

## Regulatory Overview

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Institutions are required to follow certain regulations and policies that pertain to the use of animals in research and testing. The two main pieces of legislation that mandate the creation of standards and regulations of animal care and use are the Animal Welfare Act (AWA) and the Health Research Extension Act (HREA). However, the regulations and standards written to address the AWA and HREA address minimal requirements only. There is much debate over whether or not the existing regulations offer adequate protection to animals used in research. LPAG feels that the standards do not offer adequate protection to primates in research, and, furthermore, LPAG does not support the use of primates in research.

### Brief Overview of the Animal Welfare Act

The Animal Welfare Act (7 USC sec. 2131 et seq.)<sup>1</sup> was passed in 1966 and amendments were made in 1970, 1976, 1985 and 1990. The original bill mainly pertained to the acquisition, transportation and handling of dogs and cats. However, amendments made in 1970 addressed more issues pertaining to the laboratory, such as the use of anesthetics and analgesics following painful procedures.

In 1985, further amendments to the AWA were made, one of which mandated that each institution form an Institutional Animal Care and Use Committee (IACUC). However, LPAG and many others believe that IACUCs do not receive adequate input from local citizens and those concerned about animal welfare. Furthermore, if an institution is not a state or federal institution subject to open records laws or the Freedom of Information Act (FOIA), the activities of the IACUC and documents maintained by the IACUC are not subject to public scrutiny, even if the institution in question receives grants funded by taxpayer dollars. The public does have access to annual reports submitted to the USDA by each institution, which provide limited information about the institution's activities and records.

According to the AWA, IACUCs must consist of at least three members and include a veterinarian and an outside member who is not affiliated with the institution. The AWA mandates that IACUCs "ensure compliance with the provisions of

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<sup>1</sup> Animal Welfare Information Center, National Agriculture Library, USDA, Animal Welfare Act and Regulations, available at <<http://www.nalusda.gov/awic/legislat/usdaleg1.htm>>.

this Act to minimize pain and distress in animals." IACUCs must approve all research protocols that use animals and have the ability to require modifications to or withhold approval of a protocol. Each researcher is required to search for alternatives to protocols that have the potential to produce pain and/or distress, even if drugs are used for alleviation. It is also the duty of the IACUC to determine if a thorough search for alternatives was performed.

Additional 1985 AWA amendments mandated exercise for dogs<sup>2</sup> and increased "psychological well-being" of primates.<sup>3</sup> In 1999, The USDA sought public comment on a draft policy on environmental enhancement for nonhuman primates,<sup>4</sup> intended to strengthen and clarify the existing rules, but has yet to announce the final rule on this proposal. Unfortunately, there are instances when institutions are exempt from addressing the psychological needs of primates. Visit [www.lpag.org/bureaucracy/bureaucracy.html](http://www.lpag.org/bureaucracy/bureaucracy.html) to read about the Animal Welfare Act's failure to promote the well-being of nonhuman primates used in research.

### **The Role of the US Department of Agriculture (USDA)**

The Animal Care division of the USDA's Animal and Plant Health Inspection Service (APHIS)<sup>5</sup> is charged with developing regulations and enforcing the AWA. Regulations pertaining to the AWA are published in the Code of Federal Regulations, Title 9, Chapter 1, Animal Welfare – commonly referred to as 9 CFR.<sup>6</sup> It is important to emphasize that the AWA is the legislation itself, while 9 CFR consists of the actual regulations and standards (such as cage sizes, lighting, and ventilation) pertaining to the AWA. The AWA language pertains to all warm-blooded animals, but the USDA has arbitrarily excluded birds, mice and rats from regulations. The USDA also has a manual that includes policies issued by APHIS/Animal Care<sup>7</sup>, which clarify the regulations that pertain to the AWA. These policies include issues such as painful/distressful procedures (Policy #11) and veterinary care (Policy #3).

The Animal Care division inspects each institution that conducts research on warm-blooded animals (except those that perform research on birds, mice and/or rats only) annually as a means of enforcing AWA requirements. The Animal Care division

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<sup>2</sup> Animal Welfare Information Center, National Agriculture Library, USDA, Animal Welfare Act Interpretive Summaries, "A Quick Reference to the Requirement for the Exercise of Dogs Under the Animal Welfare Act," *available at* <<http://www.nal.usda.gov/awic/legislat/awabrief.htm#Q10>>, March 6, 2001.

<sup>3</sup> *Id.* at "A Quick Reference to the Requirement for Environmental Enhancement for Primates Under the Animal Welfare Act," *available at* <<http://www.nal.usda.gov/awic/legislat/awabrief.htm#Q9>>, March 6, 2001.

<sup>4</sup> Animal and Plant Health Inspection Service, USDA, Animal Welfare; Draft Policy on Environment Enhancement for Nonhuman Primates, 64 Fed. Reg. 38,145 (July 15, 1999), *available at* <<http://www.aphis.usda.gov/ac/ee.html>>.

<sup>5</sup> Animal Care, Animal and Plant Health Inspection Service, USDA, <<http://www.aphis.usda.gov/ac/>>.

<sup>6</sup> 9 C.F.R. §§ 1.1 et seq., *available at* <[http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=66cfe3b1538f7e9a769e855f5f99630d&c=ecfr&tpl=/ecfrbrowse/Title09/9cfrv1\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=66cfe3b1538f7e9a769e855f5f99630d&c=ecfr&tpl=/ecfrbrowse/Title09/9cfrv1_02.tpl)>.

<sup>7</sup> Animal Care, Animal and Plant Health Inspection Service, USDA, Animal Care Policy Manual, *available at* <<http://www.aphis.usda.gov/ac/polmanpdf.html>>.

also oversees the IACUC activities at each institution. If violations of the AWA are found during an inspection, the inspector can choose to give the facility a warning. If it is found at the next inspection that improvements have not been made, the facility may receive penalties, including monetary fines. However, there have been cases in which facilities have received numerous warnings and fines, but are still allowed to operate; meanwhile, the animals are forced to live in conditions that don't even meet minimum standards. Finally, USDA inspections are supposed to be unannounced, but we have personally observed that research institutions are often alerted (either by the inspectors themselves, or other labs in the area) as to when inspections will occur.

Each institution must also file an annual report to the USDA. The annual report requires that the number of species used be categorized according to whether or not the animals were subjected to pain and distress, and if so, whether or not anesthetics or analgesics were given. Currently, changes to the pain and distress categorization system are being considered. You can read the 1998 through 2002 USDA annual reports submitted by registered facilities.<sup>8</sup> Check the USDA's web site for a list of all institutions currently registered with the USDA.<sup>9</sup>

## The Role of the Public Health Service

The Health Research Extension Act (HREA)(P.L. 99-158)<sup>10</sup> was passed in 1985 and pertains to the care and treatment of animals used in research that is funded by the Public Health Service. The Public Health Service consists of the National Institutes of Health (NIH), the Food and Drug Administration, the Centers for Disease Control and eight other agencies. NIH is the lead institution with regard to funding of animal research. As a result of the HREA, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals<sup>11</sup> was written. The US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training<sup>12</sup> were also created in 1985. These principles were adopted by federal government agencies that either develop requirements for or sponsor procedures involving the use of vertebrate animals.

The Office of Laboratory Animal Welfare<sup>13</sup> at NIH is responsible for the administration and coordination of PHS Policy, which applies to all vertebrate animals

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<sup>8</sup> AC, APHIS, USDA, Animal Care Publications and Policy, *available at* <<http://www.aphis.usda.gov/ac/publications.html>>.

<sup>9</sup> *Id.*, scroll down to "Facility Lists."

<sup>10</sup> Pub. L. No. 99-158 (1985), *available at* <<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>>.

<sup>11</sup> Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (OER), National Institutes of Health (NIH), Public Health Service Policy on Humane Care and Use of Laboratory Animals, August, 2002, *available at* <<http://grants.nih.gov/grants/olaw/references/phspol.htm>>.

<sup>12</sup> OLAW, OER, NIH, US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, *available at* <<http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples>>.

<sup>13</sup> OLAW, OER, NIH, *available at* <<http://www.grants.nih.gov/grants/olaw/olaw.htm>>.

(unlike USDA regulations). In 1996, the Institute for Laboratory Animal Research (ILAR)<sup>14</sup> published a reference of recommendations on animal care and use entitled the Guide for the Care and Use of Laboratory Animals, (often referred to as "the Guide").<sup>15</sup> The first edition was published 1963 and was entitled Guide for Laboratory Animal Facilities and was also referred to as "the Guide." PHS Policy mandates that institutions use the Guide as a basis for developing and implementing an animal care and use program.

Those institutions receiving funding from NIH are required to sign statements of assurance, form IACUCs to oversee all PHS-funded research at the institution, and follow PHS Policy and the US Government Principles. Check OLAW's web site for a list of domestic institutions that have an animal assurance on file at OLAW.<sup>16</sup> The NIH also maintains a database, referred to as CRISP (Computer Retrieval of Information on Scientific Projects),<sup>17</sup> of all research that is PHS-funded (taxpayer dollars) and allows you to search by institution, name of investigator, subject and so on.

The PHS-mandated IACUCs fulfill a role similar to that of AWA-mandated IACUCs (see the IACUC Guidebook).<sup>18</sup> PHS Policy requires that the IACUC consist of at least five members and must include a veterinarian, a scientist experienced in animal research, a member who is involved in a nonscientific area and a member who is not affiliated with the institution. The IACUCs must review the institution's program and animal facilities (using the Guide as the basis for evaluation) at least once every six months. A report of meetings and inspections, which includes recommendations regarding deficiencies, is prepared for the Institutional Official (person who signs the institution's statement of assurance). OLAW is informed annually of the dates of the semiannual inspections and the dates the reports were submitted to the Institutional Official. These reports must be made available to OLAW upon request; however, these documents are not made available to the public upon request if the institution in question is not a government-funded institution. PHS may also perform spot checks on occasion or evaluate allegations of noncompliance with PHS Policy. Violations of PHS policy could result in withdrawal of funding.

## Conclusion

In conclusion, standards pertaining to the Animal Welfare Act are written and enforced by the USDA. All institutions that conduct research on warm-blooded animals, with the exception of birds, mice and rats, are required to abide by the

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<sup>14</sup> Institute for Laboratory Animal Research (ILAR), *available at* <<http://dels.nas.edu/ilar>>.

<sup>15</sup> ILAR, National Research Council, Guide for the Care and Use of Laboratory Animals, (National Academies Press, Washington DC, 1996), *available at* <<http://www.nap.edu/readingroom/books/labrats/>>.

<sup>16</sup> OLAW, OER, NIH, Domestic Institutions with a PHS Approved Animal Welfare Assurance, *available at* <<http://grants.nih.gov/grants/olaw/assurance/300index.htm>>.

<sup>17</sup> Computer Retrieval of Information on Scientific Projects, OER, NIH, *available at* <<http://crisp.cit.nih.gov/>>.

<sup>18</sup> OLAW and Applied Research Ethics National Association (ARENA), Institutional Animal Care and Use Committee Guidebook, 2002, *available at* <<http://grants.nih.gov/grants/olaw/Guidebook.pdf>>.

Animal Welfare Act. All institutions performing research on vertebrate animals with funding from the Public Health Service (taxpayer dollars) must follow PHS Policy and the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. The Office of Laboratory Animal Welfare of the NIH enforces PHS policy. Finally, those institutions that receive PHS funding and conduct research on warm-blooded species besides birds, mice and rats are monitored by and must comply with both USDA and NIH regulations and policies.