A training primer for Institutional Officials

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The laws and policies governing the care and use of animals in research in the US require institutions to establish training programs to assure that personnel are qualified for their roles in animal care and use programs. Few programs define specific training requirements for the Institutional Official (IO), one of the most important roles in an animal care program. In some cases, IOs may have little or no experience in biomedical science. In this article, the author provides an overview of the IO’s role in an animal care and use program as defined by US government laws and policies for use in training IOs and chief executive officers. The author outlines the key responsibilities of the IO in an animal care program, the implications of noncompliance with federal requirements and some of the pitfalls in program design.

Institutions in the US that use animals in research must comply with federal regulations for animal care and use. These regulations require institutions to establish a program for animal care and use that includes specific roles, such as the Institutional Official (IO), the Institutional Animal Care and Use Committee (IACUC) and the Attending Veterinarian (AV). Each of these roles carries a set of responsibilities within an animal care and use program that are defined in federal regulations. Here I provide a training primer for IOs and other institutional leaders detailing their responsibilities in an animal care and use program under federal regulations. I also provide some analysis of the programmatic responsibilities of the IO, the IACUC and the AV and how these roles should work together. I detail the ramifications of noncompliance with federal laws and policies. Finally, I define ‘self-regulation’ of an animal care and use program and identify some common pitfalls in organizational structure that can weaken a program's self-regulation.

This primer is focused on the US model for animal care and use programs. In Europe, a different model is in place. The European Union currently operates under the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (ETS 123) that defines principles of animal use and controlling authorities. A new legislative strategy has been advanced to clarify principles of animal welfare, to improve compliance and communication with consumers and to enhance training and competency for personnel handling animals. It is currently unclear how this new legislative agenda, slated for 2012-2015, will affect animal care and use in Europe.

Laws and Policies

The IO is often referred to humorously as the ‘go to jail’ person in an animal program. Although imprisonment is rarely an outcome, IOs may be held responsible for institutional noncompliance with laws and policies governing animal care and use, which can entail paying fines or returning grant money to the National Institutes of Health (NIH). Therefore, IOs should clearly understand what is expected of them and should be familiar with the operating principles of animal care and use programs. Several different laws and policies define the role of the IO.

Animal Welfare Act

The Animal Welfare Act (AWA) is administered by the US Department of Agriculture (USDA). This Act of Congress was first passed in 1966 and has been amended several times since then. The AWA defines an animal as any live or dead dog, cat, hamster, guinea pig, rabbit, nonhuman primate or any other warm-blooded animal used for research teaching, testing or experimentation. It excludes rats of the genus Rattus and mice of the genus Mus, which comprise roughly 90% of the animals used in research. With increasing pressure on the USDA to include rats and mice in the regulatory
efforts, it is reasonable to expect that these species will someday come under regulation by the USDA.

The AWA recognizes multiple components of an animal care and use program at a research facility, the predominant components being the institution itself, the IO, the IACUC and the AV. The AWA defines the IO as “the individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of 9 CFR parts 1, 2 and 3 will be met.” Hence, the IO, the chief executive and the institution itself have roughly the same responsibilities.

These responsibilities are detailed in the AWA. If regulated animals are used in research, the IO, the chief executive and the institution must do the following: (i) register with the USDA (9 CFR, subpart C, 2.30a); (ii) acknowledge the regulations with which the institution must comply (9 CFR, subpart C, 2.30b); (iii) notify USDA of changes in operation (9 CFR, subpart C, 2.30c); (iv) not interfere with, threaten, abuse or harass any USDA Animal and Plant Health Inspection Service (APHIS) official (9 CFR, subpart C, 2.30d); (v) ensure that all scientists, research technicians, animal technicians and other personnel involved in animal care, treatment and use are qualified to perform their duties (9 CFR, subpart C, 2.32a); (vi) have an AV (9 CFR, subpart C, 2.33a); (vii) establish a properly constituted IACUC (9 CFR, subpart C, 2.31); (viii) establish and maintain programs of adequate veterinary care through provision of appropriate facilities, personnel, equipment and services sufficient to comply with the regulations (9 CFR, subpart C, 2.33b1); (ix) maintain records of IACUC function, animal acquisition and other records for 3 years, including those of animal activities 3 years beyond the close of the project (9 CFR, subpart C, 2.35); and (x) file annual reports that meet the regulatory requirements (9 CFR, subpart C, 2.36).

Health Research Extension Act of 1985
The Health Research Extension Act four empowers the Public Health Service (PHS) to establish standards of animal care and use for federally funded research programs. To this end, the PHS created its Policy for the Humane Care and Use of Laboratory Animals (PHS Policy), which mandates that institutions establish programs of adequate care and use of animals based on the recommendations of the Guide for the Care and Use of Laboratory Animals (the Guide). An institution’s program of animal care and use is detailed in an assurance document negotiated with the Office of Laboratory Animal Welfare (OLAW) of the NIH. The NIH Assurance describes how an institution will comply with the Guide and the PHS Policy. Compliance with the Guide is a requirement in order to receive federal funds for animal-based research. The Guide covers all vertebrate animals, including rats and mice; hence, rats and mice are regulated under the Health Research Extension Act and the PHS Policy.

The Guide defines the IO as the person who “bears ultimate responsibility for the program” but indicates that an animal care program should be a collaborative effort between the IO, the IACUC and the AV. The IO carries the authority to allocate the institutional resources needed to ensure the program’s overall effectiveness, including planning resource allocation to align program goals of quality animal care and use with the institutional mission. The IACUC is mandated to assess the animal care program. The AV must be given the authority to oversee the adequacy of the program.

Relationship between the USDA and the PHS
Institutions that use animals in research are thus subject to two sets of regulations implemented by two separate agencies: the AWA administered by the USDA, and the PHS Policy. The relationship between these two regulations needs to be clarified. The PHS Policy requires compliance with the AWA, as clearly stated in footnote 2: “This Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals and that they comply with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.”

Some ambiguity exists regarding the use of rats and mice, which are not covered by USDA but are covered in the Guide. Is a PHS-Assured institution required to comply with the AWA if it does not use any USDA-regulated animals? The IO must answer that question. The PHS Policy does not state that Assured institutions must comply with the AWA only if they use regulated animals. That contingency is not included the absolute statements in footnote 2 of the PHS Policy. Hence, attempts to interpret the federal policies literally provide no answer because the ambiguity exists and is unresolved. However, the ultimate goal of both regulations is for each institution that uses animals in research to establish and maintain a quality animal care and use program that is adequately funded, resourced and staffed and is based on the relevant laws and policies.

It is important to note that the USDA and the PHS have a Memorandum of Understanding. Any significant adverse findings or evidence of serious noncompliance identified by either agency will be communicated to the other. Thus, findings of a USDA inspection are transferred to the OLAW and vice versa.

FUNCTIONS OF THE IO, THE IACUC AND THE AV
The IO may be the chief executive of an institution or his or her designee. The IO is responsible for appointing...
the AV and the IACUC, for organizing the program and reporting structure and for arranging the relationships of the IACUC and the AV with the IO. The IO is legally authorized to commit the institutional resources necessary for an institution's animal program to comply with federal regulations.

When listing responsibilities of the IO, the AWA and the Guide include important phrases such as “establish and maintain,” “bears ultimate responsibility” and “legally commit on behalf of the institution.” These phrases indicate that according to federal law, the IO must provide adequate institutional resources to maintain compliance with the standards. The standards are elaborate and detailed and require considerable expertise from many different people and considerable resources, including funds for personnel, equipment, facilities, repairs and replacement of worn-out equipment. The standards also require that institutions meet regulatory targets for post-approval monitoring, cagewash temperatures, climate control (temperature and humidity), air turnover rates, IACUC functions, etc. In order to maintain compliance with these standards, institutions must project anticipated growth in the research program and plan ahead to match resources with the growing needs. Compliance will be compromised if institutional infrastructure does not keep pace with research program growth.

The IACUC must assess the institution's animal program, facilities, procedures and all animal activities (9 CFR, subpart C, 2.31). Extensive lists of IACUC responsibilities are included in the AWA and the Guide. The IO should contemplate the meaning of the phrase “animal activity” as used in the AWA as it pertains to the IACUC's scope. “Activity means, for purposes of part 2, subpart C of this subchapter, those elements of research, testing, or teaching procedures that involve the care and use of animals.” The definition includes both care (husbandry, sanitation, waste disposal, record-keeping, veterinary care, population health, animal acquisition, etc.) and use (research procedures, surgery, pain management, treatments, outcomes, compliance, record-keeping, etc.).

The AV “provides adequate veterinary care to the animals in compliance with this section with the appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use” (ref. 3, 9 CFR, subpart C, 2.33a). The phrase “authority to ensure…and oversee…” places considerable responsibility on the AV but does not imply an overarching authority to manage compliance. The AV has myriad responsibilities detailed in the AWA and the Guide relating to the provision of veterinary care, including consultations on pain management, anesthesia, surgery, medical treatment, husbandry oversight and much more.

In essence, the guidelines require the IO, the IACUC and the AV to collaborate to define and execute a program of animal care and use. The program involves personnel, procedures, facilities and equipment. The institution must remain in compliance, keep records and file reports with relevant federal agencies. The underlying concept is for institutions to adopt a strategy of ‘self-regulation’ in which they find and fix their own problems.

**AREAS OF CONCERN FOR THE IACUC AND THE AV**

As the person responsible for appointing the IACUC and the AV, the IO should be aware of the challenges involved in these roles. The IO should recognize that a large amount of work is involved when serving on an IACUC that is correctly performing the full scope of its duties. Despite this dedication, many IACUC members receive little academic credit for this work. Membership on the IACUC should be positively acknowledged in promotion papers and in any incentive plan. In addition, sufficient professional IACUC and compliance staff members should be provided to support the work of the committee.

The IO should also beware of assigning compliance responsibilities to the AV. Job descriptions for AVs frequently include statements indicating a responsibility for compliance. For example, this statement was the opening sentence in a job description for a major research institution, posted on the American College of Laboratory Animal Medicine website (http://www. aclam.org/): “Responsibilities of the Director/Attending Veterinarian will include oversight of veterinary care, husbandry, space management, business operation, and compliance with all Federal, State and Local regulations.” But very few veterinarians are empowered by their academic institutions to allocate the human and financial resources necessary to maintain compliance with all federal, state and local regulations. Perhaps the intent of such statements is to indicate that the AV is responsible for the regulations governing animals in research. Even with that limitation, veterinarians are seldom empowered to manage faculty compliance, to fund major building repairs to resolve noncompliance in infrastructure, or to fund a compliance program. Maintaining compliance is an institution-level responsibility, not a responsibility of the AV. There is potential for conflict with research faculty if the AV is responsible for compliance, and veterinarians seldom emerge from such conflicts unscathed.

**PROGRESSIVE REGULATION**

The IO must consider that the current era is one of progressive regulation. The 2011 version of the Guide is considerably longer than its predecessors. The USDA uses a policy manual to provide more in-depth interpretations of its own regulations. The APHIS Animal Care Inspection Guide (ref. 11), used by the USDA field inspectors to evaluate animal care programs, includes a
few additional standards not detailed in the regulations or the policy manual. The IO should also keep in mind that institutions must provide documentation to prove that they met the regulatory targets. Failure to document compliance is considered noncompliance.

The OLAW has developed guidance on self-reporting of noncompliance, probably because it is reasonable to assume that noncompliance exists. At active research institutions, particularly those that are underfunded, it is almost impossible to control the activities of numerous senior faculty, post-doctoral fellows, graduate students, research technicians and animal care personnel. Many research personnel in the US today have substantial language barriers, rendering communication on compliance standards difficult at best. Animal care personnel may cut corners when they are understaffed and overworked. In addition to personnel, institutions are responsible for overseeing large inventories of equipment, which requires maintenance to continue operating within its designed specifications. The OLAW indicates that it expects an institution to self-report noncompliance that affects the health and well-being of laboratory animals or unapproved deviations from the institution’s PHS Assurance. Minor incidents that do not affect the health and well-being of animals are not necessarily reportable but should be managed by the IACUC. The IACUC and the IO are usually charged with making those determinations. When reporting noncompliance, the institution’s report should indicate the nature of the noncompliance, its investigation, its remediation and the measures taken to prevent recurrence. The institution and the IO carry the responsibility for self-reporting deficiencies as they are discovered, not just in the required annual reports. Prudent institutions will track noncompliance and remediation carefully. The 2011 version of the Guide requires institutions to have a mechanism of post-approval monitoring of animal activities. The AWA has always required continued monitoring of such activities.

In its efforts to document compliance with regulations governing animal use, an institution might consider seeking accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). AAALAC International is a nonprofit corporation that evaluates and accredits programs of animal care and use. Its work is confidential. The primary benchmarks for evaluation are the Guide, the Guide for the Care and Use of Agricultural Animals in Research and Teaching, and the European Convention for the Protection of Vertebrate Animals Used for Experimentation and Other Scientific Purposes, Council of Europe. Laws, policies and other reference documents are also used. AAALAC International’s primary goal is to define and acknowledge programs that meet or exceed required standards. Accreditation from AAALAC International is a good marketing tool for recruiting faculty and is a symbol of a quality product to peer institutions. Institutions accredited by AAALAC International are certainly not perfect, but their animal care programs have been peer-reviewed and approved by professionals who know these programs and the regulatory requirements. That peer review is a fair indicator of status.

Noncompliance with federal laws and policies is unacceptable for an institution. The USDA has recently declared a new era called the “age of enforcement” for the AWA. I heard a USDA inspector state, “We expect you to be 100% in compliance, 100% of the time.” This has serious implications for registered research facilities and for IOs in particular because they bear the ultimate responsibility for the program’s compliance.

Noncompliance may compromise animal well-being, result in financial penalties and attract negative attention from the public. In fact, some animal rights extremist groups attempt to infiltrate animal research institutions for the sole purpose of revealing noncompliance and animal abuse. Any examples found are then publicized through the modern media of television and the internet. Noncompliance of major research institutions is a media event. This information often makes its way to newspapers, internet and television very quickly. Institutions must then scramble to control the damage through media relations and faculty communications.

The embarrassment of public airing of violations is surpassed only by the monetary implications. Federal fines of up to $10,000 per animal affected per incident per day may be levied on an institution by the USDA. These fines can quickly add up to large sums if the violations involve high-profile species (such as primates). In addition, if the NIH determines that funded research was conducted while the institution was in noncompliance with its PHS Assurance and with the Guide, the NIH can request return of grant money.

Managing noncompliance is the work of the IACUC in its post-approval monitoring, facility inspections and program review. The IACUC is empowered to suspend animal activities; when this happens, only the IACUC can re-instate the activities. The IO is also empowered to stop noncompliance and usually has the authority to manage investigator noncompliance. The AV is not delegated compliance authority by the laws and regulations, and few institutions grant the AV compliance authority over faculty. The AV is primarily empowered to provide veterinary care and oversight.

What happens when the IO, the IACUC and the AV disagree on the management of a noncompliance event? What happens if an animal care program incurs major media fallout or financial penalties, regardless of who was at fault? In many cases, the IO,
the IACUC, the AV and the research faculty come under intense scrutiny. Regardless of who was at fault in the failure, regulators assign responsibility to the institution because the institution is responsible for compliance. Most institutions have policies in place to offer rights and protections to those who disclose noncompliance activities publicly or to the NIH, but these programs offer little real protection to personnel employed on an ‘at-will’ basis. The NIH has a somewhat unclear ‘whistleblower protection’ program that has little impact on individuals in grantee institutions. When there is strong disagreement among the key players regarding noncompliance, the IO generally rules. IOs are seldom asked to step down. IACUC members may resign from the committee of their own accord or be replaced by the IO. Faculty noncompliance rarely results in termination or forced resignation of the involved researcher. Veterinarians unfortunately have little protection and are frequently blamed, replaced or forced to resign, whether or not they were the point of failure.

COLLABORATION BETWEEN THE IO, THE IACUC AND THE AV
A successful animal care and use program is a collaboration between the IO, the IACUC and the AV. The strongest programs maintain direct links and frequent communication among the three roles. The IACUC must carefully evaluate animal facilities and activities, identify deficiencies and deadlines for their correction and communicate its findings to the IO. The AV must carefully evaluate program needs and resources and request adequate staffing and resources to sustain adequate veterinary care and husbandry from the IO. The IO must acknowledge and act on the information provided by the IACUC and the AV to maintain compliance.

Pitfalls
Maintaining direct links and communication among the IO, the IACUC and the AV presents some unique challenges. The organization charts of large, active research institutions often show layers of separation between IO, the IACUC and the AV. Links between the roles may be drawn with dotted lines, accurately reflecting an indirect and weak connection. Such layers of separation between key operating components may weaken the authority structure in the program and create distance between personnel responsible for budgetary decisions and those responsible for compliance.

Many large animal care and use programs impose additional controls on the activity of the AV through resource advisory committees independent of the IACUC. These accessory committees are intended to give guidance to the animal care program director. But federal laws and policies empower the IACUC to deal with any concerns in the animal care and use program. Unless carefully conceived, these non-IACUC committees may weaken the authority of the AV or influence the program’s financial stability by creating unfunded or unstaffed mandates. The IO should give careful consideration to the organization of the institutional animal care and use program, avoiding structures that weaken the authority of the primary programmatic components.

CONCLUSIONS
An institutional animal care and use program is a collaboration between the institution, the IO, the IACUC and the AV, each of which has responsibilities under federal laws and policies. The institution must provide the facilities, personnel and resources sufficient to meet the requirements of the laws and policies and empower the IO, the IACUC and the AV to do their work. The IO, the IACUC and the AV must define the program, usually in a set of operating procedures and standards. The IACUC must evaluate the program and the facilities using the AWA, the PHS Policy and the Guide as benchmarks and must review and monitor all animal activities. The IACUC and the AV must provide detailed analyses of program status, deficiencies and needs. The IO must read those analyses carefully and act on them, optimizing resources to sustain compliance and build a high-quality program. When operating with a clear understanding of each party’s responsibilities and authority in an environment of collaboration, such a program of self-regulation works well and provides exceptional care for the animal subjects.

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