separation of species or isolation of individual projects when necessary;
- Materials storage;
- Other specialized spaces, facilities, and/or equipment that are required for the conduct of certain studies;
- Performance of aseptic surgery.

All animal facilities must meet relevant physical plant performance standards. The institution must assure that veterinary, IACUC, and Program staff have input into facility planning, design, and construction to ensure that new or remodeled facilities meet Program needs. It must establish a plan to monitor and maintain the physical plant, and establish procedures to identify, communicate, and correct all deficiencies.

Animal environment, housing, and management

“Proper housing and management of animal facilities are essential to animal well-being, to the quality of research data and teaching or testing programs in which animals are used, and to the health and safety of personnel⁷.” This category constitutes another obvious Program component.

Provision of appropriate animal housing must consider:

- The shape, size, and construction of the animals’ primary enclosures (cage, pen, etc.);
- Temperature, humidity, ventilation, and illumination;
- Behavioral management, including any needs for social housing and/or activity.

Appropriate management of animals and animal facilities must consider:

- Animal husbandry, including selection, storage, preparation, and provision of food, bedding, and water; sanitation of enclosures and physical plant; waste disposal; pest control; and emergency, weekend, and holiday animal care;
- Population management, including animal identification and records, and genetics and nomenclature;
- Preparation of a disaster plan that takes into account both personnel and animals.

Adequate management requires appropriate and sufficient physical, procedural, and human resources. The *Guide* establishes performance standards in each of these areas⁸. The institution must establish a plan to monitor and maintain the physical, procedural, and human contributions to adequate animal environment, housing, and management, to ensure that it meets all performance standards for all animals. It must establish procedures to identify, communicate, and correct all deficiencies.

Personnel qualifications and training

“AWRs and PHS Policy require institutions to ensure that people caring for or using animals are qualified to do so⁹.”

Personnel represent both a tremendous resource and a source of complexity in maintaining an effective Program. For these reasons, proper training is essential. The *Guide* makes the following statements about personnel:

- Personnel caring for animals should have appropriate training;
- The institution should provide for formal and/or on-the-job training to facilitate effective implementation of the Program and humane care and use of animals;
- Personnel using or caring for animals should also participate regularly in continuing education activities that are relevant to their responsibilities.

Several categories of personnel must receive appropriate training. These include:

- Physical plant and security staff;
- Animal care staff;

- Management and supervisory personnel;
- Veterinarians and veterinary staff;
- Research personnel, including PIs, instructors, technicians, trainees, and students;
- IACUC members and IOs.

In view of the importance of training and the diversity of training needs, the training program must be comprehensive and flexible. Each member of the animal research and care community must understand the components of the Animal Care and Use Program, understand his or her role within that Program, and understand how that role interacts with the roles of other members of the community. The institution must establish a plan to provide appropriate training and continuing education to all individuals working with animals, and to evaluate the effectiveness of this training. It must establish procedures to identify, communicate, and correct all deficiencies.

Occupational health and safety

“An occupational health and safety program must be part of the overall animal care and use program.... An effective program relies on strong administrative support and interactions among several institutional functions or activities, including the research program (as represented by the investigator), the animal care and use program (as represented by the veterinarian and the IACUC), the environmental health and safety program, occupational-health services, and administration (e.g., human resources, finance, and facility-maintenance personnel)⁹.” As this statement suggests, the OHS component of the Program requires that several groups work together closely and effectively.

The *Guide* establishes performance criteria for OHS in several areas:

- Hazard identification and risk assessment associated with animal care, animal experimentation, teaching, and outreach using animals;
- Personnel training;
- Personal hygiene;
- Facilities, procedures, and monitoring;
- Personal protection;
- Medical evaluation and preventive medicine for personnel.

The *Guide* specifically identifies the need for formal safety programs to address these performance standards, both for routine animal care and for animal experimentation involving hazards. The institution is responsible for creating and maintaining an OHS program and for monitoring its effectiveness. The institution must establish procedures to identify, communicate, and correct all deficiencies.

Veterinary medical care

“Adequate veterinary care must be provided, including access to all animals for evaluation of their health and well-being⁹.”

Adequate veterinary care is a Program component that closely affects all other components. The *Guide* establishes performance standards for adequate veterinary care in the following areas:

- Animal procurement and transportation;
- Preventive medicine, including animal quarantine, stabilization, and separation, as well as surveillance, diagnosis, treatment, and control of disease;
- Management of experiment-associated disease, disability, or other sequelae;
- Assessment of animal well-being;
- Establishment of appropriate surgical and post-surgical care, including appropriate use of anesthesia and analgesia;
- Proper selection and conduct of euthanasia;
- Participation in protocol development and review.

The *Guide* further states that “...AWRs and PHS Policy require that the attending veterinarian have the authority to oversee the adequacy of other aspects of animal care and use. These can include animal husbandry and nutrition, sanitation practices, zoonosis control, and hazard containment⁹.” Clearly, the intent of the *Guide* is that laboratory animal veterinarians should participate in all aspects of Program development, implementation, and evaluation.

To achieve this objective, the institution must:

- Employ a sufficient number of appropriately trained veterinarians to meet Program needs;
- Provide effective evaluation and mentoring of laboratory animal veterinarians;
- Establish “...a mechanism for direct and frequent communication...to ensure that timely and accurate information is conveyed to the veterinarian on problems associated with animal health, behavior, and well-being⁵.”
- Establish mechanisms to ensure appropriate veterinary participation in decisions about animal husbandry, preventive medicine, and experiment design and conduct, including surgical and postsurgical care;
- Provide veterinarians with sufficient authority to carry out their duties;
- Require records to document provision of adequate veterinary care to all animals.

The institution must develop methods to monitor veterinary care and ensure that it remains adequate and appropriate. The institution must establish procedures to identify, communicate, and correct all deficiencies.

IACUC

“The responsible administrative official at each institution must appoint an IACUC...to oversee and evaluate the institution’s animal program, procedures, and facilities to ensure that they are consistent with the recommendations in this *Guide*, the AWRs, and the PHS Policy⁹.”

The IACUC is a critical component of the Animal Care and Use Program. In short, “the committee is

responsible for oversight and evaluation of the animal care and use program and its components⁹. The *Guide* describes required Committee membership, meeting frequency, and maintenance of records. It also establishes performance criteria for several Committee functions:

- Review and evaluation of the institution's Program for the care and use of animals;
- Inspection of facilities;
- Evaluation of animal activity areas;
- Submission of reports to IOs;
- Review of proposed uses of animals in research, testing, teaching, or outreach (*i.e.*, protocols), including special review requirements regarding physical restraint, multiple major surgical procedures, and food or fluid restriction;
- Establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution, including a whistleblower policy;
- Advise and make recommendations to the IO on any aspect of the Program;
- The IACUC has the authority to suspend any animal activity that does not comply with applicable regulations and policies.

More than any other group, the IACUC is directly responsible for ensuring the adequacy of all aspects of the Program. It also is true that, for most IACUC members, Committee service represents only a small part of their job responsibilities. An effective IACUC that can protect the institution's privilege to use animals in research, testing, or education requires support in several areas:

- There must be institutional backing of Committee authority;
- There must be adequate administrative support;
- "It is the institution's responsibility to provide suitable orientation, background materials, access to appropriate resources, and, if necessary, specific training to assist IACUC members in understanding and evaluating issues brought before the committee⁹;"
- There must be a mechanism for direct and frequent communication to ensure that timely and accurate information is conveyed to the IACUC regarding problems in any Program component.

The institution must establish procedures to monitor and maintain Committee activities and effectiveness, and to identify, communicate, and correct all deficiencies.

Institutional Official

Each institution must appoint an IO, who legally commits the institution to meet all requirements embodied in the AWA, AWRs, and PHS *Policy* by ensuring that the Program satisfies all performance criteria just described. The IO also must submit annual and other

reports to federal agencies in a timely manner.

To accomplish this objective, the IO must:

- Understand Program structure and be able to monitor Program functions, including IACUC activities and membership;
- Receive appropriate and timely communications from the IACUC and other members of the Program;
- Have authority to enforce Program policies;
- Have access to necessary financial resources.

The institution must ensure that the IO receives appropriate administrative, financial, and legal support to develop and maintain the Program of animal care.

Support of the institutional mission

The Program must effectively and efficiently support and enhance the institution's mission in the areas of animal research, teaching, testing, or outreach. Evaluation of the Program must consider whether and how well it fulfills its reason for existence.

There are both legal and ethical reasons to develop and maintain an outstanding Animal Care and Use Program. In particular, "all who care for or use animals in research, teaching, or testing must assume responsibility for their well-being⁵." This responsibility cannot be met without appropriate Program components, appropriate Program integration, and a plan for monitoring Program effectiveness on a continuing basis.

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