

Answers to questions on notice

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The regulation of the use of animals in research differs slightly from the situation in NSW. However, the end result is largely the same. Regulation is covered by one law as well as PHS policy for research covered by funds from federal agencies. This includes the Animal Welfare Act and the Public Health Service Policy on Humane Care and Use of Laboratory Animals. In addition the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training provide an ethical framework that underlies all U.S. laws governing the treatment of animals. In addition, many institutions participate in a private program for accreditation of animal care programs, the AAALAC International.

Animal Welfare Act

The Animal Welfare Act (AWA) regulates the use of most warm-blooded vertebrates in research, teaching and testing. This includes guinea pigs, rabbits, hamsters, cats, dogs, non-human primates and farm animals when used in medical research. As distinct from the situation in NSW, rats, mice and birds that were bred for research are excluded from the AWA. However, these are covered either under the PHS Policy or through AAALAC, International accreditation. (See below.) The U.S. Department of Agriculture enforces the AWA, ie it is a Federal not a State act

Public Health Service Policy (PHS) on Humane Care and Use of Laboratory Animals

Institutions that seek funds from federal agencies for research with *any* vertebrate animals must follow the PHS Policy on Humane Care and Use of Laboratory Animals. This applies to all the animals covered under the AWA as well as purpose-bred rats, mice and birds and cold-blooded vertebrates such as fish and reptiles. To qualify for federal funding, institutions must follow the *Guide for the Care and Use of Laboratory Animals* and provide an Assurance document describing their program for the care and oversight of research animals. NIH's Office of Laboratory Animal Welfare (OLAW) enforces the PHS Policy.

Institutional Animal Care and Use Committees

The AWA and the PHS Policy both require that proposals for research involving animals must be reviewed and approved in advance by an Institutional Animal Care and Use Committee (IACUC), similar to our Animal Research Ethics Committee. This is composed of scientists, at least one veterinarian and someone who is unaffiliated with the institution. Whilst it is the overall responsibility of the IACUC there is not a requirement to have members specifically appointed to represent animal welfare. The IACUC determines whether or not the use of animals is necessary and makes certain that researchers have made appropriate plans to minimize the animals' pain and distress. IACUCs must approve of a study before it can begin and they have the authority to halt ongoing research if they find it no longer in compliance.

AAALAC, International

AAALAC, International, is a private organization that provides independent, voluntary accreditation for animal care programs in industry, academia, and government. To earn AAALAC accreditation, institutions must demonstrate that they have a rigorous care and use program for all vertebrate animals that meets the standards set forth in the *ILAR Guide*. AAALAC accreditation is broadly accepted in industry and academia as an indicator of excellence in animal care.

Differences Between US and NSW. The overall objective in both jurisdictions is to ensure that there is appropriate care and use of animals in research. There is no evidence, that I am aware of, that animal welfare is less in the US than in NSW. The major difference is that the majority of medical research falls under PHS policy and is administered by the National Institute of Health's Office of Animal Welfare (the equivalent of our NHMRC). This ensures that the regulations are line with modern research practice and technologies. Also there is a

de facto assumption within the NIH that animals research is an essential and necessary component of medical research. It is worth noting that the US leads the world in basic as well as applied medical research and as a result has the greatest success in the commercialisation of its research investment. When comparing NSW and US regulatory framework there is a general acceptance that it is more straight forward and less bureaucratic in the US.

References:

<https://olaw.nih.gov/policies-laws/phs-policy.htm>

<https://www.physiology.org/career/policy-advocacy/animal-research/how-animal-research-is-regulated?SSO=Y>

Signed:

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