

Standards for Wildlife Research: Taxon-Specific Guidelines versus US Public Health Service Policy

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The Guide for the Care and Use of Laboratory Animals (NRC 2011) serves as the principal reference for the oversight of most vertebrate use in research and teaching in the United States. The Guide was developed as a reference for biomedical research. Beyond guiding ethical principles, the Guide contains little information useful for the oversight of research involving wild taxa. To fill this breach, and at the behest of the National Science Foundation, taxon-specific societies in the United States developed independent guidelines that held to the principles of ethical use of animals in research and that were specific to wildlife. Recognition of these taxon-specific guidelines by federal grantmaking agencies and the animal welfare community as appropriate standards for wildlife research will facilitate the required oversight of research involving wild taxa and the ethical use of wild animals in research and teaching.

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Compliance with the US Public Health Service (PHS) policy on the humane care and use of laboratory animals, which in turn requires compliance with the Animal Welfare Act (AWA), is required for research funded by the PHS that involves live vertebrates. Other federal funding agencies have voluntarily adopted the 1986 PHS policy, which expressly requires that research be conducted in a manner consistent with the *Guide for the Care and Use of Laboratory Animals* (NRC 2011). The *Guide* is a suitable standard for biomedical research, but beyond the basic guiding principles of humane research (reduction, refinement, and replacement; Russell and Burch 1959), it is not useful for research involving wildlife, particularly when that research is conducted in a natural setting. Application of the *Guide* to research involving free-ranging terrestrial and aquatic vertebrates has proved vexing for institutional animal care and use committees (IACUCs) and researchers alike, because it provides no guidance on most issues and methods of central importance in wildlife research. Taxon-oriented professional societies long ago recognized this incongruence. At the request of the National Science Foundation (NSF), these societies developed guidelines consistent with the *Guide* and other existing legal and ethical requirements but oriented toward wild species and field research. These documents were developed specifically to aid investigators and oversight bodies in designing and reviewing protocols involving the wild taxa for which the societies were the recognized authorities. Current versions of scientific society guidelines mesh the guiding principles of

the *Guide* and the legal and ethical regulatory requirements of the PHS policy and of the AWA with the methods used in wildlife research. Society guidelines are updated to ensure currency with changing regulatory landscapes and evolving techniques. The taxon-specific guidelines of these professional societies represent the primary and most appropriate standards for the care and use of wildlife in research.

The history of animal welfare policy in the United States accounts for its poor fit relative to wildlife research. The AWA, enacted in 1966, authorized the US Department of Agriculture Animal and Plant Health Inspection Service to regulate the use of vertebrate animals in research (7 U.S.C. §2131 et seq.). This important legislation was prompted by outrage over the mistreatment of dogs by dealers supplying animals to biomedical research laboratories (Cowan 2010). The seven amendments to the AWA over the following 22 years were focused largely on laboratory research.

In 1985, Congress enacted the Health Research Extension Act (42 U.S.C. §289 (d)), requiring the National Institutes of Health to establish guidelines for the proper care and treatment of animals used in biomedical and behavioral research. PHS grant recipients and their institutions would now be required to comply with these guidelines as a condition of eligibility for funding. As a result of this 1985 legislation, responsibility for the development of policies to ensure compliance with the AWA in research fell to the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) because most biomedical research is PHS funded.

Then known as the Office for Protection from Research Risks, OLAW had for some years made reference to the *Guide* in its animal care policies. However, when OLAW issued its 1986 PHS policy in response to the congressional directive, the *Guide* acquired a quasiregulatory status because the PHS policy required compliance with the *Guide* as a condition for PHS funding. Each institution must provide the PHS with written assurance that it will use the *Guide* as the basis for developing and implementing their institutional program for activities involving animals (PHS Policy IV.A.1).

A detailed history of the development of the *Guide* (Wolfe 1999) provides important context (table 1). In 1950, a group of scientists described by Wolfe (1999) as “the giants of laboratory animal science” (p. 44) met in Chicago to discuss laboratory animal care. The meeting led to the creation of the nongovernmental Animal Care Panel (ACP). Two years later, the National Research Council (NRC) of the National Academy of Sciences convened a conference that led the NRC to request that the academy establish a committee on animal resources “for the purpose of recommending a long-term procurement and supply mechanism of animals for biologic, medical, and agricultural research” (Wolfe 1999, p. 44). That committee’s work resulted in the formation of the Institute of Animal Resources—now the Institute of Laboratory Animal Research (ILAR)—in 1953; its leadership and council were major names in biomedical research. According to Wolfe (1999), “The need by investigators and colony managers for well-defined parameters of animal care and use fueled the development of one of the most significant advancements yet to be made in laboratory animal science: the 1963

Guide for Laboratory Animal Facilities and Care published by the ACP under contract from the Division of Research Resources, [National Institutes of Health]” (p. 47). At the time, the same person chaired both ILAR and the ACP’s Standards for Laboratory Animal Facilities. He also chaired the authoring committee of the *Guide*, whose authors Wolfe (1999) characterized as “legends in laboratory animal science” (p. 47). ILAR collaborated with the ACP in developing this first edition of the *Guide* and soon endorsed it, “giving it the influential imprimatur of the National Academy of Sciences” (Wolfe 1999, p. 47). After only 2 years, ILAR was asked by the National Institutes of Health to develop the second edition (Wolfe 1999). From its inception and through the following seven revisions (1965, 1968, 1972, 1978, 1985, 1996, 2011), there is no evidence that practicing wildlife biologists were ever consulted, included on the committee of experts assigned to revise the text, or included among the reviewers. It is not surprising, then, that the *Guide* never addressed wildlife biology. When the 1986 policy linked compliance with the *Guide* to eligibility for federal funding, the attempted application of guidelines never intended for wildlife research inevitably led to problems for researchers and IACUCs. As a consequence, each of the vertebrate taxon societies (representing mammalogy, ornithology, and herpetology and ichthyology) developed or extensively revised guidelines designed specifically to aid investigators and oversight personnel in evaluating wildlife research (ASIH 1987a, 1987b, ASM 1987, American Ornithologists’ Union 1988).

The intended scope of the eighth edition of the *Guide* (NRC 2011) is seemingly inclusive, in that it states explicitly

that “laboratory animals (also referred to as animals) are generally defined as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching” (p. 2). This edition was written by a 14-member committee for revision and reviewed by 17 referees. Each of the participants is highly credentialed, and their backgrounds reflect extensive experience in the care and use of laboratory animals and in the operation of animal facilities but little or no experience with research involving wildlife in the field or in captivity. A literature search using the Web of Science (http://thomsonreuters.com/products_services/science/science_products/a-z/web_of_science) yields over 450 publications for the members of the revision committee, but not one involved significant components of a field study. Fewer than 30 listed any type of even quasiwild animals held in captivity, and most of these involved

Table 1. Chronology of key events relating to the oversight of animal research in the United States.

Date	Event
1953	Institute for Animal Resources (now the Institute of Laboratory Animal Research [ILAR]) was established. It was originally intended to develop a procurement mechanism of animals destined for biomedical research.
1963	The first edition of the <i>Guide for the Care and Use of Laboratory Animals</i> was published. It was intended as a standard for animal care in biomedical research.
1966	The Animal Welfare Act, prompted by public outrage over the use of dogs in biomedical research, was signed into law. This Act authorized the US Department of Agriculture Animal and Plant Health Inspection Service to regulate the use of vertebrate animals in research. The initial Act and the subsequent seven amendments were focused primarily on laboratory research.
1986	The Health Research Extension Act and US Public Health Service (PHS) policy on the humane care and use of laboratory animals extended coverage to most vertebrates and linked eligibility for PHS funding to compliance with PHS policy. This policy requires that research be conducted in a manner consistent with the ILAR <i>Guide</i> , which makes the <i>Guide</i> quasiregulatory.
1986	The National Science Foundation and other federal granting agencies voluntarily adopted the PHS policy. The National Science Foundation solicited guidelines from taxon societies because of the absence of information in the ILAR <i>Guide</i> relating to field research.
1987–1988	Taxon-specific guidelines covering the use of wild vertebrates in research were published or revised by the American Society of Ichthyologists and Herpetologists, the American Society of Mammalogists, and the American Ornithologists’ Union.
2012	A request for the formal recognition of taxon-specific guidelines as appropriate standards for wildlife research was made (i.e., the present article).

various nonhuman primates, zoo or aquarium animals, or pathological reports in a few wild individuals. Importantly, not a single one of these latter studies was focused on the biology of the species as a whole. The unavoidable result of this focus on biomedical research with laboratory animals is that regulatory personnel and IACUCs—most of which are populated by biomedical researchers—are left without relevant guidance when tasked with reviewing protocols submitted by their field-oriented colleagues.

The *Guide's* five chapters, which are followed by appendices with additional reference sources, are designed as explicit instructions for efficient operation of IACUCs and, therefore, include a reasonably comprehensive set of references to facilitate committee deliberations on proposed laboratory research procedures. However, nowhere in any of these chapters, except for several species of nonhuman primates frequently used in laboratory research, is even a single reference concerning wildlife beyond the taxon-specific guidelines of a few professional societies. The *Guide* omits entirely considerations that are of central importance to IACUCs, investigators, and the well-being of free-ranging native animals, such as the humane and ethical capture of individuals, identification marks useful in the field, and the integrity of wild populations. To be fair, the *Guide* states that it “does not purport to be a compendium of all information regarding field biology and methods used in wildlife investigations” (p. 32), and society guidelines are referenced in the appendices. This statement notwithstanding, lacking official recognition, taxon-specific guidelines are neither consulted nor accepted by many IACUCs. Field techniques aside, even husbandry requirements for wild taxa held in captivity, including those closely related to laboratory strains, frequently differ substantially. Therefore, husbandry practices typical with domesticated species might constitute inhumane treatment of wild taxa in captivity (Sikes et al. 2011). These circumstances result in a mosaic of interpretations about which practices are acceptable and under what conditions.

In strict legal terms, the *Guide* is not regulatory in nature. Furthermore, the *Guide* allows for deviations or exceptions when they are justified. Operationally, however, IACUCs and institutional veterinarians—particularly those who lack experience with or information on wildlife biology—tend to view these documents as absolute requirements rather than as general guidelines. Departures from the *Guide*, even when they are warranted, are further discouraged by the fact that IACUC composition is mandated to include members from diverse fields and for whom service on an IACUC (and the deliberations involved) is a voluntary additional duty usually well outside their normal responsibilities. Committee members often have only basic—if any—IACUC training and frequently take the circumspect approach of simply denying requests for deviations when proposed procedures do not closely match the examples presented in the reference standards. Clearly, appropriate guidance for wildlife research is essential to ensure the ethical use of animals consistent

with their biology, but reliance on the *Guide*, as it is mandated by PHS policy, serves only to force researchers, educators, IACUCs, and wildlife alike into molds never intended for the species and projects in question. This incompatibility unnecessarily limits the creativity of investigators and impedes appropriate and ethical use of wild animals in field and laboratory studies. IACUCs, which are required to review and approve every study involving live vertebrates, find themselves struggling to apply the language and prescribed methodologies of laboratory research to the questions and methodologies of biological field research. As a result of these difficulties, studies that should be performed might be inappropriately curtailed, and studies that should be avoided might be erroneously approved.

How might the incongruity between the *Guide* and wildlife research be corrected? First, OLAW should revise the PHS policy to give formal recognition to the taxon-specific guidelines as the appropriate reference standards for wildlife research. In other words, PHS should state that compliance with the relevant taxon-specific guidelines will satisfy the PHS requirements. Second, ILAR should issue an addendum to the *Guide* stating that the relevant professional society's guidelines are appropriate for evaluating animal care and use in wildlife protocols. As it currently stands, the *Guide* simply acknowledges the existence of taxon-specific guidelines in an appendix and encourages investigators to consult such resources. It is expected that such an addendum would, of course, be incorporated into subsequent revisions of the *Guide*. If these changes are implemented, the ethical use of animals will be enhanced because oversight will be consistent with the highest level of taxon-specific professional recommendations.

History suggests that this solution is appropriate. Prior to 1986, PHS policy covered mainly the maintenance of laboratory animals in captivity. In 1986, that policy was extended to cover experimental procedures. Because the NSF, which funded the most substantial part of wildlife research, required adherence to the PHS policy, this change also affected wildlife research. At the time, there were no accepted humane policies pertaining to field research. As a result, IACUCs had no guidance for reviewing protocols for wildlife research and were making widely varying decisions. Recognizing this problem, the NSF urged the presidents of the appropriate scientific societies in 1986 to develop guidelines for the appropriate handling of their taxa. Funding from the NSF facilitated these efforts, and 1987 and 1988 saw the publication of taxon-based guidelines for mammals, birds, reptiles and amphibians, and fishes (Orlans 1988). That these guidelines were solicited by this major federal grantmaking agency for the express purpose of correcting the absence of information about wildlife in the ILAR *Guide* should leave little doubt that it is appropriate for the PHS to formally recognize these documents in its policy, much as it recognizes the ILAR *Guide* as a reference standard. Most of these society guidelines are already recognized as reference resources by the Association for the Assessment and

Accreditation of Laboratory Animal Care International, a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. It might be argued that there is no need to formally recognize these documents, because little wildlife research is funded by the PHS. However, the PHS policy has been adopted by the NSF and other grant-making agencies that fund wildlife research. Official recognition of the taxon-based guidelines as appropriate standards for wild taxa would facilitate consistent decisions among IACUCs. Furthermore, it would allow IACUCs to require that researchers make more and better use of these guidelines to promote the ethical use of wildlife in research.

Society guidelines are entirely consistent with the guiding principles and legal requirements of animal research, but because the interest of these societies is usually a better understanding of the taxa themselves, their guidelines make extensive use of references and examples directly relevant to field studies and to the well-being of wild populations, as well as that of individuals maintained in captivity. An important distinction between the biomedical guidelines and taxon-specific guidelines is that the latter, although they maintain humane standards of handling and care, place substantial emphasis on the safety and viability of the species and natural populations—topics that are not relevant in biomedical research.

Current editions of society guidelines comprise approximately 333 printed pages (formatting varies widely among the documents) and collectively make reference to 875 articles, the vast majority of them peer-reviewed papers. Of particular importance is that most of the references are focused primarily or exclusively on wild taxa. (Some articles are referenced by more than one set of guidelines or in more than one chapter.) Furthermore, these guidelines are authored and reviewed by individuals with recognized taxon-specific expertise. A search of the 35 authors or editors listed on each of the current guidelines reveals more than 1400 publications indexed by the Web of Science. Even a cursory scan of their titles reveals that most of the papers are focused primarily on the biology of wild species in their native environments or in captivity.

It is not feasible or necessary for ILAR to replicate the wildlife-specific standards that already cover hundreds of different methods and considerations specific to wildlife research. The taxon-specific guidelines for birds (Fair et al. 2010), fish (Nickum et al. 2004), mammals (Sikes et al. 2011), and reptiles and amphibians (Beaupre et al. 2004) that already exist cover the diversity of vertebrates (more than 52,000 species); are consistent with the *Guide*; and have been extensively revised and peer reviewed by the various professional societies, knowledgeable veterinarians, and other professionals. These documents need only be recognized and endorsed as appropriate standards for the care and use of wild animals in research.

Society guidelines were initially developed to supplement rather than to replace the *Guide*. As a consequence, some topics included in the *Guide* are omitted in society documents.

In some instances, the omission was made simply to avoid duplication, but in others, material was omitted because it was not relevant to wildlife research. Nonreplicated sections include, most notably, details on IACUC operations, institutional reporting structure, and physical plant requirements for animal holding facilities. If society guidelines are recognized as standards for wildlife research, future revisions of all such guidelines should expressly incorporate relevant sections of the *Guide* by reference.

The benefits from the recognition of relevant guidelines for all parties concerned are diverse. Interpretation difficulties that arise from IACUCs having to force wildlife protocols into a framework designed for biomedical research will largely disappear, investigators will have appropriate examples for use in designing and executing research, and animals will be handled and maintained in taxon-appropriate ways. Relevant guidelines might also facilitate broader application of the AWA. Some federal and state agencies have resisted AWA compliance under the field studies exemption. To the extent that such resistance stems from the perception that the AWA and its implementing regulations are viewed as applying to captive situations only and are therefore not relevant to wildlife research, recognition of taxon-specific guidelines makes the relevance obvious and greatly facilitates compliance. Perhaps the most significant benefit is that as the animal care and use committees of the professional societies are recognized as authorities on the ethical use of wildlife in research, they will become go-to resources for investigators and IACUCs for species-specific requirements or methods. The beneficiaries of this level of collegial interaction are the investigators, oversight personnel, and—most especially—the animals themselves.

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