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General

- [The Institutional Animal Care and Use Committee \(IACUC\)](#)
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The Institutional Animal Care and Use Committee (IACUC)

(Excerpted from National Institutes of Health (1992). *Institutional Animal Care and Use Committee Guidebook*, NIH Publication no. 92-3415. Washington, D.C.: U.S. Government Printing Office.) The full text of this document is available at <http://grants1.nih.gov/grants/olaw/GuideBook.pdf>

A-2. Authority, Composition and Functions

Each institution which falls under authority of the AWA and/or receives PHS support for research and teaching involving laboratory animals must operate a program with clear lines of authority and responsibility, a properly functioning Institutional Animal Care and Use Committee (IACUC), procedures for self monitoring, adequate veterinary care, a program of occupational health, sound animal husbandry practices, and appropriate maintenance of facilities for housing animals.

The IACUC also monitors the use of animals in teaching activities as specified in the USDA Regulations, but this does not come under the Policy, unless it is supported by PHS.

The IACUC must have at least five members, including a veterinarian with program responsibilities, a scientist experienced in laboratory animal research, a non-scientist and an individual who has no other affiliation with the Institution besides membership in the IACUC. The IACUC must have the full support of the Institutional Official responsible for the program; evaluate the entire program every six months; prepare a report on the evaluation and the inspection of the facilities which is to be filed with the Institutional Official; and make recommendations to this Official concerning deficiencies, with a proposed timetable for corrections. The IACUC has the authority to suspend PHS-supported research activities.

The IACUC has an obligation to review all research projects, proposed for PHS support, prior to their receiving funding. A written report of this review confirms that the project will be conducted in accordance with PHS Policy, the Guide and the AWA. At least one member of the Committee must review each proposal, but all members must have prior opportunity to request full Committee review. The IACUC has authority to approve, require modifications before approval, or withhold approval of proposals submitted to it for review. No activity involving animals can begin unless it is first approved by the IACUC.

The frequency of IACUC consideration of approved, ongoing activities is one of the few areas in which PHS and USDA have differing requirements, i.e., PHS requires it at least once every three years, whereas USDA requires it annually. Ideally, institutions should choose to establish a uniform mechanism which satisfies both federal requirements. In deliberating this issue it is helpful to refer to consideration of ongoing activities by the use of the term

"annual review" as opposed to the function of the IACUC performed at the outset of a new activity and at the expiration of an approved activity, referred to as "review." OPRR has interpreted PHS Policy to require an institutional process which provides review of proposed activities, with committee approval for a specified period of time generally not to exceed three years. This "initial renewal review" and approval may be accomplished by either convened Committee action or by a "designated reviewer/expedited review" process which meets the PHS Policy requirements... During this period of approval, annual review must be accomplished to meet USDA requirements. The purpose of annual review is to confirm that no changes have taken place in the approved activity which might require further consideration by the IACUC, and to ensure that any new requirements of PHS, USDA or the institution are transmitted to the investigator. Annual review need not require a convened IACUC or designated reviewer/expedited action but must be adequately documented. Planned modifications must be brought to the attention of the IACUC prior to initiation. A relatively simple mechanism to meet USDA requirements is the annual circulation of a standard form giving current basic IACUC information, e.g., approval number, date, title, species, etc., to all investigators with IACUC-approved activities. The investigator then notes that either no changes have taken place, or he/she describes any changes which have occurred. The IACUC may then separate responses, filing those indicating no changes and passing along the remainder to an IACUC-designee for assessment of the changes reported. Any changes to the approved activity which are deemed of sufficient magnitude to merit further consideration may then be presented to the IACUC. All of these dispositions should be documented as official IACUC actions.

Table I: Federally Mandated IACUC Functions

- 1. Review, at least once every 6 months, the research facility's program, using USDA Regulation/Guide as basis.
- 2. Inspect, at least once every 6 months, all of the animal facilities, including animal study areas/satellite facilities, using USDA Regulations/Guide, as basis.
- 3. Prepare reports of IACUC evaluations and submit the reports to the Institutional Official.
- 4. Review and investigate legitimate concerns involving the care and use of animals at the research facility resulting from public complaints and from reports of non-compliance received from facility personnel or employees.
- 5. Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities or personnel training.
- 6. Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals.
- 7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.
- 8. Suspend an activity involving animals when necessary; take corrective action and report to funding agency and USDA.

Bibliography

Allen, T. (1992). *Animal Care and Use Committees, Special Reference Brief 92-16*. Beltsville, Maryland: Animal Welfare Information Center, National Agricultural Library, 45 p.

NAL call number: aS21.D27S64

Descriptors: animal welfare, bibliographies, committees, protocol review.

American Medical Association (1991). **Use of animals in medical education.** *JAMA, The Journal of the American Medical Association* 266(6): 836.

NAL call number: 448.9 Am37

Descriptors: laboratory animals, usage, physicians, ACUC.

Animal Rights, the Threat to Research. The New Research Environment Foundation for Biomedical Research, Washington, DC; 2 videocassettes (VHS) (44 min., 28 sec.) 1987. In cooperation with John Hopkins University School of Medicine. CT: Tape 1. The animal rights movement: The threat to research. (14 min.) -- Tape 2. pt. 1. The animal care and use committee. -- pt. 2. Common procedures & techniques. -- pt. 3. Survival surgery. (30 min.).

NAL call number: Videocassette no. 194

Descriptors: animal experimentation, animal models in research, law and legislation, animal welfare.

Baker, H.J. (1987). **Essential functions of animal care and use committees.** *Laboratory Animal Science* 37(special issue): 30-34.

NAL call number: 410.9 P94

Descriptors: animal welfare, conferences, organizations, animal experiments, projects.

Benedict, R.C. (1987). **University of Southern California model for the humane care and utilization of animals in research and teaching.** *Laboratory Animal Science* 37(special issue): 90-92.

NAL call number: 410.9 P94

Descriptors: animal welfare, animal research, ethics.

Berne, T.V., W.M. Blackmore, D. Marsh, E. Horowitz, M.J. Baker, J.D. Peck, J.W. Robb, and B. Berry (1987). **The University of Southern California's committee in action.** *Laboratory Animal Science* 37(special issue): 81-89.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal experiments, ethic, universities, ACUC.

Britt, D. (1986). **Conference report - Institutional Animal Care and Use Committees.** *Alternatives to Laboratory Animals: ATLA* 13(3): 236-239.

NAL call number: Z7994 L3A5

Descriptors: animal research, review boards, evaluations.

Dell, R.B. (1987). **Institutional Animal Care and Use Committee at Columbia University's Health Sciences Division.** *SCAW Newsletter* 9(4): 3-4.

NAL call number: QL55 N48

Descriptors: animal welfare, laboratory animals.

Geraci, J.R. and D.H. Percy (1987). **Are animal care and use committees really needed?** *Laboratory Animal Science* 37(special issue): 111-112.

NAL call number: 410.9 P94

Descriptors: animal welfare, research institutions, animal experiments.

Goodpasture, J. (1987) **Animal care committees in the pharmaceutical industry.** *Laboratory Animal Science* 37(special issue): 132-133 (January 1987).

NAL call number: 410.9 P94

Descriptors: animal welfare, laboratory animals, pharmacy.

Hannah, H.W. (1997). **The statutory offense of cruelty to animals.** *Journal of the American Veterinary Medical Association* 211(1): 47-48.

NAL call number: 41.8 Am3

Descriptors: animal welfare, veterinary jurisprudence, legislation.

Haywood, S., S.R.L. Clark, and D. Judson (1985). **Ethical committees and animal experimentation.** *Veterinary Record* 117(18): 479.

NAL call number: 41.8 V641

Descriptors: animal welfare, research, ACUC.

Haywood, S. (1984). **The role of the ethical committee in biomedical research.** *Alternatives to Laboratory Animals: ATLA* 11(4): 226-228.

NAL call number: Z7994 L3A5

Descriptors: animal experiments, medical research, ethics, regulations, animal welfare, ACUC.

Institutional Animal Care and Use Committees (1986). *Alternatives to Laboratory Animals: ATLA* 14(2): 96-99.

NAL call number: Z7994 L3A5

Descriptors: laboratory animals, animal welfare, animal research, guidelines.

Johnston, N. E. (ed.) (1995). **Animals in Science Conference, perspectives on their use, care and welfare: proceedings, April 1995,** Research Ethics Unit, Clayton, Victoria, Australia: The Unit, 262 pp.

NAL call number: HV4704.A56 1995

Descriptors: animal welfare, laboratory animals, animal experimentation.

Kelly, J.A. (1986). **Animal care committees: Changing their long-standing role as research rubber stamps.**

PsyETA - Psychologists for the Ethical Treatment of Animals Bulletin 8(2): 2-5.

NAL call number: HV4701.B85

Descriptors: review, animal welfare, experiments, ACUC.

King, F.A. (1987). **A primate research center perspective: Animal Care and Use Committees.** *Laboratory Animal Science* 37(special issue): 134-136.

NAL call number: 410.9 P94

Descriptors: animal welfare, laboratory animals.

Massachusetts Institute of Technology (1993). **Animal care matters.** Video, Cambridge, Massachusetts: Massachusetts Institute of Technology, 25 minutes.

NAL call number: Videocassette no. 2194

Abstract: Explores the issues surrounding experimentation on animal subjects through interviews with veterinarians, researchers, and animal rights activists, and provides an introduction to community oversight of animal research..

Descriptors: animal experimentation, laboratory animals, research, committees.

McKelvie, D.H. (1987). **Perspective of a small institution.** *Laboratory Animal Science* 37(special issue): 125-126.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal experiments, guidelines, ACUC.

Mench, J.A. (1989). **Institutional animal care and use committees: Making them responsible and responsive.** In *Animal Care and Use in Behavioral Research: Regulations, Issues, and Applications* J.W. Driscoll (ed.), Beltsville, Maryland: United States Department of Agriculture/National Agricultural Library, pp. 15-22.

NAL call number: aHV4762 A3A64

Descriptors: federal regulations, training, peer review, ACUC.

Morton, D. (1992). **A fair press for animals.** *New Scientist* 134 (1816): 28-30.

NAL call number: 472 N42

Descriptors: animal experiments, ethics, animal welfare, animal husbandry, tips for improving scientific writing.

New York Academy of Sciences (1997). **The use of animals in research and testing.**

In *Background readings for the joy of experimental psychology (3rd ed.)*, Dubuque, Iowa: Kendall/Hunt Publishing Co., pp. 24-29.

Descriptors: animal welfare, ethics, animal models, regulations, duplication of research, pain, distress, euthanasia, animal disposal, research, education.

Olson, H.M., T.E. Eurell, S.J. Hermansky, and A.K. Hubbard(1996). **From teachers to toxicologists: answering the tough questions about animal research.** *Fundamental and Applied Toxicology* 34 (1): 5-14.

NAL call number: RA1190.F8

Descriptors: toxicology; animal research, public relations, communication

Parker, H.R. (1974). **Report from the Committee on Animal Care and Experimentation (American Physiological Society).** *Physiologist* 17(2): 133-134.

NAL call number: 447.8 P564

Descriptors: laboratory animals, research, cats, dogs, physiology, ACUC.

Prentice, E.D. and L. Krulisch (1996). **Scaw study of IACUC activities in the U.S.** *The Johns Hopkins Center for Alternatives to Animal Testing Newsletter* 13(2): 6-7.

NAL call number: HV4701.J6

Descriptors: animal welfare, committees, organizations, surveys.

Public Responsibility in Medicine and Research (1997). **Educational materials for animal care and use in a changing research environment , ethics, technology, accountability, and efficiency: March 17-18, 1997: the San Diego Princess Resort, San Diego, California sponsored by Public Responsibility in Medicine and Research (PRIM&R) and co-sponsored by Office for Protection from Research Risks, NIH.** Boston, Massachusetts: Public Responsibility in Medicine and Research, 415 p.

NAL call number: HV4913.E38 1997

Descriptors: animal experimentation, laboratory animals, animal welfare, training, committees.

Rankin, J.D. (1986). **Comment on ethical committees.** *Acta Physiologica Scandinavica* 128(554): 169-171.

NAL call number: QP1 A2 Suppl

Descriptors: animal welfare, ethics, inspection, cruelty, ACUC.

Snyder, M. D. *et al.* (1992). **Animal care and use committees.** *Science-Teacher* 59(2): 28-35.

Abstract: Describes the structure, activities, responsibilities, and practices of animal care and use committees established to review classroom activities and student research using animals. Provides six hypothetical situations with suggested solutions to test a committee's decision-making ability. Includes a proposed activity form for teachers.

(MDH)

Descriptors: biological sciences, science activities, science education, secondary education, secondary school science, advisory committees animal husbandry, ethics, laboratory animals, science instruction, student research.

Snyder, M.D., N.K. Hinton, J.F. Cornhill, and L.E. Elfner (1992). **"Animal care use committees: Deciding what is appropriate, necessary, and humane."** *Science Teacher* 59(2): 28.

Descriptors: animal models in research, management, science teachers, ACUC.

Sweet, J.F.R. (1985). **Ethical committees and animal experimentation.** *Veterinary Record* 117(18): 479.

NAL call number: 41.8 V641

Descriptors: college, research, experimental animals, ACUC.

Wust, C.J. and P.W. Concannon (eds.) (1990). **Animal Research From the Perspective of the Institutional Animal Care and Use Committee.** *Animal Research, Animal Rights, Animal Legislation, Proceedings of Two Forums on the Use of Animals in Research Held at the Annual Meetings of the Society for the Study of Reproduction, Columbia, Missouri, USA, August 7, 1989 and Knoxville, Tennessee, USA, July 16, 1990*, Champaign, Illinois: Society for the Study of Reproduction, pp. 38-42.

NAL call number: QL876 S6

Descriptors: Animal Welfare Act, facilities, ethology, policy.

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Bibliography

Anderson, D., M.J. Reiss, and P.N. Campbell (1993). *Ethical issues in biomedical sciences, animals in research and education: proceedings of a national conference organized by the Institute of Biology's Biomedical Sciences and Education Divisional Committees, in collaboration with the British Toxicology Society held in London, October 1992* London: Institute of Biology, 103 pp.

NAL call number: HV4913.E84 1993

Descriptors: animal experimentation, animal rights, animal welfare.

Appleby, M.C. (1998). **Genetic engineering, welfare, and accountability.** *Journal of Applied Animal Welfare Science* 1(3): 255-273.

NAL call number: HV4701.J68

Descriptors: experimental techniques, advisory committees, effects of genetic modification on welfare of individual animals, direct effects, side effects, husbandry and related effects, transgenics, effects on attitudes, farm animals used for agricultural products, farm animals used for biomedical products, laboratory animals, commercial exploitation, public perception, ethical evaluation, legislation and control.

Balls, M.. (1995). **Chimpanzee medical experiments: moral, legal and scientific concerns.** *Alternatives to Laboratory Animals: ATLA* 23 (5): 607-614..

NAL call number: Z7994.L3A5

Abstract: FRAME's (Fund for the Replacement of Animals in Medical Experiments) role in drawing attention to the special scientific and ethical concerns raised by the use of non-human primates as laboratory animals is reviewed, with special emphasis on the FRAME/CRAE proposals to the British Government (1987) and the RSPCA/FRAME survey of research on non-human primates conducted in Great Britain between 1984 and 1988. Attention is then focused on the moral case and the scientific case against using chimpanzees as laboratory animals, with particular emphasis on research on AIDS. Finally, a call is made for universal agreement that no more laboratory experiments should ever be performed on chimpanzees.

Descriptors: chimpanzees, animal experiments, medical research, animal welfare, ethics.

Blatz, C. (1987). **Mad bears and innocent hares: Remarks toward a theory of diminished responsibility.** *Between the Species* 3: 3-11.

NAL call number: HV4701 B4

Descriptors: ethics, responsibility, animal experimentation, innocence.

Boothe, D.M., M.R. Slater, R.F. Playter (1992). **Ethical considerations in clinical research.** *Journal of the American Veterinary Medical Association* 200(11): 1616-1621.

NAL call number: 41.8 AM3

Descriptors: veterinary informed consent, laboratory animal care, animal welfare, guidelines.

Boyce, J.R. (1990). **Care and use of animals. Probing four views of animal use.** *Journal of the American Veterinary Medical Association* 196(9): 1368-9.

NAL call number: 41.8 Am3

Descriptors: animal welfare, ethics, veterinary medicine.

Britt, D. (1984). **Ethics, ethical committees and animal experimentation.** *Nature* 311(5986): 503-506.

NAL call number: 472 N21

Descriptors: public concern, research, animal welfare, ACUC.

Caplan, A.L. (1987). **Doing ethics by committee: Problems and pitfalls.** *Laboratory Animal Science* 37(special issue): 45-47.

NAL call number: 410.9 P94

Descriptors: animal welfare, animal experiments, ACUC.

Carriero A., A. Spinazzi A, and L. Bonomo (1996). **Ethics and research.** *European Radiology* 6 (2): 11-15.

Descriptors: animal welfare, ethics committees, guidelines, human experimentation, informed consent, research design.

Cheong, J. (1989). **The use of animals in medical education: A question of necessity versus desirability.** *Theoretical Medicine* 10: 53-57.

Descriptors: ethics, animal rights, medicine.

Cohen, C. (1995). **An ethical perspective on animal research.** *Journal of the American Veterinary Medical Association* 206 (4): 458-461.

NAL call number: 41.8 Am3

Descriptors: animal experiments, bioethics, animal welfare, moral values.

Cohen, B.J. (1981). **Animal rights and animal experimentation.** In *Rights and Responsibilities in Modern Medicine* M.D. Basson (ed.), New York: Liss Publishing, pp. 85-92.

NAL call number: R724.C6 1979

Descriptors: ethics, animal experimentation, alternatives.

de Cock Buning, T. (1998). **Xenotransplantation: A problematic world behind a glamorous facade.** *Journal of Applied Animal Welfare Science* 1(3): 275-281.

NAL call number: HV4701.J68

Descriptors: ethics, scientific problems, graft rejection, potential for development of zoonotic diseases, IACUC review, alternatives, animal suffering, isolation of animals, repeated blood and tissue sampling, immunosuppression, preclinical research, scientific goals, public perception, cost-benefit balance.

Donnelly, S. (1999). **How and why animals matter.** *ILAR Journal* 40(1): 22-28.

NAL call number: QL55 A1I43

Descriptors: moral concern, moral decision making, institutional policies, animals in different contexts, laboratories, home, wild, human involvement in the wild, Charles Darwin, Aldo Leopold, Alfred North Whitehead, Hans Jonas.

Donnelley, S. and K. Nolan (eds.) (1990). **Animals, Science, and Ethics.** *Hastings Center Report* 20(3Supp.): 1-32.

NAL call number: R724 H27

Descriptors: animal experimentation, anthropomorphism, bioethics, research, ACUC.

Donnelley, S. (1989). **Speculative philosophy, the troubled middle, and ethics of animal experimentation.** *Hastings Center Report* 19(2): 15-7.

NAL call number: R724 H27

Descriptors: animal experimentation, animal welfare, decision making, ACUC.

Dresser, R. (1989). **Measuring merit in animal research.** *Theoretical Medicine* 10(1): 21-34.

Descriptors: attitude of health personnel, disease models, ethics, peer-review, laboratory animals.

Dresser, R. (1988). **Standards for animal research: Looking at the middle.** *Journal of Medical Philosophy* 13: 123-143.

Descriptors: ethics, animal experimentation, standard, balance, utilitarianism.

Finsen, L. (1988). **Institutional animal care and use committees: A new set of clothes for the emperor?** *Journal of Medicine and Philosophy* 13(2): 145-158.

Descriptors: animal welfare, ethics.

Flemming, A.H. (1987). **Animal suffering: How it matters.** *Laboratory Animal Science* 37(special issue): 140-144.

NAL call number: 410.9 P94

Descriptors: animal welfare, pain, animal experiments, ACUC.

Fraser, D. (1996). **Animal ethics and animal welfare science: bridging the two solitudes.** *Proceedings of the 30th International Congress of the International Society for Applied Ethology: 14-17 August, 1996, Guelph, Ontario, Canada*, p. 3.

NAL call number: SF756.7.I57 1996

Descriptors: animal welfare, ethics.

Fraser, D., D.M. Weary, E.A. Pajor, and B.N. Milligan (1997). **A scientific conception of animal welfare that reflects ethical concerns.** *Animal Welfare* 6 (3): 187-205.

NAL call number: HV4701.A557

Descriptors: animal welfare, quality of life, ethics, values.

Galvin, S. L. and H.A. Herzog (1992). **The ethical judgment of animal research.** *Ethics and Behavior* 2(4): 263-286.

Descriptors: animal welfare, decision making, ethics, research, gender differences.

Gendin, S. (1991). **Reply to Stephenson on Biomedical Research.** *Between the Species* Winter: 9-11.

NAL call number: HV4701 B4

Descriptors: animal rights, biomedical research, ethics, ACUC.

Goodall, J. (1995). **Why is it unethical to use chimpanzees in the laboratory?** *Alternatives to Laboratory Animals: ATLA* 23 (5): 615-620.

NAL call number: Z7994.L3A5

Abstract: Chimpanzees are more like humans than any other living beings, differing in the composition of their DNA by just over one per cent. There are striking similarities in the anatomy and wiring of the chimpanzee and human brains and central nervous systems. Thus, it should not be surprising to find that there are also striking similarities in the social behaviour, emotional needs and expressions, and cognitive abilities of chimpanzees and humans. These similarities have become increasingly apparent during the last 15 years. Chimpanzees in the wild develop close affectionate bonds between family members that may persist throughout their lifetime of 50 years or more, and examples of true altruism, when individuals protect or even save the lives of non-related companions. Chimpanzees use many objects as tools, and tool-using behaviours differ from place to place across their range. Indeed, there are a number of behaviours that vary between different groups - evidence of cultural traditions passed from one generation to the next through observational learning and imitation. Thus chimpanzees have a very special relationship with humans. A healthy adult chimpanzee is more similar to a healthy adult human in the expression of the intellect than a brain-damaged human, yet in many medical research facilities, chimpanzees are maintained in bleak, bare cages measuring only 5' X 5' X 7'. They may remain in these prisons for life. We do not treat hardened human killers so badly in our society today - there would be a public outcry if we did. I feel strongly that the use of a being so like us, as a human guinea-pig, is not morally justified, and to that end the Jane Goodall Institute has been involved in three workshops with the, aim of clarifying the extent to which they are seen to be useful in diseases such as hepatitis and AIDS research. There is no consensus among scientists regarding their usefulness at the present time. If the proposed experiments of transplanting chimpanzee bone marrow tissue into AIDS patients go ahead in the Netherlands, it will be a sad blow for chimpanzee liberation. The attitude of those who believe that any use of non-human primates can be justified provided it results in some benefit, or expected benefit, to humankind, is of precisely the same mind set as that which once allowed us to exploit human

beings of another race and use them as slaves. Once we admit that chimpanzees have minds and feelings, are capable of sadness, fear and despair, are able to feel pain, show altruism, and are capable of communicating with each other and with humans in a man-made language, we have to ask serious questions, initially of ourselves, as to whether we should continue to use them in medical research.

Descriptors: chimpanzees, laboratory animals, animal experiments, medical research, animal welfare, ethics.

Haynes, R.P. (1996). **The muddled middle: the search for ethical principles to regulate the use of animals in research.** *Between Species* 12(1-2): 19-33.

Descriptors: laboratory animals, ethics, principles, biomedical research.

Herzog, H. (1996). **Ethical ambiguities and moral standing: practical lessons from animal care and use Committees.** *Lab Animal* 25 (6): 29-32.

NAL call number: QL55.A1L33

Descriptors: animal experiments, animal welfare, ethics, regulations.

Jamieson, D. (1993). **Ethics and animals: a brief review.** *Journal of Agricultural & Environmental Ethics* 6 (special suppl.1): 15-20.

NAL call number: BJ52.5.J68

Descriptors: animal welfare, ethics, animal behavior, philosophy.

Jennings, M. and S. Silcock (1995). **Benefits, necessity and justification in animal research.** *Alternatives to Laboratory Animals: ATLA* 23 (6): 828-836.

NAL call number: Z7994.L3A5

Abstract: The cost-benefit assessment in the Animals (Scientific Procedures) Act 1986 is said to ensure that animals are only used in experiments which are justified and necessary. The way in which the Home Office Inspectorate derives the cost-benefit assessment is explained in the Report of the Animal Procedures Committee for 1993. However, evaluation of both costs and benefits is largely subjective, as are concepts such as "necessity" and "justification". These concepts mean different things to different people in different places and at different times, depending on the pressures to which they are subject. These include the socio-economic climate and the context in which the proposed research is to be earned out. Animal use cannot, therefore, be said to be necessary and/or beneficial unless serious questions are answered with respect to who or what the research is necessary for, who or what will benefit from it and who defines the criteria used in the justification process. Retrospective analysis of whether the proposed benefit was actually achieved and applied is also important. Discussion regarding the necessity, benefits and justification of individual research projects, and of overall research goals or directions, tends to be obscured by the polarised debate over the morality and scientific validity of animal experiments as a whole. This paper raises some of the issues that could be discussed in a wider view of the cost-benefit assessment, with reference to selected areas of animal use as examples.

Descriptors: animal experiments, animal welfare, ethics, regulations.

Lehman, H. (1993). **Are value judgements inherent in scientific assessment?** *Journal of Agricultural & Environmental Ethics* 6 (special suppl.2): 60-67.

NAL call number: BJ52.5.J68

Descriptors: values, ethics, methodology.

McCarthy, C.R. (1995). **Ethical aspects of animal-to-human xenografts.** *ILAR Journal* 37 (1): 3-8.

NAL call number: QL55.A1I43

Descriptors: xenografts, organs, genetic engineering, transplantation, recipients, animal welfare, bioethics.

McCarthy, C.R. (1995). **How and why should IACUC's develop a code of ethics?** In *Current Issues and New Frontiers in Animal Research*, K.A.L. Bayne, M. Greene, and E.D. Prentice, (eds.), Greenbelt, Maryland: Scientists Center for Animal Welfare, pp. 31-33.

NAL call number: HV4913 C87 1995

Descriptors: arguments for and against IACUC's exercising leadership in developing a code.

Mephram, T.B. (1993). **Approaches to the ethical evaluation of animal biotechnologies.** *Animal Production*. 57 (pt.3):

353-359.

NAL call number: 49 An55

Descriptors: transgenic animals, animal welfare, biotechnology, bioethics.

Orlans, F. B. (1997). **Ethical decision making about animal experiments.** *Ethics Behavior* 7(2): 163-171.

Descriptors: laboratory animals, ethics, research, pain, distress.

Remfry, J. (1985). **Ethical committees and animal experimentation.** *Veterinary Record* 117(19): 508.

NAL call number: 41.8 V641

Descriptors: animal research, review, ethics, ACUC.

Rodenburg, F. (1997). **The ethical use of animals in research, teaching, and testing.** *CALAS/ACSAL* 31(4): 116-119.

NAL call number: SF405.5 C36

Descriptors: Canadian approach to ethical review, tools for ethical analysis, Dutch model, ethical scoring system, British model, biotechnology.

Rollin, B.E. (1993). **Animal welfare, science, and value.** *Journal of Agricultural & Environmental Ethics* 6 (special suppl.2): 44-50.

NAL call number: BJ52.5.J68

Descriptors: animal welfare, zoology, pain, stress, moral values, ethics.

Rollin, B.E. (1996). **Bad ethics, good ethics and the genetic engineering of animals in agriculture.** *Journal of Animal Science* 74(3): 535-541.

NAL call number: 49 J82

Abstract: Genetic engineers have been remiss in addressing ethical and social issues emerging from this powerful new technology, a technology whose implications for agriculture are profound. As a consequence of this failure, society has been uneasy about genetic engineering of animals and has had difficulty distinguishing between genuine and spurious ethical issues the technology occasions. Many of the most prominent concerns do not require a serious response. On the other hand, concerns about a variety of possible risks arising from genetic engineering of animals require careful consideration and dialogue with the public. Such concerns are an admixture of ethics and prudence. A purely ethical challenge, however, hitherto not addressed, is represented by problems of animal welfare that arise out of genetically engineering agricultural animals. A principle of "conservation of welfare" is suggested as a plausible moral rule to guide such genetic engineering.

Descriptors: animal welfare, genetic engineering, ethics, transgenic animals, risk, species differences, domestic animals.

Russow, L-M. (1999). **Bioethics, animal research, and ethical theory.** *ILAR Journal* 40(1): 15-21.

NAL call number: QL55 A1I43

Descriptors: ethical theory, moral reasoning, treatment of animals within traditional ethical theory, differential treatment of humans and animals, morally relevant differences, animal rights, animal welfare, animalwell-being.

Sideris, L., C. McCarthy, and D.H. Smith (1999). **Roots of concern with nonhuman animals in biomedical ethics.** *ILAR Journal* 40(1): 3-14.

NAL call number: QL55 A1I43

Descriptors: historical overview of animal protection, British origins, American origins, biomedical ethics, animal regulations, Silver Spring monkeys, University of Pennsylvania head trauma studies, 1985 amendments to the Animal Welfare Act, harmonization of Federal policies, guidelines and regulations.

Simpson, J. (1984-85). **Animal rights re-evaluated.** *Free Inquiry* 5: 37-40.

Descriptors: ethics, treatment, economics.

Smith, J.A. and M. Jennings (1998). **Ethics training for laboratory animal users.** *Laboratory Animals* 32(2): 128-136.

NAL call number: QL55.A1L3

Abstract: In the UK, all applicants for licences under the Animals (Scientific Procedures) Act 1986 must receive

training in ethical aspects of laboratory animal use. There is, however, considerable uncertainty about the aims, suitable content and most appropriate means of delivery of such training. In this review a series of aims for licensee training in ethics are proposed, the key content is described and possible approaches to delivering such training are critically evaluated. Ethics training, it is argued, should: (i) be rooted in practice, focusing on the practical application of the Act to licensees' own work and encouraging them to take all possible steps to reduce or resolve any moral conflicts which the work entails; (ii) promote discussion, encouraging licensees to challenge their own views and critically appraise their work; and (iii) provide the necessary theoretical background to inform and stimulate such discussion. A variety of means of generating discussion and a range of practical considerations are explored.

Stephenson, W. (1991). **Institutional Animal Care and Use Committees and the Moderate Position.** *Between the Species* Winter: 6-8.

NAL call number: HV4701 B4

Descriptors: animal rights, biomedical research, ethics, justification, value.

Sumner, L.W. (1988). **Animal welfare and animal rights.** *Journal of Medicine and Philosophy* 13:159-175.

Descriptors: ethics, animal experimentation.

Universities Federation for Animal Welfare (1972). **The Rational Use of Living Systems in Bio-Medical Research.**

Universities Federation for Animal Welfare: Hertfordshire, UK.

NAL call number: QL55 R37

Descriptors: ethics, animal experimentation, utility, vaccine, transplantation, feeling, reason, consent.

Webster, A.J.F. (1993). **Animal welfare: the five freedoms and the free market.** *BSAP occasional publication* (17): 45-49. In *The Series Analytic: Safety and Quality of Food from Animals*, J.D. Wood and T.L.J. Lawrence (eds.),

Proceedings of a symposium held June 1992 at Bristol.

NAL call number: SF5.B74

Descriptors: animal welfare, animal behavior, regulations.

Useful World Wide Web Sites

Guidelines for Ethical Conduct in the Care and Use of Animals

<http://www.apa.org/science/anguide.html>

Developed by the American Psychological Association's Committee on Animal Research and Ethics.

Center for Bioethics, University of Pennsylvania

<http://www.med.upenn.edu/bioethics/center>

A general site devoted to bioethics.

National Bioethics Advisory Commission

<http://bioethics.georgetown.edu/nbac/>

A government advisory body mainly concerned with research involving humans but has an interesting report on the science of animal cloning

National Reference Center for Bioethics Literature

<http://bioethics.georgetown.edu/nrc/>

The National Reference Center for Bioethics Literature (NRCBL), is a specialized collection of books, journals, newspaper articles, legal materials, regulations, codes, government publications, and other relevant documents concerned with issues in biomedical and professional ethics.

University of Minnesota, Research Animal Resources

<http://www.ahc.umn.edu/rar/ethics.html>

A brief article on the ethics of animal research and the use of alternative methods.

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Last updated March 11, 2002

IACUC Administration and Program Review

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IACUC Oversight of Animal Care and Use Program

Excerpted from the *Institutional Animal Care and Use Committee Guidebook* developed by Applied Research Ethics National Association and the National Institutes of Health. NIH Publication number 92-3415. The full text of this document is available at <http://grants.nih.gov/grants/olaw/guidebook.pdf>

C-1. Policies, Procedures and Responsibilities

Introduction

Under PHS Policy and USDA Regulations, the IACUC must inspect all institutional animal facilities every six months. These inspections provide an ongoing mechanism for ensuring that the institution maintains compliance with the applicable animal care and use policies guidelines and laws. They can also benefit programs for animal care by serving an educational function for the animal care personnel, research staff and IACUC members. Also, by giving the facility personnel a prior warning, the IACUC can assist an institution to prepare for subsequent visits by outside inspectors. The interaction of an IACUC and the animal care personnel at their institution should be constructive, and not adversarial, as both ultimately share the same goals of good animal care.

Staffing and Scheduling Inspection

The IACUC must schedule the inspections of facilities. This may be accomplished by assigning specific facilities to subcommittees which must contain at least two members as required by the USDA Regulations. No IACUC member should be excluded should he/she wish to attend a particular inspection, and additional ad hoc consultants may be used. The inspection team must have a working knowledge of the Guide and USDA Regulations in order to fully evaluate the facilities which are being inspected. Section C-2 of this Guidebook also provides general guidance in this regard. It is helpful for the team to have a prepared list of the categories to be inspected, such as sanitation, food and water provisions, animal identification, waste disposal, animal health records, environmental control, staff training, etc.

The IACUC may determine whether the supervisory personnel of various facilities should be notified of the date and time of an inspection. Advance notification allows individuals to be available to answer questions, but an unexpected visit shows the facility during usual operations.

Performing Inspections

An updated list of all facilities to be inspected should be maintained by the IACUC. All proposals submitted to the IACUC must contain details of all locations at which animal research is to be performed. The USDA Regulations require inspection of the centrally designated or managed animal resource facilities as well as any other animal containment facilities in which animals are kept for more than twelve hours. PHS Policy requires inspection of all surgical facilities and areas in which animals are maintained longer than 24 hours. It is helpful to keep a list of all facilities by room number, use, species and deficiencies noted in the last inspection. For satellite areas a contact person is useful. For facilities with multiple rooms, a map will assist the inspectors.

Notes should be taken throughout the visit to assist in preparation of the final report. Apparent deficiencies should be discussed with the person in charge of the facility to ensure that the team's perception of the situation is correct. In some cases an apparent deviation will be due to the experimental proposal in process, for example, withholding of food prior to surgery.

Documentation

After the visit a formal report is prepared. Any deficiencies must be categorized as minor or significant. The latter is defined, by USDA Regulations and PHS Policy, as one of significant threat to animal health or safety. A plan and timetable for correction of all deficiencies must be included in the final report. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic. If the institution is unable to meet the plan, the IACUC through the Institutional Official must inform Animal and Plant Health Inspection Service (APHIS) officials within fifteen working days of the lapsed deadline. If the activity is federally funded, the relevant agency also must be informed.

The report must be reviewed and approved by a quorum of the IACUC, and in cases involving USDA Regulations, be signed by all those who accept the report. Minority views should be included in the final document. A copy is then sent to the Institutional Official and must be kept on file for a minimum of three years. It is often useful for the report to be delivered in person in order to emphasize the findings and plans for action. Annually, the institution must notify OPRR of the dates of the semiannual inspections and the dates the report was submitted to the Institutional Official.

Program Evaluation

Both the PHS Policy and USDA Regulations include a requirement that semiannually the IACUC conduct an evaluation of the animal care and use program. Neither of these documents includes specific guidance regarding the mechanisms or procedures to employ in conducting this evaluation. OPRR has recommended that institutions use the Table of Contents of the Guide, exclusive of the facility and physical plant chapters, as an outline for program evaluation. The USDA Regulations refer institutions to other portions of those Regulations as a basis on which to conduct this program evaluation.

Key aspects of an animal care and use program that should be emphasized in the semiannual evaluation include IACUC functions and procedures, including proposal review practices, provisions for dealing with whistle blower" or other concerns regarding animal care and use, and the procedures employed to meet reporting requirements. In addition, the institution's occupational health program, veterinary care procedures and personnel qualification review process should be evaluated. Specific procedures to accomplish program evaluation may include presentations by appropriate individuals, e.g., the institutional veterinarian, occupational health personnel, etc. Written institutional policies such as standard operating procedures may be reviewed and modified if necessary.

Program evaluation deals principally with administrative aspects of the animal care and use program. In most instances these aspects will not change nor need to be modified with the same aspects of the facility or physical plant. Thus, when large changes are made in program aspects, a comprehensive evaluation by the committee should be conducted, while the review of that aspect six months later may be merely a brief evaluation of its implementation to date. Ongoing review of established practices allows the opportunity for institutions to detect a gradual change in practices from written procedures, thereby allowing modification of one or the other as appropriate. Institutions that are AAALAC accredited will find their pre-site visit package helpful in identifying areas for inclusion in the semiannual

evaluation.

Occupational Health

Purpose of Occupational Health Programs

The health of individuals working in animal care Programs is an area of institutional concern. PHS Policy and the Guide identify the need for an occupational health program for all personnel who work in laboratory animal facilities or who have substantial animal contact. The emphasis of such a program is the prevention of illness, but it also includes provisions for early diagnosis and treatment when such illnesses occur.

Elements of an Occupational Health Program

An effective program will have the following components: 1) replacement medical evaluation; 2) periodic medical surveillance; 3) educational component; 4) provisions for treating illness or injury; and 5) provisions for consultation with other professional staff. The specific elements will be dictated by the extent and nature of the employee's exposure [see table].

Replacement and periodic medical evaluations: Replacement evaluations are conducted to ensure that the individual is capable of the demands and exposure of the job, and also to provide a medical reference baseline. The evaluation may include: clinical history, physical examination, spirometry, baseline tests such as TB test and serum sample collection, appropriate immunizations, educational/instructional component and appropriate feedback to the employee on all test results. Specific tests will depend on the species of animals and the nature of the procedures employed.

Periodic evaluations allow detection of early stages of disease, updating of immunizations and a re-evaluation of medical restrictions.

A uniformity in the evaluation of different individuals and the same person at different times is important to enable accurate comparisons to be made. These comparisons may allow a possible problem to be identified and corrected before it becomes a major health hazard.

Education

There are ethical and legal requirements to inform individuals of health risks and precautions which affect them. This must be part of an employee's overall orientation and job training. Some institutions rely on formal courses.

Bibliography

Barber, A.A (1987). **University administration of animal care and use programs.** *Laboratory Animal Science* 37(special issue): 93-96.
NAL call number: 410.9 P94
Descriptors: animal welfare, administration, policy, animal experiments.

Bascom, R. (1997). **Developing and implementing personnel safety programs Part 1: Occupational health and safety program in a research animal facility.** *Lab Animal* 26(6): 23-26.

NAL call number: QL55 A1L33

Descriptors: five key institutional activities, administration support for health and safety programs, hazard recognition, institutional trends for health and safety, who is at risk, developing and implementing a work plan, control strategies, tracking program effectiveness.

Bowman, P.J. (1991). **A flexible occupational health and safety program for laboratory animal care and use programs.** *AALAS Bulletin* 30(6): 15-17.

NAL call number: SF405.5 A23

Descriptors: zoonoses, PHS policy, factors likely to dictate type and degree of hazards, list of type of personnel that should be included in program, categories of risk, facets of an occupational health program timelines for physical exams, TB skin tests, chest x-rays, immunizations, serum banking, allergies, injuries, Q Fever.

Bowne, G.W. (1999). **Financial management in an animal research facility.** *Lab Animal* 28(1): 33-37.

NAL call number: QL55 A1L33

Descriptors: budget development and maintenance, cost analysis, review of major costs in an animal facility, expenditures, income, equipment and amortization, tracking and monitoring costs, Circular A-2, basic points for saving money, repairing a deficit.

Carey, R. (1990). **Public responsibility in medicine and research conference on administration, education and the animal care committee.** *Journal of Medical Primatology* 19(1): 75-6.

NAL call number: QL737 P9J66

Descriptors: animal welfare, legislation and jurisprudence, laboratory animals, research, ACUC.

Donnelly, T.M. (1996). **Hazardous chemicals and anesthetics in the laboratory animal facility.** *Lab Animal* 25(4): 39-41.

NAL call number: QL55 A1L33

Descriptors: list of commonly used hazardous chemicals and anesthetics, xylene, DMSO, picric acid, formaldehyde, peracetic acid, chloroform, ether, halothane, nitrous oxide, urethane, common use of each compound in the lab, hazards associated with chemicals, recommended protective action, miscellaneous information about each chemical.

Driscoll, J.W. and T.C. Rambo (1989). **Forming an IACUC at a small institution.** In *Animal Care and Use in Behavioral Research: Regulations, Issues, and Applications* J.W. Driscoll (ed.), Beltsville, Maryland: U.S. Department of Agriculture/National Agricultural Library pp. 23-28.

NAL call number: aHV4762 A3A64

Descriptors: universities, regulatory requirements, committee responsibility, ACUC.

Ellenberger, M.A., and B.F. Corning (1999). **The animal care and IACUC offices: United or divided?** *Lab Animal* 28(1): 44-47.

NAL call number: QL55 A1L3

Descriptors: missions of an animal care program and the IACUC, animal care office, administrative support, advantages and disadvantages of separate vs combined animal care and IACUC offices, factors involved in determining the suitability of program for a facility, recommendations for an effective and efficient IACUC.

Fox, J.G. (1987). **Gaining institutional support.** *Laboratory Animal Science* 37(special issue): 115-117.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal welfare, animal experiments, ACUC.

Gordon, B (1987). **Unique problems of animal care and use in small institutions.** *Laboratory Animal Science* 37(special issue): 127-128.

NAL call number: 410.9 P94

Descriptors: animal welfare, research institutes, animal experiments.

Green, R.J. (1997). **Developing and implementing personnel safety programs part II: Safety training and education in animal research.** *Lab Animal* 26(6): 27-29.

NAL call number: QL55 A1L33

Descriptors: management responsibility, dealing with time constraints, on-site training, providing regular updates, modular courses, maximizing class time, pre-class assignments, employee interaction, distance learning, computer-based training, top 10 training tips.

Hassall, G. (1999). **Committees and conflict resolution.** *ANZCCART News* 12(1): 1-3.

NAL call number: SF405.5 A3

Descriptors: conflict resolution, definitions, disputes, conflicts, conflict resolution continuum, mediation, skills, listening, empathizing, assertiveness, timeliness, mapping, strategies for resolving conflicts.

Herscowitz, H.B. (1987). **Institutional responsibilities.** *Laboratory Animal Science* 37(special issue): 118-119.

NAL call number: 410.9 P94

Descriptors: animal welfare, laboratory animals, ACUC.

Hiiemae, K., H. Rozmiarek, J.F. Williams, J.E. LeBeau, and M. Ross (1987). **Report of a panel discussion on how to run an effective Animal Care and Use Committee.** *Laboratory Animal Science* 37(special issue): 39-44.

NAL call number: 410.9 P94

Descriptors: animal welfare, animal experiments, policy, institutions.

Hittelman, J. (1987). **Operating principles for committees on animal research.** *Laboratory Animal Science* 37(special issue): 97-100.

NAL call number: 410.9 P94

Descriptors: animal welfare, institutions, ACUC.

Holden, F. (1997). **Alternatives committee established at Indiana.** *The Johns Hopkins Center for Alternatives to Animal Testing Newsletter* 14(3): 6-7.

NAL call number: HV4701 J6

Descriptors: subcommittee to IACUC, communications between researchers and campus animal protectionists, monthly round table, institutional support at highest levels, membership includes information specialists, public relations/education representative, departmental representatives, IACUC liaison, animal protectionist, veterinarian, research assistant.

Holt, M.A. (1996). **Institutional animal care and use issues: creativity and innovation.** *The Johns Hopkins Center for Alternatives to Animal Testing Newsletter* 13(2): 12-13.

NAL call number: HV4701.J6

Descriptors: animal welfare, committees, innovations.

Institute of Laboratory Animal Resources (U.S.), Committee on Occupational Safety and Health in Research Animal Facilities (1997). **Occupational health and safety in the care and use of research animals.** Washington, DC:

National Academy Press, 154 p. This document is available at <http://books.nap.edu/books/0309052998/html/index.html>

NAL call number: RC965.A6O23 1997

Descriptors: Laboratory animal technicians, health risk assessment, animal health technicians, occupational diseases, prevention, guidelines, program design and management, physical, chemical, and protocol-related hazards, allergens, zoonoses, principal elements of an occupational health and safety program, occupational health care services.

James, M.L., L.A. Mininni, and L.C. Anderson (1995). **Establishment of an animal alternatives committee.** *Contemporary Topics in Laboratory Animal Science* 34 (3): 61-64.

NAL call number: SF405.5.A23

Descriptors: animal testing alternatives, committees, programs.

Kasting, G. (1996). **Revisiting medical surveillance in research animal facilities.** *Lab Animal* (25(4): 27-31.

NAL call number: QL55 A1L33

Descriptors: animal caretaker medical surveillance, occupational safety, hazard recognition, concepts of workplace surveillance, components of a medical surveillance program, recommendations, minimum criteria, reasons for conducting a surveillance program.

Krulich, L. (ed.) (1992). **Implementation strategies for research animal well-being: institutional compliance with regulations: proceedings of a conference held in Baltimore, Md. on December 5-6, 1991 about compliance with USDA regulations for the well-being of canines and nonhuman primates in research.** Bethesda, Maryland: Scientists

Center for Animal Welfare, 178p.
NAL call number: HV4764 I46 1992
Descriptors: enrichment strategies, dogs, nonhuman primates.

Lamborn, C. and M. Denny (1998). **Preparing for an animal rights related crisis.** *Lab Animal* 27(1): 32-35.
NAL call number: QL55 A1L33
Descriptors: crisis management, physical security, research and animal care policy, public relations, outsourcing your physical security program, check list for crisis preparation.

Lewis, S.M., B. Leard, J.L. Martin, and S.A. Martin (1995). **An automated feed inventory tracking system for an animal facility.** *Lab Animal* 24(8): 37-40.
NAL call number: QL55 A1L33
Descriptors: automated data handling, simplified reporting capabilities, inventory control, GLP accountability, system and user management.

McGarry, M.P., M.A. Imamovic, and D.J. Piccione. **Institutional animal care and use committee (IACUC) required facility inspections - objectives and implementation.** *Laboratory Animal Science* 37(4):544 (1987).
NAL call number: 410.9 P94
Descriptors: laboratory animals, public health, conference, ACUC.

National Research Council (1997). **Occupational health and safety in the care and use of research animals.** *ILAR Journal* 38(2): 89-93.
NAL call number: QL55.A1I43
Descriptors: laboratory workers, laboratory hazards, occupational health, animal experiments.

Orlans, F.B., R.C. Simmonds, and W.J. Dodd (eds.) (1987). **Consensus recommendations on effective institutional animal care and use committees.** *Laboratory Animal Science* 37(special issue): 11-13.
NAL call number: 410.9 P94
Descriptors: laboratory animals, animal welfare, workshop, research institutes, training, ethics, animal experiments.

Orlans, F.B., R.C. Simmonds, and W.J. Dodd (eds.) (1987). **Effective animal care and use committees.** *Laboratory Animal Science* 37(special issue): 1-178.
NAL call number: 410.9 P94
Descriptors: animal welfare, laboratory animals.

Poling, J. (1990). **An effective IACUC: A Johns Hopkins experience.** *Animal Welfare Information Center Newsletter* 1(4): 1-2,6.
NAL call number: aHV4701.A952
Descriptors: bioethics, animal welfare.

Public Responsibility in Medicine and Research (1991). **Animal Care and Use Programs: Regulatory Compliance and Education in an Age of Fiscal Constraint** Public Responsibility in Medicine and Research (PRIM & R), Tufts University School of Veterinary Medicine and Tufts University School of Medicine, Boston, Massachusetts: PRIM & R, 408 pp.
NAL call number: HV4913.A54
Descriptors: educational material, bibliographies, animal welfare.

Rehbinder, C., P. Baneux, D. Forbes, H. van Herck, W. Nicklas, Z. Rugaya, and G. Winkler (1998). **FELASA recommendations for the health monitoring of breeding colonies and experimental units of cats, dogs and pigs. Report of the Federation of European Laboratory Animal Science Associations (FELASA) Working Group on Animal Health.** *Laboratory Animals* 32(1):1-17
NAL call number: QL55 A1L3
Descriptors: animal welfare, physiology, breeding standards, cats, dogs, health status, swine, bacterial infections, diagnosis, data collection, mass screening, mycoses, parasitic diseases, virus diseases.

- Russell, C.K., F.X. Buckingham, R. Daniels, L. Bertan, P. Fetty , and D. Klein (1994). **Monsanto's computer animal proposal system (CAPS)**. *Quality Assurance* 3(2): 206-10.
Abstract: Regulations and standards must include the minimum requirements with respect to veterinary care, sanitation, handling, feeding, and housing. Part 1 of the Animal Welfare Act regulations was amended to update, clarify, and expand the list of definitions of terms and standards. Section 9 CFR, Part 1, contains definitions and deals with animal welfare, animal housing, dealers, exhibitors, research facilities, and humane animal handling. The subjects in 9 CFR, Part 2, pertain to licensing, registration, identification of animals, records, institutional animal care and use committees, and adequate veterinary care. Animal welfare, humane animal handling, pets, transportation, and reporting and recordkeeping requirements are the subjects listed in 9 CFR, Part 3.
Descriptors: organizational models, animal welfare, clinical laboratory information systems, computer networks, facility regulation and control.
- Sapolsky, H.M. (1987). **Assuring the effectiveness of animal research committees**. *SCAW Newsletter* 9(1): 7-8.
NAL call number: QL55.N48
Descriptors: laboratory animals, animal experiments, policy, legislation, ACUC.
- Seps, S.L. (1997). **An efficient approach to performing and documenting semiannual institutional animal care and use committee inspections of animal facilities**. *Contemporary Topics in Laboratory Animal Science* 36 (2): 51-53.
NAL call number: SF405.5.A23
Descriptors: laboratories, animal experiments, inspection, documentation.
- Shepherd, M.J. (1996). **Meeting large regulatory requirements in small institutions**. *Lab Animal* 25 (9):35-37.
NAL call number: QL55.A1L33
Descriptors: training, personnel, animal experiments, animal welfare, regulations, programs.
- Silverman, J. (1997). **Do pressure and prejudice influence the IACUC?** *Lab Animal* 26(5): 23-25.
NAL call number: QL55 A1L33
Descriptors: survey of NIH assured institutions, ethical challenges, questions included: how does the IACUC handle allegations of non-compliance or animal mistreatment, does the dollar value of a grant influence deliberations, what is the perceived role of the community representative- active voice or seen not heard, does the status of an investigator influence deliberations, does the species of animal involved influence deliberations.
- Silverman, J. (1994). **IACUC handling of mistreatment or noncompliance**. *Lab Animal* 23 (8):30-32.
NAL call number: QL55.A1L33
Descriptors: laboratory animals, animal welfare, committees, animal husbandry, policy, monitoring.
- Stephens, M. (1989). **Oversight of the care and use of animals in animal behavior research in the United States**. In *Animal Care and Use in Behavioral Research: Regulations, Issues, and Applications* J.W. Driscoll (ed.), United States Department of Agriculture/National Agricultural Library, Beltsville, MD, pp. 2-8.
NAL call number: aHV4762 A3A64
Descriptors: Animal Welfare Act, ACUC, field research.
- Talham, D.J. (1997). **A computerized method for taking animal census**. *Lab Animal* 26(9): 32-35.
NAL call number: QL55 A1L33
Descriptors: manual systems, bar-coded systems, in-house programming, integration with billing and accounting systems, screen shots.
- Talham, D.J., R.W. Murray, G.E. Lee, and J.M. Linn (1997). **In-house development of an integrated management information system for a laboratory animal facility**. *Contemporary Topics in Laboratory Animal Science* 36(5): 77-80.
NAL call number: SF405.5 A23
Descriptors: commercial software vs. in-house development, system objectives, design and implementation, operational areas, protocol management, animal procurement, animal facilitygenerate delivery schedules, cage cards, receipt of

animals, animal census, billing, cost accounting.

Thomas, J.A., and M.E. Greene (1994). **Institutional policies and educational programs: Animals in research.**

Journal of the American College of Toxicology 13(4): 308-313.

NAL call number: RA1190.J61

Descriptors: laboratory animals, toxicity testing, education, communication, policies.

Tillman, P. (1994). **Integrating agricultural and biomedical research policies: conflicts and opportunities.** *ILAR News* 36 (2): 29-35.

NAL call number: QL55.A1I43

Descriptors: livestock, agricultural research, medical research, committees, guidelines, regulations, animal welfare.

Tillman, P. (1997). **Automating the Institutional Animal Care and Use Committee.** *ILAR Journal* 38(4): 184-189.

NAL call number: QL55 A1I43

Descriptors: productivity, e-mail, WWW, communications, training materials, privacy, security.

Tillman, P.C. (1985). **Microcomputer assisted management of an institutional animal care and use committee.**

Laboratory Animal Science 35(5): 540-541.

NAL call number: 410.9 P94

Descriptors: abstract, clerical aspect, record keeping, committee organization.

Wolff, A. and P.D. Smith (1994). **Compliance at the institutional and programmatic level.** *Lab Animal* 23 (8): 28-29.

NAL call number: QL55.A1L33

Descriptors: laboratory animals, animal welfare, policy, committees, animal husbandry, animal experiments, control, project control, monitoring.

Useful World Wide Web Sites

A tutorial on the Public Health Service Policy on humane care and use of laboratory animals

<http://grants.nih.gov/grants/olaw/tutorial/index.htm>

A tutorial for new animal care and use committee members, institutional administrators, investigators, animal care personnel, veterinarians, or others who are interested in learning about the PHS Policy on Humane Care and Use of Laboratory Animals.

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition HHS Publication No. (CDC) 93-8395

<http://bmbf.od.nih.gov>

This 4th edition of the BMBL continues to specifically describe combinations of microbiological practices, laboratory facilities, and safety equipment, and recommend their use in four categories or biosafety levels of laboratory operation with selected agents infectious to humans. For sale by the Superintendent of Documents, U.S. Government Printing Office (GPO). Contact GPO by telephone between 7:30 a.m. and 4:30 p.m. EST at 1-202-512-1800, by fax at 1-202-512-2250 or on the Internet at <https://orders.access.gpo.gov/> or write to: Superintendent of Documents, U.S. GPO, Washington D.C. 20402. The stock number for this document is 017-040-00547-4.

Conflict Resolution in NIH Intramural Research Program

<http://www.training.nih.gov/handbook/conflict.html>

General information on conflict resolution procedures

Guidelines on Classifying Deficiencies Identified During Semiannual Reviews

<http://oacu.od.nih.gov/ARAC/FinalClassfyDefic0204.pdf>

This guideline is intended to expand upon the specific language in paragraph IV. B. 3. of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), which states: "The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgement of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency."

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

<http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

Includes a section on work with research animals.

Occupational Health and Safety in the Care and Use of Research Animals

<http://books.nap.edu/books/0309052998/html/1.html>

This site provides access to this book produced by the National Academy Sciences in 1997.

Semiannual Program and Facility Review Checklist

<http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm>

This sample checklist is a tool designed to assist IACUCs in conducting thorough semiannual reviews. The sample checklist covers the major topics of the Guide, and the requirements of the PHS Policy. Endnotes are included to reference specific United States Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy.

Semiannual Report to the Institutional Official

<http://grants.nih.gov/grants/olaw/sampledoc/ioreport.htm>

This sample format may be used as a template to prepare the Semiannual Report to the Institutional Official.

University of California, Davis Institutional Animal Care and Use Committee Advisory Committee

<http://safetyservices.ucdavis.edu/programs-and-services/animals/institutional-animal-care-and-use>

A comprehensive site that includes: occupational health and safety in the care and use of research animals; protocols for animal care and use; AUCAAC policy statements; UC Davis policy & procedure manual excerpts; biosafety in animal facilities; how to order controlled substances; analgesic drug doses for laboratory animals; lab animal classes; searching the literature for alternatives to animal use; USDA inspections at Davis and other UC campuses; do you know as much as you ought to? Test yourself! and ; reference documents for researchers and others.

University of Colorado Health Sciences Center Animal Care & Use Program Occupational Health Program

<http://www.colorado.edu/vcr/iacuc>

An excellent example of a comprehensive occupational health program. Access is found by scrolling down to Occ Health & Safety in the left frame of the web page. See also Animal Biohazards.

Working Safely with Research Animals

Proceedings of the 4th National Symposium on Biosafety: Working Safely with Research Animals

http://www.cdc.gov/od/ohs/symposium/symp_idx.htm

This site contains the proceedings of a conference by the Centers for Disease Control and Prevention in Atlanta, Georgia on January 27-31, 1996. The content includes: animal biosafety levels 1-4: an overview; biosafety issues related to xenograft transplantation; sop writing; defining the risks and the risk reduction strategies; infectious risks in using baboons; xenosis from swine: assessing the infectious risks of xenotransplantation; PHS perspective on xenograft transplantation; symposium keynote: practicing safe science in animal research; biosafety and emerging infections: key issues in the prevention and control of viral hemorrhagic fevers; research with small animals; research with nonhuman primates; biohazards in research involving large animals; occupational health and safety program in a research animal facility; strategies for safe use of chemicals in animal research; chemical management in research animal facilities; physical hazards in research animal facilities; chemical containment in the animal care facility; safe practices and procedures when working with chemical hazards; zoonoses in animal care facilities; breakout session on topics including: face protection in animal research; sharps management in animal care; special containment devices for

research animals; quality assurance techniques in animal facilities; strategies of managing macaque monkeys and Herpes Virus Simiae (B-virus); working safely with research animals: employee and employer responsibilities; effective management in animal research communication & interaction; occupational health programs; Americans With Disabilities Act issues; controlled access; safety training and education in animal research; risk assessment and; interactions that make OHS programs work.

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Last updated June 11, 2005

Protocol Review

- [The IACUC Process: Facilitating Science in a Well-Managed Animal Care and Use Program](#)
(links to the article previously published in the Animal Welfare Information Center Newsletter)
- [Federal Criteria for Granting IACUC Approval](#)
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Federal Criteria for Granting IACUC Approval

(From the ARENA/NIH IACUC Guidebook)

Activities	Must be in accord with USDA Regulations/PHS Policy.
Pain/Distress	Must avoid/minimize discomfort, distress, and/or pain. If pain/distress is caused, appropriate sedation, analgesia or anesthesia will be used. Attending veterinarian must be involved in planning. Use of paralytics without anesthesia is prohibited. Animals with chronic/severe unrelievable pain will be painlessly killed.
Surgery	Must meet requirements for sterile surgery and pre/postoperative care. Cannot use one animal for several major operative procedures from which it will recover, without meeting specified conditions.
Euthanasia	Euthanasia method must be consistent with USDA Regulations/AVMA recommendations.
Housing/Health	Animal living conditions must be consistent with standards of housing, feeding and care directed by veterinarian or scientist with appropriate expertise.
Alternatives	There must be considered alternatives to painful procedures; also must document consideration of alternatives if animals experience pain or suffering.
Rationale and Methods	Must provide written narrative of methods/sources.
Duplication	Must provide assurance that activities do not unnecessarily duplicate previous efforts.
Qualifications	Personnel must be appropriately qualified.
Deviations from Requirements	Must be justified for scientific reasons, in writing.

Bibliography

Cohen, J.M. (1987). **Protocol preview and review.** *Laboratory Animal Science* 37(special issue): 57-58.

NAL call number: 410.9 P94

Descriptors: animal experiments, institutions, animal welfare, ACUC.

de Cock Buning, T. and E. Theune (1994). **A comparison of three models for ethical evaluation of proposed animal experiments.** *Animal Welfare* 3(2): 107-128.

NAL call number: HV4701 A557

Descriptors: hypothetical case studies, quality of animal experiment, research goals, potential to achieve objective, animal species, number of animals, quality of animal care, discomfort, duration of discomfort, significance of discomfort, credentials of investigators, decision trees, animal welfare, cost-benefit analysis, animal experiments.

Dresser, R. (1987). **Refining the IACUC process: Policies and procedures.** *SCAW Newsletter* 9(1): 3-6.

NAL call number: QL55.N48

Descriptors: animal welfare, animal experiments, pain, stress, institutions, ACUC.

Dresser, R. (1989). **Developing standards in animal research review.** *Journal of the American Veterinary Medical Association* 194(9): 1184-1191.

NAL call number: 448.9 Am37

Descriptors: animal welfare, laboratory animals, protocols, standards, United State Public Health Service.

Everitt, J. and W. Griffin (1995). **Proposed IACUC guidelines for the review of rodent toxicology studies.**

Contemporary Topics in Laboratory Animal Science 34 (3): 72-74.

NAL call number: SF405.5.A23

Descriptors: laboratory animals, rodents, toxicology, committees, guidelines, animal

Gillett, C.S. (1986). **Animal use protocol review is here now.** *Laboratory Animal Science* 36(5): 579.

NAL call number: 410.9 P94

Descriptors: abstract, educational materials, ACUC.

Hart, L.A. (1995). **The animal subjects protocol process: Applying the 3Rs.** *Lab Animal* 24(5): 40-43.

NAL call number: QL55 A1L33

Descriptors: protocol preparation, protocol review, investigator's responsibilities, IACUC responsibilities, importance

of animal wellbeing, alternatives, reducing sources of discomfort, approaches for the investigator, review of the literature, literature searching.

Hughes, H.G. (1989). **An effective industrial animal care and use committee.** In *Science and Animals: Addressing Contemporary Issues* H.N. Guttman, J.A. Mench, and R.C. Simmonds (eds.), Bethesda, Maryland: Scientists Center for Animal Welfare, pp. 49-50.

NAL call number: HV4704 S33 1988

Descriptors: ethics, protocols, drug development.

Johnston, N.E. (1994). **Is a second, independent-review animal ethics committee of real benefit.** In *Welfare and Science: Proceedings of the Fifth Symposium of the Federation of European Laboratory Animal Science Associations, 8-11 June 1993, Brighton, UK.* London: Royal Society of Medicine Press, pp. 281-282.

NAL call number: QL55.F43 1993

Descriptors: animal welfare, committees, university research, standards, regulations

Knauff, D.R. (1987). **Animal research review in an industrial facility.** *Laboratory Animal Science* 37(special issue): 129-131.

NAL call number: 410.9 P94

Descriptors: animal welfare regulations, animal experiments, ACUC.

Ledney, G.D., C.L. Hadick, and R.H. Weichbrod (1996). **The IACUC process: facilitating science in a well-managed animal care and use program.** *Animal Welfare Information Center Newsletter* 7(1): 1-2, 14-15.

NAL call number: aHV4701.A952

Descriptors: animal welfare, committees, communication, legislation, protocol review.

Moreland, A.F. (1987). **Animal research protocol review in the Veterans Administration.** *Laboratory Animal Science* 37(special issue): 137-139.

NAL call number: 410.9 P94

Descriptors: animal experiments, policy, regulations, medical research.

Mueller, R. and M.E. Landi (1989). **An effective industrial animal care and use committee.** In *Science and Animals: Addressing Contemporary Issues* H.N. Guttman, J.A. Mench, and R.C. Simmonds (eds.), Bethesda, Maryland: Scientists Center for Animal Welfare, pp. 123- 124.

NAL call number: HV4704 S33 1988

Descriptors: protocol, Good Laboratory Practices, training.

Oki, G.S.F., E.D. Prentice, N.L. Garnett, D.F. Schwindaman, and C.Y. Wigglesworth (1996). **Model for performing institutional animal care and use committee: continuing review of animal research.** *Contemporary Topics in Laboratory Animal Science* 35 (5):53-56.

NAL call number: SF405.5.A23

Descriptors: animal experiments, laboratory animals, animal welfare, regulations, reviews.

Orlans, F.B. (1987). **Review of experimental protocols: Classifying animal harm and applying 'refinements'.** *Laboratory Animal Science* 37(special issue): 50-56.

NAL call number: 410.9 P94

Descriptors: animal welfare, ethics, injuries, animal testing alternatives, ACUC.

Orlans, F.B. (1987). **Case studies of ethical dilemmas.** *Laboratory Animal Science* 37(special issue): 59-64.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal experiments, animal welfare, ACUC.

Orlans, F.B. (1987). **Research protocol review for animal welfare.** *Investigative Radiology* 22: 253-258.

Descriptors: ACUC, animal use in research, alternatives, humane treatment of animals.

Orlans, F.B. (1987). **Pioneering in-house policies on animal procedures.** *Laboratory Animal Science* 37(4): 512-513.

NAL call number: 410.9 P94

Descriptors: laboratory animals, ACUC.

Prentice, E., A. Jameton, D. Antonsen, and I. Zucker (1988). **Prior ethical review of animal versus human subjects research.** *Investigative Radiology* 23(9): 695-697.

Descriptors: ACUC, institutional review board.

Prentice, E.D., D.A. Crouse, and R.W. Rings (1990). **Approaches to increasing the ethical consistency of prior review of animal research.** *Investigative Radiology* 25(3): 271-4.

Descriptors: animal testing alternatives, legislation, ethics.

Prentice, E.D., D.A. Crouse, and M.D. Mann (1992). **Scientific merit review: The role of the IACUC.** *ILAR News* 34 (1/2): 15-19.

NAL call number: QL55.A1I43

Descriptors: laboratory animals, scientific merit review, committees, animal welfare.

Prentice, E.D. and I. Zucker (1987). **Protocol review at the University of Nebraska Medical Center.** *SCAW Newsletter* 9(4): 5-6,9.

NAL call number: QL55.N48

Descriptors: ACUC, animal review committee, expedited process, full committee review.

Protocol Review

This is a regular column in the magazine *Lab Animal* (NAL call number: QL55 A1L33). The column coordinator is Jerald Silverman, DVM, who describes a hypothetical IACUC scenario and has members of the research community resolve the issue. Below is a partial list of column references.

Going fishing. (1999) 28(4): 16-17.

Descriptors: questionable hypothesis unsupported by scientific literature, unpublished data, toxicology protocol previously approved for other compounds, scientific validity for testing compounds received under contract.

The moral balance. (1999). 28(3): 18-20.

Descriptors: pain, neonatal animals, use of 1 rabbit kit per litter from 75 animals, disposition of remaining animals, options available to the IACUC.

To have and to hold. (1999). 28(2): 14-15.

Descriptors: animals with unique genotype, completed research project, conflict between grantee IACUC and IACUC at facility where research was conducted over authorization to transfer animals to another institution, adoption, payment of shipping costs, PHS, animal protocol form, investigator- IACUC communication, establishment of ownership.

Proprietary paranoia. (1999) 28(1): 18-19.

Descriptors: proprietary information, confidentiality, toxicology of pharmaceuticals, humane endpoints.

So much work, so little time.(1998) 27(8): 16-18.

Descriptors: workflow, communication, voting, role of the IACUC chair, OPRR and USDA commentary provided.

Playing by the rules. (1998) 27(3): 19-21.

Descriptors: post operative analgesics, Animal Welfare Act interpretation, interference with proposed methods.

Don't bug me. (1998) 27(2): 19-20.

Descriptors: funding, parasites due to animal transport within the facility, limited space for animal care.

Power struggle. (1997) 27(1): 22-23.

Descriptors: communication, authority over animal care, standard operating procedures.

Long Distance IACUC. (1997) 26(10): 22-24.

Descriptors: electronic meetings, email, conference calls.

By the book? (1997) 26(9): 23-25.

Descriptors: pain perception, *Xenopus*, multiple survival surgeries.

Much ado about nothing? (1997) 26(8): 24-26.

Descriptors: pain, analgesics confound research results, acupuncture.

Form follows function. (1997) 26(7): 22-24.

Descriptors: continuity of a protocol when transferring from one institution to another, new review.

Someone squealed. (1997) 26(6): 20-22.

Descriptors: whistleblowing, confidentiality, subcommittee.

Triangulating company politics. (1997) 26(5): 19-22.

Descriptors: authority conflicts, public-private collaborations.

Attempted pig embezzlement. (1997) 26(4): 18-20.

Descriptors: animal housing at home, investigator-IACUC disagreements.

Optimal animal use. (1997) 26(3): 20-22.

Descriptors: dead animals, shared tissues, redundant protocols, USDA and PHS responses.

Choose wisely. (1997) 26(2): 19-20.

Descriptors: choosing a non-affiliated member, community representation, criteria.

An information specialist's domain. (1997) 26(1): 20-21.

Descriptors: databases, alternatives searches, search strategies, usefulness.

Pilot to IACUC. (1996) 25(10): 21-22.

Descriptors: justifying animal numbers, pilot studies.

Adaptation or distress. (1996) 25(9): 21-22.

Descriptors: identification of distress, disease studies, adaptation to disease, unalleviated distress.

Majority rules. (1996) 25(8): 21-22.

Descriptors: quorum, full committee, voting, USDA and PHS responses.

Pentobarbital and the Cheshire cat. (1996) 25(7): 22-25.

Descriptors: anesthesia methods, professional guidelines and accepted practices, personal experience.

Pig hearts and dog models. (1996) 25(6): 21-22.

Descriptors: choice of animal models, validating and justifying new models.

A chicken and egg situation. (1996) 25(5): 20-23.

Descriptors: nonvertebrate embryos become vertebrate hatchlings, policy development, planning.

Socrates meets the Great Eastern University. (1996) 25(4): 22-23.

Descriptors: justification of research, scientific merit, open meetings.

An IACUC confounded. (1996) 25(3): 24-26.

Descriptors: vaccine testing, alternatives, Food and Drug Administration, primate requirements.

Playing favorites. (1996) 25(2): 20-21.

Descriptors: multiple major survival surgeries, technician concern, animal welfare.

Problem child. (1996) 25(1): 19-20.

Descriptors: multiple minor animal care and use problems with a single principal investigator over time, case considerations, constructive approaches.

Does a fetus feel pain? (1995) 24 (9): 21-22.

Descriptors: rats, fetus, pain, animal welfare, animal experiments.

A researcher's quagmire. (1995) 24(5): 24-25.

Descriptors: survival surgery, refinement, reporting, multiple surgeries.

Subcontractor or merchant? (1994) 23(7): 21-22.

Descriptors: animal transfer to contractors, oversight, PHS assurance, ownership.

Curbing drug abuse. (1989) 18(5): 23.

Descriptors: drug use, rodents, drug effects, ACUC.

Survival surgical procedures. (1988) 16(6): 25-26.

Descriptors: personnel requirements, facilities, aseptic surgical procedures.

Surgical suite alternative. (1989) 18(7): 22.

Descriptors: surgical procedures, guinea pigs, laboratory operating area.

Project reassessment. (1987) 16(2): 23-24.

Descriptors: rabbits, hemorrhage, projects, ACUC.

Limb regeneration in mammals. (1988) 17(5): 22-23.

Descriptors: rats, limbs, amputation, wound healing.

Unattended animals. (1989) 18(1): 15.

Descriptors: rat, investigator responsibilities.

Experimental hypothermia. (1989) 18(3): 18.

Descriptors: rats, submersion, animal distress.

Rowan, A.N. (1990). **Ethical review and the animal care and use committee.** *Hastings Center Report* 20(3 Supp.): 19-24.

NAL call number: R724 H27

Descriptors: Laboratory Animal Welfare Act of 1966, social aspects, Animal Welfare Act of 1970, ethics, animal experimentation, research institutes, standards.

Russow, L-M. (1995). **Protocol Review: Too much paperwork?** In *"Current Issues and New Frontiers in Animal Research*, K.A.L. Bayne, M. Greene, and E.D. Prentice, eds., Greenbelt, Maryland: Scientists Center for Animal Welfare, pp. 15-18.

NAL call number: HV4913 C87 1995

Descriptors: information required by IACUC, development of protocol forms, ethics, roles of IACUC members.

Stafleu, F.R., B.D. Baarda, F.R. Heeger, and A.C. Beynen (1993). **The influence of animal discomfort, human interest and scientific quality on the ethical acceptability of a projected animal experiment as assessed with questionnaires.** *Alternatives to laboratory animals: ATLA* 21 (2): 129-137.

NAL call number: Z7994.L3A5

Abstract: This study attempts to assess to what extent three selected variables (animal discomfort, scientific quality and human interest) determine the ethical acceptability of a projected animal experiment, as judged by animal experimenters. Two levels of each of the three variables were incorporated into otherwise identical protocols of a hypothetical animal experiment. Thus, there were eight different protocols with various combinations of the variables. In a postal survey, animal experimenters were asked to assign an acceptability score to the projected animal experiment described and to give a short written justification of their score. Human interest had the greatest influence on acceptability scores, followed by animal discomfort and scientific quality. Arguments concerning scientific quality played a major role in determining acceptability scores. At high levels of animal discomfort, the projected experiment was considered acceptable when both human interest and scientific quality were high. Thus, it remains questionable whether, in practice, a well-designed experiment with significant, expected human interest would be dismissed because of a high or moderate degree of anticipated animal discomfort.

Descriptors: animal experiments, animal welfare, bioethics.

Staflue, F.R., B.D. Baarda, F.R. Heeger, and A.C. Beynen (1994). **The influence of animal discomfort and human interest on the ethical acceptability of projected animal experiments.** In *Welfare and science: proceedings of the Fifth Symposium of the Federation of European Laboratory Animal Science Associations, 8-11 June 1993*, Brighton, London: Royal Society of Medicine Press, pp. 278-280.

NAL call number: QL55.F43 1993

Descriptors: laboratory animals, animal experiments, ethics, pain, animal welfare, questionnaires, man, health protection.

Steneck, N.H. (1997). **Role of the institutional animal care and use committee in monitoring research.** *Ethics Behavior* 7(2): 173-184.

Descriptors: animal care, ethics, committees, regulation.

Tomson, F.N. (1989). **Approving the use of animals in medical education.** *Theoretical Medicine* 10(1): 35-42.

Descriptors: animal welfare, laboratory animals, standards, attitude of health personnel.

Useful World Wide Web Sites

Protocol Review Procedures

<http://iacuc.tennessee.edu/>

This site is provided by the University of Tennessee at Knoxville Institutional Animal Care and Use Committee. Click on protocol review procedures.

Review of Protocols, National Institutes of Health, Office for Protection from Research Risks

<http://grants.nih.gov/grants/olaw/references/pubartindex.htm>

The following articles can be viewed from this site:

- Annual review (USDA) vs. triennial review (PHS)
ILAR News. 1991; 33(4):68-70, question #8.
- Authority of IACUC
Lab Animal. 1997:26(3):21.
- Expedited review

ILAR News. 1993; 35(3-4):47-49, question #3.
OPRR Reports. 1990; 90-01, 5/21/90.

- Frequency of review
ILAR News. 1993; 35(3-4):47-49, question #7.
- Model for performing continuing review of research activities
Contemporary Topics. 1996; 35(5):53-56.
- Process for review
Lab Animal. 1998;27(8):18.
- Review of grant applications
Lab Animal. 1999;28(7):21.
- Scientific merit review
ILAR News. 1991; 33(4):68-70, question #7.
- Significant changes to approved protocols
Lab Animal. 1995; 24(9):24-26, question #1.
- Tracking the number of animals used
Contemporary Topics. 1997; 36(2):47-50, question #7.
- Use of cold-blooded vertebrates
Contemporary Topics. 1997; 36(2):47-50, question #6.

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Updated March 12, 2002

Attending Veterinarian

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 - [Ensuring Adequate Veterinary Care: Roles and Responsibilities of Facility Owners and Attending Veterinarians - APHIS](#)
 - [Veterinary Care Checklist](#)
 - [Veterinary Medical Care - excerpted from the Guide](#)
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Attending Veterinarian and Adequate Veterinary Care

9 CFR, Subchapter A, Animal Welfare, §2.32

This document is available at <http://www.access.gpo.gov/nara/cfr/waisidx/9cfr2.html>

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

(1) Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;

(2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; and

(3) The attending veterinarian shall be a voting member of the IACUC; Provided, however, That a research facility with more than one Doctor of Veterinary Medicine (DVM) may appoint to the IACUC another DVM with delegated program responsibility for activities involving animals at the research facility.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

(4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and

(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

Ensuring Adequate Veterinary Care: Roles and Responsibilities of Facility Owners and Attending Veterinarians

March 1999

USDA, APHIS, Animal Care

<http://www.aphis.usda.gov/oa/pubs/tneavc.html>

Under the Animal Welfare Act, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) requires that all persons who use animals in research or for exhibition, sell them at the wholesale level, or transport them in commerce provide these animals with adequate veterinary care and animal husbandry. Toward this end, APHIS requires the owner of each licensed and registered facility to establish a formal program of veterinary care. Facility owners must also employ an attending veterinarian to oversee the care afforded the animals.

Essential Components of a Veterinary Care Program

APHIS personnel assess each facility's veterinary care program to determine whether it contains the following elements:

- Appropriate facilities, personnel, equipment, and services to provide adequate veterinary care.
- Use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.
- Availability of emergency, weekend, and holiday care for animals.
- Daily observation of all animals by employees to assess the animals' health and well-being.
- Direct and frequent communication between the facility and attending veterinarian on any veterinary care concerns.
- Adequate guidance and training of personnel who care for animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia.
- Provisions for adequate preprocedural and postprocedural care in accordance with established veterinary medical and nursing procedures.

The Role of the Attending Veterinarian

The attending veterinarian is responsible for reviewing the facility's veterinary care program at least once a year. Facilities must employ their veterinarians under the following terms:

The facility must employ its veterinarian under formal arrangements on a full-time, part-time, or consulting basis. The facility owner must be able to prove employment of the veterinarian, either through a contract or other written documentation.

- If the veterinarian is part-time or consulting, the facility owner must prepare a written program of veterinary care. The owner must also schedule regular visits by the attending veterinarian at least once a year. The facility owner is solely responsible for scheduling these visits.
- The facility owner must give the veterinarian sufficient authority to ensure adequate veterinary care for the animals.

Specifics to Check For During a Veterinary Care Program Review

When conducting a review of a facility's veterinary care program, the attending veterinarian should check for vaccinations, parasite-control programs, euthanasia methods, exercise programs for dogs, environmental enrichment programs for primates, and several other specific provisions. The checklist on this tech note provides a detailed list of these provisions for use in evaluating specific veterinary care programs. (See Veterinary Care Checklist following this article)

Additional Information

For more information, or if you have other questions about the veterinary care requirements under the Animal Welfare Act, contact your local APHIS Animal Care inspector or field veterinary medical officer, or:

Animal Care
APHIS, USDA
Unit 84
4700 River Road
Riverdale, MD 20737
Telephone: (301) 734-7833
ace@aphis.usda.gov

Web page: <http://www.aphis.usda.gov/ac>

Veterinary Care Checklist

This checklist should be used when reviewing a facility's veterinary care program and kept on file at the facility for review by APHIS personnel.

Facility Name: _____

Date of Visit: _____

Review each item below with the facility owner. Place an "x" next to each item discussed and "N/A" next to those items that are not applicable.

____ Vaccinations

- ___ Parasite control program
- ___ Emergency care
- ___ Euthanasia methods
- ___ Nutritive value of diets
- ___ Handling of biologics and drugs
- ___ Pest control and product safety
- ___ Quarantine procedures
- ___ Exercise program (dogs only)
- ___ Environmental enrichment (primates only)
- ___ Water quality (marine mammals only)
- ___ Capture and restraint methods (wild or exotic animals only)
- ___ General observations
- ___ Overall facility condition
- ___ General animal husbandry practices

Comments and recommendations on overall health of animals and effectiveness of veterinary care program:

Signature of Attending Veterinarian:

Veterinary Medical Care

Excerpted from the *Guide to the Care and Use of Laboratory Animals*, p. 56.

Veterinary medical care is an essential part of an animal care and use program. Adequate veterinary care consists of effective programs for:

- Preventive medicine.
- Surveillance, diagnosis, treatment, and control of disease, including zoonosis control.
- Management of protocol-associated disease, disability, or other sequelae.
- Anesthesia and analgesia.
- Surgery and postsurgical care.
- Assessment of animal well-being.
- Euthanasia.

A veterinary-care program is the responsibility of the attending veterinarian, who is certified or has training or experience in laboratory animal science and medicine or in the care of the species being used. Some aspects of the

veterinary-care program can be conducted by persons other than a veterinarian, but a mechanism for direct and frequent communication should be established to ensure that timely and accurate information is conveyed to the veterinarian on problems associated with animal health, behavior, and well-being. The veterinarian must provide guidance to investigators and all personnel involved in the care and use of animals to ensure appropriate handling, immobilization, sedation, analgesia, anesthesia, and euthanasia. The attending veterinarian must provide guidance or oversight to surgery programs and oversight of postsurgical care.

Adequate Veterinary Care

Public Position Statement of
The American College of Laboratory Animal Medicine

This document is available at http://www.aclam.org/Content/files/files/Public/Active/position_adeqvetcare.pdf

I. Introduction

These guidelines were prepared by the American College of Laboratory Animal Medicine (ACLAM) to assist in the formulation and evaluation of programs of veterinary care for laboratory animals. The professional judgement of a trained and experienced veterinarian is essential in the application of these guidelines to specific institutional settings.

The ACLAM recognizes that both regulatory and science sponsoring agencies such as the United States Department of Agriculture (USDA) and the Public Health Service of the United States Department of Health and Human Services (PHS/DHHS), through their respective regulations and policies, support the concept of "adequate veterinary care" within their own range of interest and specialization. This document, written by ACLAM, an organization comprised of veterinarians certified in the specialty of laboratory animal medicine, is a detailed description of adequate veterinary care and is intended to apply to animals used, or intended for use, in research, teaching or testing.

II. ACLAM Position On Adequate Veterinary Care

The institutional veterinarian must be qualified by virtue of appropriate postgraduate training or experience in laboratory animal science and medicine. Such training and experience are indicated by certification by ACLAM and/or participation in laboratory animal medicine continuing education activities of ACLAM and the American Society of Laboratory Animal Practitioners. The continuing education of the veterinarian is an essential component of maintaining competence.

The extent of the veterinary care program will depend on several factors, such as: (1) the number of animals, (2) the species used and (3) the nature of the experimentation conducted. Large units may need several veterinarians to fulfill the program's requirements. One veterinarian may be sufficient in moderately sized units, and a part-time or consulting veterinarian may be acceptable in small units.

However, in all cases, formal arrangements for the provision of veterinary care must be made. Consulting veterinarians must make regularly scheduled visits (frequency based on need), and arrangements must be made to assure that veterinary services are readily available at all other times to meet either routine or emergency needs.

The veterinarian responsible for supporting an institutional animal care and use program must have appropriate authority to execute the duties inherent in assuring the adequacy of veterinary care and overseeing other aspects of animal care and use to ensure that the program meets applicable standards. The veterinarian must be fully knowledgeable concerning the current and proposed use of animals in the institutional research, testing and teaching programs.

At least one veterinarian must be a full member of the Institutional Animal Care and Use Committee (IACUC) and actively involved in the review of all protocols and projects, and in the inspection of facilities and review of institutional programs involving animals in research, testing and teaching. For the veterinary care program to be judged "adequate", there is a continuing institutional responsibility to foster and support enhancement of the program through the identification and adoption of techniques, procedures and policies that improve laboratory animal health and well-being.

ACLAM endorses the American Veterinary Medical Association Principles of Veterinary Ethics and the specific guidelines regarding veterinarians employed by other than veterinary medical organizations. Veterinarians must be especially vigilant in ensuring that their professional veterinary judgments are neither influenced nor controlled by institutional interests to the detriment of the laboratory animals.

The provision of adequate veterinary care involves the following primary areas of responsibility:

A. Disease Detection and Surveillance, Prevention, Diagnosis, Treatment and Resolution

1. The isolation, quarantine and stabilization programs for newly arrived animals are necessary to provide time to assess their health status, allow them to recover from the stress of shipment and an opportunity to adapt to their new environment. The extent of these programs depends on several factors, including species and source of the animals as well as their intended use. For some animals, such as rodents obtained from reliable sources for which health status is known, visual inspection on arrival may suffice. For species such as nonhuman primates, farm animals, wild animals, random source dogs and cats, and non-specific pathogen free rabbits and rodents, appropriate quarantine and isolation procedures must be employed.
2. Preventive medicine programs such as vaccinations, ecto- and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular species and source. Only animals of defined health status should be used in research and testing unless a specific, naturally occurring or induced disease state is being studied. Systems should be established to protect animals within the institution from exposure to diseases. Transgenic and mutant animals may be particularly susceptible to diseases and may require special protection to ensure their health. Systems to prevent spread of disease may include facility design features, containment/isolation equipment, and use of standard operating procedures. Training of animal care and research staff is essential to prevent spread of animal diseases.
3. Daily observation of all animals by a person or persons qualified to verify their well-being is required. It is not necessary for a veterinarian to personally make this assessment each day. However, at a minimum, a trained paraprofessional or technician must observe each animal every day and there must be a timely and accurate method for conveying information regarding animal health, behavior and well-being to the veterinarian.
4. Disease surveillance is a major responsibility of the veterinarian and should include routine monitoring of colony animals for the presence of parasitic, bacterial and viral agents that may cause overt or inapparent disease. Additionally, cells, tissues, fluids, and transplantable tumors that are to be used in animals should be monitored for infectious or parasitic agents that may cause disease in animals. The type and intensity of monitoring necessary will depend upon professional veterinary judgement and the species, source, use and number of animals housed and used in the facility.
5. Diagnostic laboratory services must be available and used as appropriate. Laboratory services should include necropsy, histopathology, microbiology, clinical pathology, serology, and parasitology as well as other routine or specialized laboratory procedures, as needed. It is not necessary that all of these services be available within the animal facility if other laboratories with appropriate capabilities are available and used.
6. Animals with infectious disease must be isolated from others by placing them in isolation units or separate rooms appropriate for the containment of the agents of concern. In certain circumstances, when an entire group of

animals is known or thought to be exposed or infected, it may be appropriate to keep the group intact during the time necessary for diagnosis and treatment, for taking other control measures, or for completion of a project.

7. The veterinarian must have authority to use appropriate treatment or control measures, including euthanasia if indicated, following diagnosis of an animal disease or injury. If possible, the veterinarian should discuss the situation with the principal investigator to determine a course of action consistent with experimental goals. However, if the principal investigator is not available, or if agreement cannot be reached, the veterinarian must have authority to act to protect the health and well-being of the institutional animal colony. The veterinarian's authority should be exercised with the concurrence of the IACUC and the Institutional Official.

B. Handling and Restraint; Anesthetics, Analgesics and Tranquilizer Drugs; and Methods of Euthanasia

Adequate veterinary care includes providing guidance to animal users and monitoring animal use to assure that appropriate methods of handling and restraint are being used and to ensure proper use of anesthetics, analgesics, tranquilizers, and methods of euthanasia. Written guidelines regarding the selection and use of anesthetics, analgesics and tranquilizing drugs and euthanasia practices for all species used must be provided and periodically reviewed by the veterinarian. Guidelines may be developed in-house or provided by specific references to the current veterinary literature. In addition, the veterinarian or trained paraprofessionals should provide formal or informal instruction in the proper use of such agents and euthanasia procedures.

The veterinarian must have the responsibility and authority to assure that handling, restraint, anesthesia, analgesia and euthanasia are administered as required to relieve pain and such suffering in research animals, provided such intervention is not specifically precluded in protocols reviewed and approved by the IACUC. The veterinarian must exercise good professional judgement to select the most appropriate pharmacologic agent(s) and methods to relieve animal pain or distress in order to assure humane treatment of animals, while avoiding undue interference with goals of the experiment.

C. Surgical and Postsurgical Care

A program of adequate veterinary care includes the review and approval of all preoperative, surgical and postoperative procedures by a qualified veterinarian. The institution bears responsibility and must assure, through authority explicitly delegated to the veterinarian or to the IACUC, that only facilities with programs appropriate for the intended surgical procedures are utilized and that personnel are adequately trained and competent to perform the procedures. The veterinarian's inherent responsibility includes monitoring and providing recommendations concerning preoperative procedures, surgical techniques, the qualifications of institutional staff to perform surgery and the provision of postoperative care.

D. Animal Well-Being

Adequate veterinary care includes responsibility for the promotion and monitoring of an animal's well-being before, during and after experimentation or testing. Animal well-being includes both physical and psychological aspects of an animal's condition evaluated in terms of environmental comfort, freedom from pain and distress and appropriate social interactions, both with conspecifics and with man. The veterinarian must have the authority and responsibility for making determinations concerning animal well-being and assuring that animal well-being is adequately monitored and promoted. The veterinarian must exercise this responsibility in review of animal care and use protocols, and must have the authority to remove an animal from an experiment which is adversely affecting its well-being beyond a level reviewed and approved by the IACUC.

The following examples represent how this responsibility can be met:

Ensuring the adequacy of the physical plant, caging and ancillary equipment.

Developing, implementing and monitoring sound animal care (husbandry) programs including such areas as sanitation, nutrition, genetics and breeding and vermin control.

Establishing an acclimatization program to adapt animals to either short-term or long term restraint procedures.

Improving and enriching an animal's environment to minimize the development of physical or behavioral abnormalities.

Providing appropriate opportunities for human-animal socialization and acclimatization to the research environment or procedures.

Performing periodic physical and clinical evaluations appropriate for the species and the experimental situation.

Providing pre-procedural and post-procedural care in accordance with current established veterinary procedures.

E. Appropriate Use of Animals in Research and Testing

The veterinarian must be involved in the review and approval of all animal care and use in the institutional program. This includes advising on the design and performance of experiments using animals as related to model selection, collection and analysis of samples and data from animals, and methods and techniques proposed or in use. This responsibility is usually shared with investigators, the IACUC, and external peer reviewers.

III. Related Concerns

Other areas of professional concern and responsibility for the veterinarian which may not strictly be part of the ACLAM description of adequate veterinary care include the following:

Participating in the development and administration of training for institutional staff in the care and use of laboratory animals.

Assisting institutional health officials to establish and monitor an occupational health program for all animal care workers and others who have substantial animal contact.

Monitoring for zoonotic diseases such as leptospirosis, toxoplasmosis, rabies, Q-fever, B-virus infection, hantavirus infection, and lymphocytic choriomeningitis.

Advising on and monitoring of standards of hygiene among institutional staff involved with research animal care and use.

Advising on and monitoring of biohazard control policies and procedures as they apply to research animal care and use.

IV. Conclusions

The Diplomates of the American College of Laboratory Animal Medicine believe that adequate veterinary care is an integral component of humane animal care and use in research, teaching and testing and further, that the state of animal well-being ensured through adequate veterinary care is essential to reliability of results from experimentation with animals. The essential components of adequate veterinary care programs for laboratory animals include: a) one or more qualified veterinarians and veterinary technical staff, b) authority to implement the veterinary care program and provide oversight of related aspects of the institutional animal care and use program, c) disease prevention, diagnosis and control programs, d) guidance for research staff in animal methods and techniques, and e) the promotion of animal well-being.

Bibliography

Banks, R. (1992). **Commentary: the unwritten rules of the lam veterinarian--the IACUC experience.** *Lab Animal* 21 (4): 37-40.

NAL call number: QL55.A1L33

Descriptors: veterinarians, committees.

Fisk, S.K. (1978). **Don't overlook the lab animal veterinarian.** *Lab Animal* 7(2): 37.

NAL call number: QL55 A1L33

Abstract: What this professional can contribute to research projects.

Hannah, H.W. (1995). **The limits of confidentiality: a veterinarian's duty to report disease, cruelty, and theft.**

Journal of the American Veterinary Medical Association 206 (9): 1336-1337.

NAL call number: 41.8 Am3

Descriptors: veterinarians, professional ethics, animal diseases, animal welfare, theft.

Pakes, S.P. (1990). **Contributions of the laboratory animal veterinarian to refining animal experiments in toxicology.** *Fundamentals of Applied Toxicology* 15(1): 17-24.

Descriptors: animal pain, psychology, measurement, research design, alternatives, trends, veterinarians, ACUC.

Quimby, F.W. (1995). **The role of attending veterinarians in laboratory animal welfare.** *Journal of the American Veterinary Medical Association* 206(4): 461-5.

NAL call number: 41.8 Am3

Descriptors: Animal Welfare Act, legislation, ethics, United States Department of Agriculture.

Scott, L.R. and P.D. Carter. (1996). **The role of veterinarians on animal experimentation ethics committees.**

Australian Veterinary Journal 74 (4): 309-311.

NAL call number: 41.8 Au72

Descriptors: animal experiments, animal welfare, veterinarians, bioethics, committees, organizations.

Stark, D.M. (1989). **The American veterinarians' role and education in laboratory animal science.** *Animal Technology: Journal of the Institute of Animal Technicians* 40(3): 199-201.

NAL call number: QL55 I5

Descriptors: laboratory animals, training, animal husbandry, ACUC.

Van Hoosier, Jr, G.L. (1987). **Role of the veterinarian.** *Laboratory Animal Science* 37(special issue): 101-102.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal welfare, ACUC.

Useful World Wide Web Sites

University of Arizona Institutional Animal Care and Use Committee, Authority of the Attending Veterinarian

<http://www.iacuc.arizona.edu/handbook/special.shtml#vetreg>

An example of a short, concise policy.

University of Kansas-Lawrence, Responsibilities of the Animal Care Unit

<http://www.ku.edu/~acu/hbcontents.html>

This site lists various institutional policies and regulations.

University of Tennessee at Knoxville, Attending Veterinarian/Researcher Veterinarian

<http://iacuc.utk.edu/policies-and-procedures/attending-veterinarian/>

The purpose of this statement is to distinguish between the attending veterinarian and the veterinarian who is also a researcher and their respective responsibilities.

Veterinarians In Research Labs Address Conflicting Agendas

http://www.the-scientist.com/yr1997/may/finn_p1_970526.html

(The Scientist - Volume 11, No. 11, May 26, 1997)

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When the USDA Veterinary Medical Officer Looks at Your Training Program

Ed Slauter, DVM
Veterinary Medical Officer
United States Department of Agriculture
APHIS/Animal Care

This paper was originally presented at the 1998 Laboratory Animal Welfare Training Exchange conference held in St. Louis, Missouri.

The Animal Welfare Act mandates that each research facility shall provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in the facility.

Title 9 - Code of Federal Regulations - Chapter 1, Subchapter A - Animal Welfare §2.32 gives specific requirements for training as follows:

- (a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.
- (b) Training and instruction shall be made available, and qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section and §2.31.
- (c) Training and instruction of personnel must include guidance in at least the following areas:
 - (1) Humane methods of animal maintenance and experimentation, including:
 - (i) The basic needs of each species of animal;
 - (ii) Proper handling and care for the various species of animals used by the facility.
 - (iii) Proper pre-procedural and post-procedural care of animals; and
 - (iv) Aseptic surgical methods and procedures.
 - (2) The concept, availability, and use of research or testing methods that limit the use of animals or

minimize animal distress.

(3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility.

(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act,

(5) Utilization of Services (e.g., National Agricultural Library, National Library of Medicine) available to provide information;

- (i) On appropriate methods of animal care and use;
- (ii) On alternatives to the use of live animals in research;
- (iii) That could prevent unintended and unnecessary duplication of research involving animals; and
- (iv) Regarding the intent and regulation of the Act.

The IACUC of each research facility is charged with the responsibility of reviewing on a semi-annual basis the research facility's entire program for humane care and use of animals. A vital component of every program is the training of all personnel involved in animal care, treatment, and use.

The IACUC must determine that all personnel conducting procedures on animals being maintained or studied are appropriately qualified and trained in those procedures.

The USDA veterinary medical officer, when inspecting a research facility, has the challenging task of evaluating the facility's overall training program.

This evaluation process should involve asking the following questions:

- Is training and instruction available to all personnel involved in animal care, treatment, and use?
- Does the training program include guidance in all areas listed in §2.32 - Personnel qualifications of the regulations?
- Is there adequate documentation of qualifications and training of personnel?
- Has the IACUC been provided sufficient documentation for it to fulfill its tasks of reviewing qualifications and training of all personnel involved in all proposed or ongoing activities?
- Does the semi-annual program review of animal care and use include personnel qualifications and training?
- Has there been input and oversight by the attending veterinarian toward an effective training program?
- Are procedures being adequately monitored to insure competency in situations such as new or inexperienced personnel?
- How does the facility assess training needs of personnel on an ongoing basis?
- Is there a training program for the IACUC members, especially the non-affiliated member?
- Are there written guidelines and training for animal pain or distress assessment that is relevant to the research work at the facility?
- Are investigators adequately training on how to conduct and document a search for alternatives to painful or distressful procedures?
- Have protocols been developed for animals being used for procedure training for technicians or investigators?

A responsible training program should be in place at each research facility. Each training program may vary from one facility to another depending on the type of research being conducted and the needs of the facility. When a VMO reviews a training program, professional judgment is critical.

Documentation is important, but the "results" of a training program are the primary consideration.

Bibliography

Adsit, K.I., S.P. Tomasovic, A.J. Mastromarino, and K.N. Gray (1990). **Evaluation of the effectiveness of an animal care and use training program.** *Lab Animal* 19(4): 50, 52-54.

NAL call number: QL55 A1L33

Descriptors: University of Texas, training modules, training program assessment.

American Association for Laboratory Animal Science (AALAS) (1991). **Training Manual Series, Volume III Laboratory Animal Technologist.** Cordova, Tennessee: AALAS.

NAL call number: SF77 L26

Abstract: One of a series of manuals produced by AALAS to assist animal care personnel in obtaining certification at various levels of competence. Topics covered in this volume include" functions of management, identifying and controlling costs, regulations and security, scientific fundamentals in laboratory animal science, breeding and husbandry, laboratory animal environment, animal health, and research techniques, other manuals are available from AALAS through their website at <http://www.aalas.org>

Anderson, L.C. and M.J. Brown (1990). **Training of animal care and use personnel: principles and program implementation.** In *Anesthesia and analgesia in laboratory animals proceedings -- 1990 Forum, American College of Laboratory Animal Medicine, Columbia Inn, Columbia, Maryland, May 3-6, 1990.* [Columbia, Md. : American College of Laboratory Animal Medicine, pp. 113-115.

NAL call number: SF914 A53 1990

Descriptors: training, technicians, animal husbandry.

Bennett, B.T., M.J. Brown, and J.C. Schofield (1990). **Essentials for animal research. A primer for research personnel.** Beltsville, Maryland: Animal Welfare Information Center, 126 p.

The full text document is available at <http://www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm>

NAL call number: aQL55 B36 1994

Descriptors: regulations, animal welfare, aseptic surgery, anesthesia, alternatives, animal care as an experimental variable, euthanasia, laboratory animals, techniques.

bin Zakaria, M., N.W. Lerche, B.B. Chomel, and P.H. Kass (1996). **Accidental injuries associated with nonhuman primate exposure at two regional primate research centers (USA): 1988-1993.** *Laboratory Animal Science* 46(3): 298-304.

NAL call number: 410.9 P94

Abstract: Although occupationally acquired zoonoses of nonhuman primates have been well documented, the epidemiology of work-related injuries associated with occupational exposure to nonhuman primates has not been studied. To investigate such injuries, we retrospectively reviewed injury records at one regional primate research center and distributed a self-administered, anonymous questionnaire to at-risk personnel at two centers. Records of bite, animal-inflicted scratch, needle stick, cut, and mucous membrane exposure injuries were reviewed at one center for the 5-year period 1988 to 1993 to determine incidence and frequency of injuries and to identify possible risk factors. A total of 261 injuries were reported during this period, with an annual incidence for all injuries combined ranging from 43.5 to 65.5 injuries per 100,000 person workdays (pwd) at risk. For specific injuries the highest incidence was observed for animal-inflicted scratches and bites, with a rate of 82 and 81 per 100,000 pwd respectively. The job category Veterinary Resident was found to have the highest incidence for needle stick injuries (547 per 100,000 pwd), scratches (239 per 100,000 pwd), and cuts (171 per 100,000 pwd). The highest rates for bites were observed in the job categories Animal Health Technician and Animal Technician,

with 171 and 150 per 100,000 pwd respectively; the category Staff Veterinarian had the highest rate of mucous membrane exposures (71 per 100,000 pwd). The frequency of all injuries was greatest in personnel employed < or = 2 years. Questionnaire responses indicated that having > 20 h per week of contact with nonhuman primates or contact with more than 50 nonhuman primates per week was associated with a significantly increased risk of bites, animal-inflicted scratches, needle sticks, and mucous membrane exposures. In addition, data analysis indicated that under-reporting of work-related injuries was high; 59% of scratches, 50% of mucous membrane exposures, 45% of cuts, 37% of bites, and 20% of needle stick injuries went unreported. Results of this study identify job categories with a high incidence of specific injuries, for which additional targeted training and prevention programs may be beneficial, as well as providing quantitative baseline data for evaluating the effectiveness of any new safety programs or practices.

Descriptors: accidents, occupational statistics and numerical data, housing, animal statistics and numerical data, occupational diseases, epidemiology, primates wounds, bites, animal technicians, laboratory personnel, needle stick injuries epidemiology, primate diseases transmission, primates microbiology, retrospective-studies, risk-factors, zoonoses.

Bowd, A.D. (1998). **Animal care courses: Helping fulfill the mandate of animal care committees in Canada.** *Journal of Applied Animal Welfare Science* 1(4): 353-360.

NAL call number: HV4701 J68

Descriptors: ethics, alternatives, humane animal use, organization of animal care courses, training investigators, students, and IACUC members, topics covered include: regulations and legislation, ethical issues, alternatives, animal welfare, animal care, zoonoses and biohazards, animal surgery and euthanasia, practical handling of animals, improving statistical power, wildlife issues, case studies, teaching methods.

Duffee, N. (1999). **Alternative Training Methods I: Proceedings of the 1998 LAWTE Meeting.** *Lab Animal* 28(5): 24.

NAL call number: QL55 A1L33

Abstract: The author discusses alternative training methods presented at the 1998 meeting of the Laboratory Animal Welfare Training Exchange.

Descriptors: USDA training requirements, finding alternative training methods, simulation models, venipuncture, endotracheal intubation, surgical techniques, computer media, virtual reality, developing training programs.

Duffee, N. And M.T. Fallon (1998). **Researcher training: a new frontier.** *Lab Animal* 27(8):32-36.

NAL call number: QL55 A1L33

Descriptors: computer-based training materials, videotape, self-assessment web server, training researchers n animal care and use techniques, endotracheal intubation, project status.

Federation of European Laboratory Animal Science Associations (FELASA) (1999). **FELASA guidelines for education of specialists in laboratory animal science (Category D).** *Laboratory Animals* 33(1): 1-15.

NAL call number: QL55 A1L3

Descriptors: category D corresponds to laboratory higher management, veterinarians, facility managers, etc., level of studies, specific requirements necessary for category D, detailed description of curriculum.

Federation of European Laboratory Animal Science Associations (FELASA) (1995). **FELASA recommendations on the education and training of persons working with laboratory animals: Categories A and C.** *Laboratory Animals* 29(2): 121-131.

NAL call number: QL55 A1L3

Descriptors: category A corresponds to laboratory animal technicians/technologists, category C corresponds to study directors, levels of certification, overview of duties and responsibilities at different levels, animal care, animal husbandry, safety, legislation, responsibility for defined tasks and procedures, teaching syllabus and objectives.

Green, R.J. (1997). **Developing and implementing personnel safety programs. II. Safety training and education in animal research.** *Lab Animal* 26(6): 27 -30.

NAL call number: QL55 A1L33

Descriptors: laboratory hazards, animal experiments, biosafety, training, educational programs, laboratory workers.

Hutchison, J. (1989). **Thoughts on educating community members of animal care and use committees.** In *Science and Animals: Addressing Contemporary Issues* H.N. Guttman, J.A. Mench, and R.C. Simmonds (eds.), Bethesda, Maryland: Scientists Center for Animal Welfare, pp. 129-132.

NAL call number: HV4704 S33 1988

Descriptors: guidelines, public representation, educational programs.

Jennings, M. and P. Hawkins (1998). **Developing the ethics component of the U.K. modular training system for laboratory animal scientists: A LASA workshop report.** *Animal Welfare* 7(4): 445-458.

NAL call number: HV4701.A557

Abstract: This paper presents the report of a LASA workshop on developing the ethics component of the UK modular training system for laboratory animal scientists. The objectives were: (i) to define and agree on the goals of ethics training; (ii) to set out means of achieving these goals in terms of an appropriate syllabus, effective approaches to training, and the resources necessary; (iii) to define the audience—who should be trained and to what level; and (iv) to consider the practicalities and means of assessment of prospective licensees. Although the focus was on the UK system, the issues are similar wherever ethics is taught in the laboratory animal context.

Jones, S.A. and T.J. Sharpe (1994). **An integrated training programme to meet UK guidelines for staff at all levels working with animals.** In *Welfare and science proceedings of the Fifth Symposium of the Federation of European Laboratory Animal Science Associations, 8-11 June 1993, Brighton, UK / Federation of European Laboratory Animal Science Associations Symposium* London: Royal Society of Medicine Press, pp. 363-364.

NAL call number: QL55 F43 1993

Descriptors: laboratory workers, training, laboratory animals, animal welfare, United Kingdom.

Maltby, C.J. (1989). **Partnership in training--a winning combination.** *Lab Animal* 18(5): 38-39.

NAL call number: L55 A1L33

Descriptors: laboratory animals, research institutes, educational programs.

National Academy of Sciences (1991). **Education and Training in the Care and Use of Laboratory Animals: A Guide for Developing Institutional Programs.** Washington, D.C.: Institute of Laboratory Animal Resources, 144 p.

NAL call number: SF604 E3

Abstract: The Committee on Education Programs in Laboratory Animal Science (EPLAS) has prepared this guide to aid institutions in implementing an education and training program that will meet the expectations of the Public Health Service (PHS). This guide was designed to fulfill several purposes. First, it is intended to assist institutional officials and institutional animal care and use committees (IACUCs) in determining the scope and depth of education training programs that will meet both institutional needs and the requirements of the PHS. Second, it is offered as a reference for the person or committee assigned the responsibility for coordinating these programs. Finally, portions of the guide will be useful to those people (content experts) who develop the material to be presented. To accommodate the diverse backgrounds and needs of personnel, the committee has developed a multiphase program. Those topics considered essential elements for all personnel have been arranged into a single introductory module. The next three modules cover specific species, pain-management, and surgery. The next section of the guide contains detailed content outlines of the subjects covered in the four modules. The material in the modules is cross-referenced to appropriate subtopics in this section. Information on the following topics is provided: (1) laws, regulations, and policies that impact on the care and use of animals; (2) ethical and scientific issues; (3) alternatives to dissection; (4) responsibilities of the institution, the animal care and use committee, and the research and veterinary staffs; (5) pain and distress; (6) anesthetics, tranquilizers, analgesics, and neuromuscular blocking agents; (7) survival surgery and postsurgical care; (8) euthanasia; (9) husbandry, care, and the importance of the environment; and (10) a species-specific overview. The next section contains sources of information, selected bibliography, and audiovisual materials. The last section provides information on how to develop, deliver, and evaluate an educational program. Principles for the utilization and care of vertebrate animals used in testing, research, and training; a description of the Animal Welfare Information Center; and

samples of learning objectives or self-assessment statements that coordinators may want to use or adapt for use at their institutions are appended.

Descriptors: anesthesiology, animal caretakers, animal husbandry, higher education, high schools, laboratory equipment, resource materials, science education, surgery, animal facilities, laboratory animals, research.

Scher, S. (1987). **Technician training: Animal care and use committees.** *Laboratory Animal Science* 37(special issue): 150-151.

NAL call number: 410.9 P94

Descriptors: laboratory animal science, animal welfare, education.

Simmonds, R.C. (1987). **Role of animal care and use committees in investigator training.** *Laboratory Animal Science* 37(special issue): 152-154.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal welfare, educational programs.

Slack, G.N. (1996). **A summary of industry developed educational resources on food animal care and welfare.** In *Proceedings One-Hundredth Annual Meeting of the United States Animal Health Association, Excelsior Hotel, Little Rock, Arkansas, USA, 12-18 October 1996*, pp. 23-30.

NAL call number: 49.9 UN3R

Descriptors: livestock, education, resources, animal welfare, animal husbandry.

Smith, J.A. and M. Jennings (1998). **Ethics training for laboratory animal users.** *Laboratory Animals* 32(2): 128-136.

NAL call number: QL55 A1L3

Abstract: In the UK, all applicants for licences under the Animals (Scientific Procedures) Act 1986 must receive training in ethical aspects of laboratory animal use. There is, however, considerable uncertainty about the aims, suitable content and most appropriate means of delivery of such training. In this review a series of aims for licensee training in ethics are proposed, the key content is described and possible approaches to delivering such training are critically evaluated. Ethics training, it is argued, should: (i) be rooted in practice, focusing on the practical application of the Act to licensees' own work and encouraging them to take all possible steps to reduce or resolve any moral conflicts which the work entails; (ii) promote discussion, encouraging licensees to challenge their own views and critically appraise their work; and (iii) provide the necessary theoretical background to inform and stimulate such discussion. A variety of means of generating discussion and a range of practical considerations are explored.

Descriptors: ethics, animal welfare, training, laboratory animals, legislation, education, animal experiments.

Stark, D.M. (1989). **The American veterinarians' role and education in laboratory animal science.** *Animal Technology: Journal of the Institute of Animal Technicians* 40(3): 199-201.

NAL call number: QL55 I5

Descriptors: laboratory animals, training, animal husbandry, ACUC.

Sutherland, D.L. and D.R. Russell (1996). **Evolution of a training program built on employee involvement.** *Lab Animal* 25(9): 41-43.

NAL call number: QL55 A1L33

Descriptors: developing a training program at a large pharmaceutical facility, inclusion of veterinary care staff and training administrator in development process, subject matter experts, development of core modules e.g., husbandry and care, development of species specific modules e.g., rat, mouse, rabbits, development of task specific modules e.g., handling and restraint, development of reference materials, teaching aids, curriculum, administration support, communication techniques within house to advertise the program, participant recognition program.

Thomas, W.E., P.W. Lee, G.T. Sunderland, and R.P. Day (1996). **A preliminary evaluation of an innovative synthetic soft tissue simulation module ('Skilltray') for use in basic surgical skills workshops.** *Annals of the Royal College of Surgeons of England* 78(6 Suppl): 268-71.

Abstract: The results of a preliminary evaluation comparing the relative merits of biological (freshly-prepared animal offal tissue) and synthetic (Skilltray) simulation modalities are presented, subsequent to their use during two basic surgical skills courses organised by The Royal College of Surgeons of England and The Royal College of Physicians and Surgeons of Glasgow in September 1995, and at which 18 SHO grade surgical trainees attended. Each trainee completed a questionnaire at the end of the first session on the second day of the course to assist the evaluation. Our conclusions were as follows: 1. The synthetic tissues evaluated provided a useful and functionally reproducible means for learning the basic exercises included in the mandatory skills course. 2. Freshly-prepared animal tissues undoubtedly provided a more "realistic" medium for rehearsing the basic surgical techniques taught. Trainees preferred to use the synthetic tissues initially and then to progress to the fresh equivalents subsequently. 3. The Skilltray provided all the requisite elements for rehearsing basic tissue handling, suturing, and anastomotic techniques in a self-contained, easily transportable module. We would suggest that such a unit be given to each participant to take away at the end of the basic skills course, to enable consolidation of the skills learned. 4. Where the use of fresh tissues is not possible the highly functional nature of the synthetic simulators evaluated make it acceptable then to use them as the only training modality.

Descriptors: artificial organs, education, graduate methods, surgery education, teaching materials, attitude of personnel, evaluation studies, artificial skin, alternatives.

Tomasovic, S.P., K.N. Gray, A.J. Mastromarino, and K.I. Adsit (1989). **Animal care and training for temporary research employees.** *Lab Animal* 18(4): 27-28,30,32.

NAL call number: QL55 A1L33

Descriptors: training programs, training, animal care and use, protocol, ACUC.

University of Texas Health Science Center at San Antonio (1990). **Responsible care and use of animals in research and training: institutional animal care training program.** San Antonio, Texas: University of Texas Health Science Center, 36 p.

NAL call number: HV4933 T4U5

Descriptors: laboratory animals, animal welfare, animal models, bioethics.

Van Hoosier, G.L. Jr., M.B. Dennis, Jr, C. Pekow, and C.S.Scott (1994). **Research animal management problems as a strategy for education and training.** *Contemporary Topics in Laboratory Animal Science* 33(5): 72-74.

NAL call number: SF405.5 A23

Descriptors: veterinary education, animal husbandry, training, educational methods.

Van Hoosier, G.L. Jr., M.B. Dennis, Jr, C. Pekow, and C.S. Scott (1994). **Education and training through the use of problem-based learning exercises.** In *Welfare and science proceedings of the Fifth Symposium of the Federation of European Laboratory Animal Science Associations, 8-11 June 1993, Brighton, UK / Federation of European Laboratory Animal Science Associations Symposium*, London: Royal Society of Medicine Press, pp. 89-93.

NAL call number: QL55 F43 1993

Descriptors: veterinary education, teaching methods, research workers, discussion groups, animal welfare, class activities.

White, G.L., M.A. Perry, and S.D. Kosanke (1991). **A comprehensive health science center educational program for animal care and use.** *Lab Animal* 20(7): 47-49.

NAL call number: QL55 A1L33

Descriptors: University of Oklahoma, course focus, workshops, laboratories.

Will, J.A. and A. Gendron-Fitzpatrick (1987). **Investigator training: Animal care and use committees.** *Laboratory Animal Science* 37(special issue): 159-160.

NAL call number: 410.9 P94

Descriptors: animal welfare, continuing education, laboratory animals, research, universities, ACUC.

Zutphen, B.F.M. van and J.B.F. van der Valk (1995). **Education and training: a basis for the introduction of**

the three Rs alternatives into animal research. *Alternatives to Laboratory Animals: ATLA* 23(1): 123-127.
NAL call number: Z7994.L3A5.

Abstract: Education is a highly effective way of promoting the introduction of alternatives into the everyday practice of biomedical research and testing. In some countries, specific requirement for the education of persons involved in animal experimentation have been made compulsory by law. In The Netherlands, young scientists must take a course on laboratory animal science as part of, or in addition to, their biomedical graduate programme. This course provides information on the proper design of animal experiments, but also covers alternatives animal welfare issues and ethical aspects of animal experimentation. The Three RB of Russell & Burch are the guiding principles of the course, during which participants are challenged to seek methods or techniques that can replace, reduce or refine the use of animals. Since 1985 more than 2500 people in The Netherlands have taken the course, and evaluations have indicated that a large majority of the participants appreciated this education as a contribution to both the quality of experiments and the welfare of the animals, and considered the course to be indispensable for those who are responsible for the design and performance of animal experiments.

Descriptors: animal testing alternatives, animal experiments, educational courses, training, laboratory animals, animal husbandry.

Useful World Wide Web Sites

Arizona State University, User Training and Certification

<http://www.iacuc.arizona.edu/training/>

Nice example of on-line training at a university.

IACUC Training and Learning Consortium

<http://www.iacuc.org>

Links to laboratory animal training sites at U.S. universities and to training media produced by various professional organizations and Federal agencies.

Laboratory Animal Training Association

<http://www.latanet.com>

Provides members with access to on-line training modules, a list of training videos available for purchase, and a buyers guide.

Laboratory Animal Welfare Training Exchange (LAWTE)

<http://www.lawte.org>

The Laboratory Animal Welfare Training Exchange is an organization of trainers, training coordinators and IACUC administrators. By sharing ideas on methods and materials for training, our members can learn together how best to meet the training and qualification requirements of national regulations and guidelines. For more detail look in the section on Organizations.

The University of California, Davis, Classes / SafetyNets / Videos

<http://safetyapps.ucdavis.edu/ehs/training/#acu101>

Training resources related to animal use & care.

University of Florida On-Line Training & Materials

<http://iacuc.ufl.edu/training.htm>

This is a collection of exams, slide shows, tutorials, texts, class notes, etc. that have been put on the web.

University of Texas Health Science Center at San Antonio - Laboratory Animal Programs, Institutional Animal Care Training Program

<http://research.uthscsa.edu/IACUC/training.shtml>

This site provides a training program overview.

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Updated September 3, 2003

Whistleblowing

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Department of Health and Human Services Office of Research Integrity

Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research (November 20, 1995)

This document is available at http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.shtml

Editor's Note: These guidelines were developed to provide guidance to research institutions in handling allegations of scientific misconduct. "Scientific misconduct" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. It does not include violations of USDA's animal welfare regulations or the PHS policy on the care and use of laboratory animals. However, they may provide guidance to animal care programs in the establishment of whistleblower guidelines.

I. INTRODUCTION

The Office of Research Integrity (ORI), Department of Health and Human Services (DHHS), strongly believes in the importance of protecting whistleblowers who make good faith allegations of scientific misconduct to ORI or appropriate institutional authorities. In particular, ORI is committed to protecting good faith whistleblowers from retaliation by covered institutions and their members.

By regulation, each extramural entity that applies for a biomedical or behavioral research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act must establish policies and procedures that provide for "undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations." 42 C.F.R. Part 50.103(d)(13).

Although the regulation does not provide specific direction on how to protect whistleblowers, ORI has determined that adherence to the policies and procedures set forth in these Guidelines is one method of satisfying the requirements of the regulation. ORI will recognize an institution's substantial conformity with these Guidelines as meeting the whistleblower protection requirement of 42 C.F.R. Part 50.103(d)(13). Specifically, each institution which substantially adheres to Sections IV and V of these Guidelines in responding to whistleblower retaliation complaints will be considered in compliance with the regulatory whistleblower protection requirement for resolution of retaliation complaints. However, institutions are free to disregard these Guidelines and adopt other procedures that conform to the regulatory requirement.

If an institution elects to adopt these Guidelines, it must abide by each provision that uses the operative word "shall." On the other hand, provisions which employ the words "should" or "may" are merely practical suggestions. An institution will not be out of conformity with the Guidelines if it fails to carry out these recommendations. Rather, an institution may substitute for these suggested provisions alternative procedures that are consistent with the mandatory provisions of these Guidelines and the regulatory whistleblower protection provisions.

In addition to the requirements of 42 C.F.R. Part 50.103(d)(13), ORI encourages covered institutions to adopt policies and procedures that conform to PHS Act Part 493(e), a whistleblower protection statute enacted by Part 163 of the National Institutes of Health Revitalization Act of 1993, although Part 493 has not been implemented by regulation at the time of issuance of these Guidelines. Besides protecting good faith allegations of scientific misconduct, PHS Act Part 493(e) mandates the protection of whistleblowers for (1) good faith allegations of an inadequate institutional response to scientific misconduct allegations and (2) good faith cooperation with investigations of such allegations. The statute covers allegations of misconduct which involve research or research related grants, contracts or cooperative agreements under the PHS Act. ORI also encourages institutions to adopt principles consistent with the Whistleblower Bill of Rights (Appendix A) recommended by the Commission on Research Integrity and to foster institutional commitment to those principles. The specific principles of the Whistleblower Bill of Rights are as follows:

- (1) whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy,
- (2) institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers,
- (3) institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes and allegations of research misconduct,
- (4) institutions have a duty to follow procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias,
- (5) institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblower,
- (6) institutions have a duty to handle cases involving alleged research misconduct as expeditiously as possible without compromising responsible resolutions, and
- (7) at the conclusion of proceedings, institutions have a responsibility to credit promptly, in public or private as appropriate, those whose allegations are substantiated.

These Guidelines are consistent with the rights and responsibilities enumerated in the Whistleblower Bill of Rights.

While compliance with these Guidelines will satisfy the existing regulatory requirements at 42 C.F.R. Part 50.103 (d) (13), this publication does not bind the Department in any way as to the substantive provisions of the forthcoming new regulation implementing the whistleblower protection statute, PHS Act Part 493(e).

II. PURPOSE

The purpose of these Guidelines is to set forth ORI's suggested approach for handling whistleblower retaliation cases

which arise at covered institutions. Substantial adherence to the Guidelines in each whistleblower case affords a "safe harbor" in which conforming institutions will be deemed in compliance with Part 50.103(d)(13) of the scientific misconduct regulation. For those institutions which adopt alternative procedures to comply with the regulation, ORI may review those cases which do not abide by these Guidelines to determine whether an institution has taken diligent efforts to protect the positions and reputations of good faith whistleblowers.

These Guidelines also provide information to whistleblowers on an appropriate method of submitting retaliation complaints and subsequent procedures for resolving the complaints. ORI encourages whistleblowers to refer institutions to these Guidelines when making specific complaints of retaliation.

These Guidelines apply to all instances of possible retaliation against whistleblowers whose allegation of scientific misconduct is covered by 42 C.F.R. Part 50, Subpart A.

III. DEFINITIONS

"Adverse action" means any action taken by a covered institution or its members which negatively affects the terms or conditions of the whistleblower's status at the institution, including but not limited to his or her employment, academic matriculation, awarding of degree, or institutional relationship established by grant, contract or cooperative agreement.

"Allegation" means any disclosure, whether by written or oral statement, or any other communication, to an institutional, a Department of Justice (DOJ), or a DHHS official who receives the allegation while acting in their official capacity, that a covered institution or member thereof has engaged in scientific misconduct. Allegations made to any of the above officials may be in conjunction with communications to Congress ¹.

"Arbitration" means the process described in this Part through which an unresolved dispute regarding whistleblower retaliation is submitted to an arbitrator for a final and binding decision.

"Arbitrator" means one or more impartial persons selected according to the rules of a designated arbitration association who shall hear and decide whistleblower retaliation complaints under this Part.

"Covered institution" means any entity, whether individual or corporate, which applies for or receives funds under a research, research-training, or research-related grant or cooperative agreement under the PHS Act.

"Deciding official" means the official designated by the administrative head of a covered institution to make a final institutional determination as to whether retaliation occurred.

"Good faith allegation" means an allegation of scientific misconduct made with a belief in the truth of the allegation which a reasonable person in the whistleblower's position could hold based upon the facts. An allegation is not in good faith if made with reckless disregard for or willful ignorance of facts that would disprove the allegation

"Institutional member, or member" means a person who is employed by, affiliated with under a contract or agreement, or under the control of a covered institution. Institutional members include but are not limited to administrative, teaching and support staff, researchers, clinicians, technicians, fellows, students, and contractors and their employees.

"Office of Research Integrity (ORI)" means the office to which the Secretary has delegated responsibility for addressing scientific misconduct issues related to PHS activities, including the protection of good faith whistleblowers.

"Responsible official" means the official designated by and reporting to the administrative head of a covered institution to establish and implement the institution's whistleblower policies.

"Retaliation" means any adverse action or credible threat of an adverse action taken by a covered institution, or member thereof, in response to a whistleblower's good faith allegation of scientific misconduct. It does not include an institution's decision to investigate a good faith allegation of scientific misconduct.

"Scientific misconduct" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those

that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

"Whistleblower" means an individual who makes an allegation or demonstrates an intent to make an allegation (or what is perceived to be an allegation) while a member of the institution at which the alleged scientific misconduct occurred.

IV. PROCESSING WHISTLEBLOWER RETALIATION COMPLAINTS

A. Responsible Official

1. Covered institutions shall designate a "responsible official" to establish and implement the institution's whistleblower policies according to 42 C.F.R. Part 50.103(d)(13) and these Guidelines. The responsible official also serves as a liaison between the institution and ORI for transmitting such information as ORI may require.
2. The responsible official shall be free of any real or apparent conflicts of interest in any particular case.
3. If involvement of the responsible official in a particular case creates a real or apparent conflict of interest with the institution's obligation to protect good faith whistleblowers, and the conflict cannot be satisfactorily resolved for that case, the administrative head of the institution shall appoint a substitute responsible official who has no conflict of interest.

B. Notice of Institutional Policy

The institution shall provide to all its members notice of its whistleblower policies and these Guidelines with Appendices. The notice shall include the requirement set forth below regarding a whistleblower's deadline for filing a retaliation complaint. The institution's policies and these Guidelines shall be either disseminated or be publicized and made readily available to all institutional members.

C. Filing Complaints

1. A whistleblower who wishes to receive the procedural protections described by these Guidelines shall file his or her retaliation complaint with the responsible official at the appropriate institution within 180 days² from the date the whistleblower became aware or should have become aware of the alleged adverse action. Covered institutions shall review and resolve all whistleblower retaliation complaints and should do so within 180 days after receipt of the complaint. If the whistleblower fails to receive an institutional response to the complaint in accordance with these Guidelines within ten (10) working days³, the whistleblower may file the retaliation complaint directly with ORI at the following address:

Office of Research Integrity
Division of Policy and Education
5515 Security Lane, Suite 700
Rockville, MD 20852
Telephone: (301) 443-5300
Fax: (301) 594-0042

ORI will forward such complaints to the institution's responsible official for appropriate action.

2. In addition to prospective complaints, institutions may apply these Guidelines to complaints of retaliation made prior to the effective date of the institution's adoption of these Guidelines.
3. The retaliation complaint must include a description of the whistleblower's scientific misconduct allegation and the asserted adverse action, or threat thereof, against the whistleblower, by the institution or its members in response to the allegation. If the retaliation complaint is incomplete, the responsible official shall describe to the whistleblower what

additional information is needed in order to meet the minimum requirements of a complaint under this Part.

D. Responding to Complaints

1. Upon receipt of a whistleblower retaliation complaint, the responsible official shall notify the whistleblower of receipt within ten (10) working days ⁴ after receipt. The notice shall also inform the whistleblower of which process under Section V of the Guidelines the institution proposes to follow in resolving the retaliation complaint and the necessary actions by the whistleblower required under that process. The notice shall also notify the whistleblower of his or her choice of responses listed below.
2. The whistleblower may raise any concerns about the proposed process with the responsible official and the institution may modify the process in response to the whistleblower's concerns.
3. The whistleblower has five working days from the date of receipt of the initial notification in Part 1 above to:
 - a. accept the proposed process, although the whistleblower may also submit documentation for the official record about any concerns he or she may have about the proposed process; or
 - b. not accept the proposed process. If the whistleblower rejects the proposed process, he or she may pursue other remedies as provided by law.
4. If the whistleblower does not accept the proposed process, the institution may, but is not required to, propose the alternative option under Section V of the Guidelines.
5. The institution shall notify ORI of any whistleblower retaliation complaint it receives within ten (10) working days ⁵ after receipt of the complaint.

E. Interim Protections

1. At any time before the merits of a whistleblower retaliation complaint have been fully resolved, the whistleblower may submit a written request to the responsible official to take interim actions to protect the whistleblower against an existing adverse action or credible threat of an adverse action by the institution or member.
2. Based on the available evidence, the responsible official shall make a determination of whether to provide interim protections and shall advise the whistleblower of his or her decision in writing. Documentation underlying the decision whether to provide interim protections shall become part of the record of the complaint. When the whistleblower retaliation complaint is fully resolved, any temporary measure taken to protect the whistleblower shall be discontinued or replaced with permanent remedies.

V. RESOLUTION OF COMPLAINTS

1. For each whistleblower retaliation complaint received, a covered institution shall adhere to one of the two alternative processes for resolving the whistleblower retaliation complaint, or settle the complaint, as described below.
2. Whichever process is elected shall be implemented in a timely fashion. The process should be completed within 180 days of the date the complaint is filed, unless the whistleblower agrees to an extension of time. The institution shall promptly report the final outcome of either process or any settlement to ORI.
3. If the whistleblower declines the institution's proposed process according to these Guidelines, he or she may pursue any other legal rights available to the whistleblower for resolution of the retaliation complaint. However, ORI will deem the institution to have met its obligation under 42 C.F.R. Part 50.103(d)(13) and will not pursue the whistleblower complaint further.

Option A: Institutional Investigation

1. If the institution elects Option A, the institution shall conduct an investigation of the whistleblower retaliation complaint according to these Guidelines and implement appropriate administrative remedies consistent with the investigation's finding and institutional decision thereon.
2. An investigation of whistleblower retaliation shall be timely, objective, thorough, and competent. The investigation should be conducted by a panel of at least three (3) individuals appointed by the responsible official. The members of the investigation panel, who may be from outside the institution, shall have no personal or professional relationship or other conflict of interest with the whistleblower or the alleged individual retaliator(s), and shall be qualified to conduct a thorough and competent investigation.
3. The investigation shall include the collection and examination of all relevant evidence, including interviews with the whistleblower, the alleged retaliator(s), and any other individual who can provide relevant and material information regarding the claimed retaliation.
4. The institution shall fully cooperate with the investigation and use all available administrative means to secure testimony, documents, and other materials relevant to the investigation.
5. The confidentiality of all participants in the investigation shall be maintained to the maximum extent possible throughout the investigation.
6. The Panel members shall evaluate and respond objectively to any concerns raised by the whistleblower about the process, including concerns regarding the selection of the deciding official, responsible official and specific panel members, which are raised prior to resolution of the complaint.
7. The conclusions of the investigation shall be documented in a written report and made available to the whistleblower. The report shall include findings of fact, a list of witnesses interviewed, an analysis of the evidence, and a detailed description of the investigative process.
8. The deciding official shall make a final institutional determination as to whether retaliation occurred. This decision shall be based on the report, the record of the investigation, and a preponderance of evidence standard.
9. If there is a determination that retaliation has occurred, the deciding official shall determine what remedies are appropriate to satisfy the institution's regulatory obligation to protect whistleblowers. The deciding official shall, in consultation with the whistleblower, take measures to protect or restore the whistleblower's position and reputation, including making any public or private statements, as appropriate. In addition, the deciding official may provide protection against further retaliation by monitoring or disciplining the retaliator.
10. The institution shall promptly notify ORI of its conclusions and remedies, if any, and forward the underlying investigation report to ORI.
11. The ORI will review the institutional report to determine whether the institution has substantially followed the process described herein. If the institution has substantially conformed to the process, ORI will not review the merits of the institutional determination under Paragraphs 8 and 9.
12. Institutional compliance with Option A does not bar the whistleblower from seeking redress against the institution's decision under Paragraph 8 and 9, under State law, institutional procedure, policy or agreement, or as otherwise provided by law.

Option B: Arbitration

1. If the institution elects Option B, the institution shall offer the whistleblower the opportunity to submit the retaliation dispute to binding arbitration. The parties shall sign a written agreement that the retaliation dispute will be decided by

final and binding arbitration, identifying the person who shall conduct the arbitration.

2. The arbitration agreement shall specify that the institution and the whistleblower abrogate all other rights under Federal, State and local law, and other institutional policies or employment agreements pertinent to the resolution of the whistleblower retaliation complaint, other than enforcement of the arbitration award. However, the parties may enter into any legally enforceable settlement agreement before a final arbitration award is made. A sample arbitration agreement is attached at Appendix B.
3. Any retaliation complaint submitted to arbitration shall be arbitrated according to the rules and procedures of the presiding arbitrator and designated arbitration association.
4. An arbitration under these Guidelines shall be conducted by an arbitrator who has no personal or professional relationship or conflict of interest with the whistleblower, the institution, the alleged retaliator(s), or any person who is the subject of the underlying scientific misconduct allegation. The institution and the whistleblower shall agree on the choice of arbitrator. The arbitration should be facilitated by the American Arbitration Association or any other recognized non-profit arbitration association.
5. The institution and the whistleblower shall share equally the administrative costs of the arbitration. Each party is responsible for the cost of presenting its own case.
6. The arbitration agreement shall specify that the arbitrator shall require the institution to compensate the whistleblower for part or all of his or her arbitration costs, including attorney fees, if the arbitrator finds that the institution, or its members, retaliated against the whistleblower.
7. The arbitration agreement shall also specify that the arbitrator shall require the whistleblower to compensate the institution for part or all of any filing fees and arbitrator's costs if the arbitrator finds that the whistleblower's allegation of scientific misconduct was not made in good faith. If an institution seeks compensation on this basis, it shall make a preliminary motion to dismiss the retaliation complaint prior to commencement of a hearing. The arbitrator shall, if possible, make a threshold decision on the question of good faith based on written submissions prior to commencement of a hearing on the merits of the retaliation dispute. The institution has the burden of proving by a preponderance of the evidence that the allegation of scientific misconduct was not made in good faith.
8. The arbitration agreement shall specify a preponderance of the evidence standard in determining whether retaliation occurred or any other standard mutually agreed to by the parties.
9. The arbitration agreement shall state that the arbitrator's award is final and binding on all parties, and enforceable as provided by law.
10. If the arbitrator finds that the institution, or its members, retaliated against the whistleblower, the arbitrator may order any relief necessary to make the whistleblower whole for the direct or indirect consequences of retaliation, including protection against further retaliation through imposing a system to monitor or discipline the retaliator. The institution shall abide by the arbitrator's final award and shall implement any additional administrative actions it determines is necessary to correct the retaliation.
11. The institution shall promptly forward a copy of the final arbitration award to ORI.

C. Settlement

In lieu of the two options described above, an institution and whistleblower may, at any time after the retaliation complaint is made, enter into any binding settlement agreement which finally resolves the retaliation complaint. If both parties agree, the responsible official shall facilitate negotiation of such settlements. If such an agreement is reached, the institution and the whistleblower shall sign a statement indicating that the retaliation complaint has been resolved. The institution shall within 30 days send a copy of the signed statement to ORI. ORI does not require a copy of the actual terms of the settlement. The settlement may not restrict the whistleblower from cooperating with any

investigation of an allegation covered by 42 C.F.R. Part 50, Subpart A. ORI shall consider a settlement meeting these requirements as fulfilling the institution's regulatory obligation under 42 C.F.R. Part 50.103(d)(13).

VI. INSTITUTIONAL COMPLIANCE

At any time ORI may review a covered institution's compliance with 42 C.F.R. Part 50.103(d)(13) and these Guidelines to the extent that the institution relies on these Guidelines for regulatory compliance. Covered institutions and their members shall cooperate with any such review and provide ORI access to all relevant records. If a covered institution's procedures and implementation thereof substantially conforms to Sections IV and V above, it shall be deemed to have met its whistleblower protection obligation under 42 C.F.R. Part 50.103(d)(13).

Footnotes:

¹ Communications to Congress must be made in a way that affords "affected individual(s) confidential treatment to the maximum extent possible" consistent with 42 C.F.R. 50.103 (d)(3).

² The institution may establish a longer period of time.

³ The institution may establish a shorter period of time.

⁴ The institution may establish a shorter period of time consistent with footnote 2.

⁵ The institution may establish a shorter period of time.

APPENDIX A

Responsible Whistleblowing: A Whistleblower's Bill of Rights

a. **Communication:** Whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy. An individual or institution that retaliates against any person making protected disclosures engages in prohibited obstruction of investigations of research misconduct as defined by the Commission on Research Integrity. Whistleblowers must respect the confidentiality of sensitive information and give legitimate institutional structures an opportunity to function. Should a whistleblower elect to make a lawful disclosure that violates institutional rules of confidentiality, the institution may thereafter legitimately limit the whistleblower's access to further information about the case.

b. **Protection from retaliation:** Institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers. This duty includes providing appropriate and timely relief to ameliorate the consequences of actual or threatened reprisals, and holding accountable those who retaliate. Whistleblowers and other witnesses to possible research misconduct have a responsibility to raise their concerns honorably and with foundation.

c. **Fair procedures:** Institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes, and allegations of research misconduct. In cases of alleged retaliation that are not resolved through institutional intervention, whistleblowers should have an opportunity to defend themselves in a proceeding where they can present witnesses and confront those the charge with retaliation against them, except when they violate rules of confidentiality.

Whistleblowers have a responsibility to participate honorably in such procedures by respecting the serious consequences

for those they accuse of misconduct, and by using the same standards to correct their own errors that they apply to others.

d. **Procedures free from partiality:** Institutions have a duty to follow procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias. Whistleblowers have a responsibility to act within legitimate institutional channels when raising concerns about the integrity of research. They have the right to raise objections concerning the possible partiality of those selected to review their concerns without incurring retaliation.

e. **Information:** Institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblowers. Whistleblowers may have unique knowledge needed to evaluate thoroughly responses from those whose actions are questioned. Consequently, a competent investigation may involve giving whistleblowers one of more opportunities to comment on the accuracy and completeness of information relevant to their concerns, except when they violate rules of confidentiality.

f. **Timely processes:** Institutions have a duty to handle cases involving alleged research misconduct as expeditiously as is possible without compromising responsible resolutions. When cases drag on for years, the issue becomes the dispute rather than its resolution. Whistleblowers have a responsibility to facilitate expeditious resolution of cases by good-faith participation in misconduct procedures.

g. **Vindication:** At the conclusion of proceedings, institutions have a responsibility to credit promptly--in public and/or in private as appropriate--those whose allegations are substantiated.

Every right carries with it a corresponding responsibility. In this context, the Whistleblower Bill of Rights carries the obligation to avoid false statements and unlawful behavior.

Bibliography

Bilanski, W.K. (1986). **Whistle-blowing: the perils of professional dissent.** *Agricultural Engineering* 67 (7): 29-30.
NAL call number: 58.8 AG83

Descriptors: agricultural engineering, social consciousness, responsibility, crimewatch, law, employer-employee relationships, Whistle-blower Protection Act.

Boyle, R. D. (1990). **A review of whistle blower protections and suggestions for change.** *Labor Law Journal* 41(12): 821-830.

De-Maria, W. and C. Jan (1995). **Behold the shut-eyed sentry!: whistleblower perspectives on government failure to correct wrongdoing.** *Crime, Law and Social Change* 24(2): 151-166.

Descriptors: Australia, public sector, results evidence a tremendous disparity between whistleblower expectations and perceived success of the ensuing investigations, problems with agency investigations, whistleblowers frequently victimized for publicly disclosing their complaints, regulatory agencies rarely had the power to impose needed punishments on unjust employers, necessary changes were rarely achieved, grievances, government agencies.

Foley, D.R. (1990). **The call of the whistle blower.** *Security Management* 34(11): 47-48.

Lubalin, J.S.; M.A.E. Ardini, and J.L. Matheson (2 October 1995). (2 October 1995). **Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases. Final rept.** Rockville, Maryland: Office of the Assistant Secretary for Health, Department of Health and Human Services, 88 p. (Order this product from NTIS by: phone at 1-800-553-NTIS (U.S. customers); (703)605-6000 (other countries); fax at (703)605-6900; and email at orders@ntis.fedworld.gov. NTIS is located at 5285 Port Royal Road, Springfield, VA, 22161, USA.) Use order code:

Accession Number: PB96200449XSP; Price code: Paper copy A06/ Microfiche A01; Report number: OASH93900
Abstract: Uncovering misconduct in science, like misconduct in other areas of industry and government activities, often depends on the willingness of those aware or suspecting misconduct to report it. Uncovering such misconduct is generally recognized to be of significant value to society and to the integrity of scientific research. However, the willingness of individuals to allege misconduct is likely to depend on how the system deals with and protects them when they come forth with their allegations. Potential whistleblowers must consider whether the allegation will be taken seriously and the report treated confidentially and whether reporting will provoke retaliation not only from those accused but also from the larger academic and scientific community.

McCoy, K.A. (1998). **Litigating under the Florida Private Sector Whistle-Blower's Act: plaintiff protection and good faith.** *University of Miami Law Review* 52(3): 855-888.

Statute: Florida Whistleblower's Act

Descriptors: laws, regulations, private right of action, good faith, private sector.

Merit Systems Protection Board, Office of Special Counsel (1995). ***Employee Rights and Remedies Under 5 U.S.C., Chapters 12 and 23: United States Office of Special Counsel Training Aids for Federal Agency Informational Program Required by Public Law 103-424***, 66 p.

Abstract: Presents an overview of Federal employee rights and remedies under 5 U.S.C., chapters 12 and 23. Includes accompanying text/graphic summaries. Produced to aid agencies in carrying out their new statutory responsibility under Sec. 5/d. Covers: prohibited personnel practices; whistle blower disclosures; and Hatch Act advice and enforcement.

Miethe, T.D. and J. Rothschild (1994). **Whistleblowing and the control of organizational misconduct.** *Sociological Inquiry* 64(3): 322-347.

Descriptors: whistleblowing's effectiveness, organizational misconduct control, literature review, legal protection against retaliation, effectiveness of whistleblowing legislation.

Olson, T. P. (1995). **Taking the fear out of being a tattletale: whistle blower protection under the False Claims Act.(Case Note)** *De Paul Law Review* 44(4): 1363-1386.

Statute: False Claims Act, 31 U.S.C. 3730(h)

Descriptors: whistle blowing cases, defense industry.

Rothschild, J. (1998). ***The Suppression of Whistleblowers in the Governance of Work Organizations.*** Dept Sociology Virginia Polytechnic Institute & State University, Blacksburg 24061-0137 [tel/fax: 540-231-8974/3860; e-mail: joycer@vt.edu] Madrid: International Sociological Association.

Descriptors: first nationwide study of whistleblowers (N = 300) in the US, data indicate that employees are often punished for bringing forth valid information about wrongdoing or illegal conduct, organizations that publicly say that they want employees to "participate" & that they hold high ethical standards generally move to discredit the whistleblower & to fire them as soon as they see that they have information about waste, fraud, or abuses of power in the organization. The causes, nature, & consequences of management retaliation against whistleblowers in all types of work settings are discussed, organizational crime, ethics, sanctions.

Solomon, L.D. and T.D. Garcia (1980). **Protecting the corporate whistle blower under federal anti-retaliation statutes.** *Journal of Corporation Law* 5(2): 275-297.

Statute: Occupational Safety and Health Act of 1970

Descriptors: United States, Occupational Safety and Health Administration, occupational health and safety, laws and regulations, hazardous occupations, protection of informers.

Vinten, G. (1993). **Whistleblowing: an issue of social policy.** *International Journal of Sociology and Social Policy* 13(5-6): 53-109.

Descriptors: United States, Great Britain, whistleblowing, public sector, private industry, peer/supervisor retaliation, loss of job, social issues.

Emory University School of Medicine - Institutional Animal Care and Use Committee

<http://www.iacuc.emory.edu/documents/whistleblower.pdf>

Standard Operating Procedure for reporting incidents of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Government Accountability Project

<http://www.whistleblower.org/>

Resources for whistleblowers, information on current Federal regulations protecting whistleblowers, general articles, etc.

Municipal Research and Services Center-A resource for Washington local governments

<http://www.mrsc.org/personnel/whist.htm>

The ordinance and policy provisions contained in this compilation are offered as samples rather than models.

National Whistleblower Center

<http://www.whistleblowers.org>

The National Whistleblower Center is an educational and advocacy organization committed to government accountability and protecting the rights of employee whistleblowers.

U.S. Department of Health and Human Services, Office of Research Integrity

<http://ori.hhs.gov/guidelines-whistleblowers>

Provides information on whistleblower issues.

University of Arizona Institutional Animal Care and Use Committee

<http://www.iacuc.arizona.edu/concerns.htm>

A special policy on the investigation of concerns involving the care and use of animals.

University of California at Irvine

<http://www.policies.uci.edu/adm/procs/700/700-06.html>

Example of policies and guidelines implemented by an academic research institution

University of Tennessee, Office of Laboratory Animal Care

<http://www.vet.utk.edu/olac/>

Policy for reporting noncompliance with laboratory animal care and use guidelines.

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Updated April 11, 2005

Membership Issues and IACUC Communications

- [Appointing Animal Protectionists to IACUC's](#)
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See also [USDA Animal Care Policy 15 IACUC Membership](#) in the section [U.S. Government Principles, Regulations, Policies, and Guidelines](#)

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Bibliography

Clarke, S.P. (1998). **The newsletter as an animal care and use program communication training tool.** *Lab Animal* 27(6): 37-40.

NAL call number: QL55 A1L33

Descriptors: target audience, style and layout, content, editors, readership, supplements, cost, evaluation.

Dell, R.B. (1994). **Interacting with the IACUC.** *Lab Animal* 23 (8): 34-35.

NAL call number: QL55.A1L33.

Descriptors: laboratory animals, animal welfare, committees, communication, animal husbandry, animal experiments, project control, objectives..

Doris, P.A. (1988). **Communicating animal welfare issues to the investigator: An institutional newsletter.** *SCAW Newsletter* 10(1): 6,15.

NAL call number: QL55 N48

Descriptors: animal experiments, inspection, programs, policy, information needs.

Dresser, R. (1999). **Community representatives and nonscientists on the IACUC: What difference should it make?** *ILAR Journal* 40(1): 29-33.

NAL call number: QL55.A1I43

Abstract: During the 1980s, Congress and federal agency officials significantly revised US policy governing laboratory animal care and use. Before the revisions, activities involving laboratory animals were evaluated primarily by scientists and animal care staff employed by research facilities. The revised federal policy was designed to expand the evaluation to include other perspectives. New requirements for the participation of community members and nonscientists were established to further this aim. The revised federal policy has been in effect for more than a decade. In this article, I examine the requirements for community and nonscientist involvement in animal research oversight. First, I describe regulatory measures in the United States and other nations on public and nonscientist participation in research oversight. Then I discuss empirical data on and personal accounts of community representatives and nonscientists in the review process. I next consider different approaches to determining what these individuals can and ought to contribute. I conclude with suggestions on enhancing the participation of community representatives and non- scientists in

evaluating laboratory animal care and use. My analysis draws on the relevant literature as well as my own experience serving as a nonscientist member of four different institutional animal care and use committees (IACUCs) between 1985 and 1998.

Dyer, J.L. (1989) **Liability exposure of community members.** In *Science and Animals: Addressing Contemporary Issues* H.N. Guttman, J.A. Mench, and R.C. Simmonds (eds.), Bethesda, Maryland: Scientists Center for Animal Welfare, pp. 133-136.

NAL call number: HV4704 S33 1988

Descriptors: violations, statutory duties of the committee, private action, open meetings, Freedom of Information Act, ACUC.

Farr, C.E. (1989). **Community responsibility and the role of community members in public education.** In *Science and Animals: Addressing Contemporary Issues* H.N. Guttman, J.A. Mench, and R.C. Simmonds (eds.), Bethesda, Maryland: Scientists Center for Animal Welfare, pp. 139-141.

NAL call number: HV4704 S33 1988

Descriptors: community member functions, care and use of animals, confidentiality, public relations, ACUC.

Garnett, N. and S. Potkay (1995). **Use of electronic communications for IACUC functions.** *ILAR Journal* 37 (4): 190-192.

NAL call number: QL55.A1143.

Descriptors: animal welfare, laboratory animals, committees, communication, dissemination of information.

Gerrity, L.W. (1989). **Committee knowledge of protocol adherence.** In *Science and Animals: Addressing Contemporary Issues* H.N. Guttman, J.A. Mench, and R.C. Simmonds (eds.), Bethesda, Maryland: Scientists Center for Animal Welfare, pp. 137 -138.

NAL call number: HV4704 S33 1988

Descriptors: community representative, reduction, replacement and refinement, community member concerns, ACUC.

Hutchison, J. (1989). **Thoughts on educating community members of animal care and use committees.** In *Science and Animals: Addressing Contemporary Issues* H.N. Guttman, J.A. Mench, and R.C. Simmonds (eds.), Bethesda, Maryland: Scientists Center for Animal Welfare, pp. 129-132.

NAL call number: HV4704 S33 1988

Descriptors: guidelines, public representation, educational programs.

Keefer, E. and F. Westbrook (1995/96). **The role of the librarian in the work of the institutional animal care and use committee (IACUC).** *Animal Welfare Information Center Newsletter* 6 (2/4): 9-11.

NAL call number: aHV4701.A952.

Descriptors: laboratory animals, animal welfare, committees, libraries, information services, resource materials, information needs..

Krulisich, L. and D. Faryna (1999). **The 3 Cs of IACUC - principle investigator interaction.** *SCAW Newsletter* 21(1): 11.

NAL call number: QL55 N48

Descriptors: communication, consistency, and creation of a positive atmosphere, meeting overview, education, standard operating procedures, regulatory issues, IACUC procedures, training courses.

Levin, L.H. and M.L. Stephens (1994/1995). **Appointing animal protectionists to institutional animal care and use committees.** *Animal Welfare Information Center Newsletter* 5 (4): 1-2, 8-10.

NAL call number: aHV4701.A952.

Descriptors: animal welfare, committees, nonaffiliated member, membership.

Milhaud, C.L. (1997). **Role of the veterinarians in the ethical committees.** *STAL (Sciences et Techniques de l'Animal de Laboratoire)* 22(1): 33-39.

Descriptors: ethics, communication, regulations, veterinarians, committees.

National Institutes of Health (1998). **Development of the role of nonaffiliated and nonscientist members of Institutional Animal Care and Use Committees.** A manual distributed at a workshop sponsored by the NIH Intramural Research Program and the Office for Protection from Research Risks, January 16, 1998, Bethesda, Maryland: NIH. Descriptors: IACUC general functions, who should serve, alternatives, personal experiences, ethical and scientific issues, pain and distress, ethics, anesthesia and analgesia, survival surgery and postsurgical care, euthanasia, education and training resources, sample IACUC policies and guidelines, *Essentials for Animal Research*.

Powers, M.K. (1994). **Gauging reactive styles: a guide to stress free investigator/IACUC interactions.** *Lab Animal* 23 (10): 31-33.

NAL call number: QL55.A1L33.

Descriptors: work stress, communication, committees.

Recommended terms of reference for local animal care committees (1980). *Journal of Medical Primatology* 9(1-2): 145-148.

NAL call number: QL737.P9J66

Descriptors: ethics, guidelines, Canadian Council on Animal Care, ACUC.

Robb, J.W. (1995). **Why should anyone want to be an unaffiliated member of an IACUC?** In *Current Issues and New Frontiers in Animal Research*, K.A.L. Bayne, M. Greene, and E.D. Prentice, (eds.), Greenbelt, Maryland: Scientists Center for Animal Welfare, pp. 35-39.

NAL call number: HV4913 C87 1995

Descriptors: personal satisfaction, factors against serving, anecdotal incidents, challenge of inter-disciplinary dialogue, ethical reasons.

Robb, J.W. (1993). **Personal reflections: the role and value of the unaffiliated member and the nonscientist member of the institutional animal care and use committee.** *ILAR News* 35 (3/4): 50-53.

NAL call number: QL55.A1I43.

Descriptors: animal welfare, committees, nonaffiliated member, membership.

Scott, L.R. and P.D. Carter. (1996). **The role of veterinarians on animal experimentation ethics committees.** *Australian Veterinary Journal* 74 (4): 309-311.

NAL call number: 41.8 Au72

Descriptors: animal experiments, animal welfare, veterinarians, bioethics, committees, organizations..

Sprouse, S.R. (1993). **Connecting two worlds: a high school teacher's work on IACUC fosters communication between scientists and students.** *ILAR News* 35 (3/4): 54-55.

NAL call number: QL55.A1I43.

Descriptors: animal welfare, committees, membership, teachers.

Stephens, U.K. (1987). **Role of laboratory animal technicians as committee members.** *Laboratory Animal Science* 37(special issue): 103.

NAL call number: 410.9 P94

Descriptors: animal care, research, animal welfare, participation, ACUC.

Strandberg, J.D. (1987). **Membership issues: Animal care and use committees.** *Laboratory Animal Science* 37(special issue): 35-38.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal experiments, animal welfare.

Van Hoosier, Jr, G.L. (1987). **Role of the veterinarian.** *Laboratory Animal Science* 37(special issue): 101-102.

NAL call number: 410.9 P94

Descriptors: laboratory animals, animal welfare, ACUC.

Useful World Wide Web Sites

The University of Arizona Institutional Animal Care and Use Committee Handbook

<http://www.ahsc.arizona.edu/uac/iacuc/member.shtml>

The University of Arizona IACUC maintains at least 3 Community Representative membership positions. This page details the role of the IACUC community members.

The University of Tennessee Institutional Animal Care and Use Committee

<http://iacuc.tennessee.edu/>

IACUC Membership--a very complete description of the composition, officers and their responsibilities, terms and appointments, and member responsibilities.

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Updated March 12, 2002

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Bibliography

Bustad, L.K. (1987). **Investigators' interrelationship with laboratory animals.** *Laboratory Animal Science* 37(special issue): 167-170.

NAL call number: 410.9 P94

Descriptors: animal welfare, animal housing, animal nutrition, animal experiments, animal health, handling.

Francione, G.L. (1990). **The importance of access to animal care committees: A primer for activists.** *The Animal's Agenda* 10(7): 44-47.

NAL call number: HV4701 A45

Descriptors: laboratory animals, animal welfare, access, information, ACUC.

Francione, G.L. (1990) **Access to animal care committees.** *Rutgers Law Review* 43n1: 1-14.

Descriptors: sunshine laws, animal welfare, law and legislation, animal experimentation, management, ACUC.

Glosser, J.W. and P.B. York (1988). **"The Animal Welfare Act's impact on the scientist."** *Journal of the American College of Toxicology* 7(4): 447-451.

NAL call number: RA1190 J61

Descriptors: law, United States, enforcement, amendments.

Haywood, S. (1987). **Attitudes to animal usage and the review system in the US.** *Alternatives to Laboratory Animals: ATLA* 14(4): 369-374.

NAL call number: Z7994 L3A5

Descriptors: animal experiments, education, research.

Mandel, I.D. (1996). **On being a scientist in a rapidly changing world.** *Journal of Dental Research* 75(2): 841-844.

Abstract: The practice of biological science has changed dramatically since mid-century, reshaped not only by a rapid series of landmark discoveries, but also by governmental directives, institutional policies, and public attitudes. Until 1964, the major influences were the mentor, who provided direction and indoctrination into the culture of science, and in dentistry, the newly established NIDR, which fueled the research engine with an expanding research and training program. The 1965-74 period witnessed the advent of the Institutional Review Board, an increased social involvement of biological scientists, and a recognition of the need for biological and physical safeguards in the conduct of research. The most turbulent years were 1975-89, when there was a confluence of animal rights activism and regulation, growing concerns with scientific fraud and publication malpractice, and the stresses and strains (and opportunities) resulting from the rapid expansion of the academic-industrial complex. The current period is characterized by rapid pace, high volume, and an increased depth and breadth of knowledge-a major change in scale in the conduct of science. It is an

exciting time but one in which ethical issues are multiplying. Attention must be paid.

Descriptors: science trends, animal rights trends, biological sciences trends, dental research trends, ethics, fraud, government agencies, human experimentation, interinstitutional relations, public opinion, public policy.

Moss, T. (1984). **The Modern Politics of Laboratory Animal Use.** *Science, Technology and Human Values* 9: 51-56.

Descriptors: ethics, animal rights, animal experimentation, public opinion.

Murphy, R.A. (1988). **Animal Care and Use Committees: Focus on the investigator.** *SCAW Newsletter* 10(1): 9-10.

NAL call number: QL55 N48

Descriptors: animal welfare, animal experiments, inspection.

Orlans, F.B. (1985). **Survey of attitudes to Animal Care and Use Committees.** *Laboratory Animal Science* 35(5): 539-540.

NAL call number: 410.9 P94

Descriptors: abstract, scientists, humane, standard, compliance animal welfare, mandatory, protocol review.

Orlans, F.B. (1987). **Scientists' attitudes toward animal care and use committees.** *Laboratory Animal Science* 37(special issue): 162-166.

NAL call number: 410.9 P94

Descriptors: animal welfare, training, surveys.

Powers, M.K. (1994). **Gauging reactive styles: a guide to stress free investigator/IACUC interactions.** *Lab Animal* 23 (10): 31-33.

NAL call number: QL55.A1L33.

Descriptors: work stress, communication, committees.

Roebuck, B.D. (1996). **IACUC review: an investigator's perspective.** *The Johns Hopkins Center for Alternatives to Animal Testing Newsletter* 13 (2): 9-10. Available at

<http://caat.jhsph.edu/publications/Newsletter/volume13/Number%202/investigator.html>

NAL call number: HV4701.J6

Descriptors: animal welfare, scientist's viewpoint, committees.

Rowell, H.C. (1987). **Animal care and use committees and the public concern.** *Laboratory Animal Science* 37(special issue): 122-124.

NAL call number: 410.9 P94

Descriptors: animal welfare, animal research, public relations.

Sandoe, P. (1994). **Involving the public in ethical decisions.** In *Welfare and science : proceedings of the Fifth Symposium of the Federation of European Laboratory Animal Science Associations, 8-11 June 1993*, Brighton, London: Royal Society of Medicine Press, pp.331-334.

NAL call number: QL55.F43 1993.

Descriptors: laboratory animals, public opinion, animal welfare.

Traystman, R.J. (1987). **IACUC, who needs it? The investigator's viewpoint.** *Laboratory Animal Science* 37(special issue): 108-110.

NAL call number: 410.9 P94

Descriptors: animal welfare, animal experiments, laboratory animals, ACUC.

Tugwell, M. (1987). **Analyzing conflicts between the institution, the scientist, the animal care committee, and the concerned public.** *Laboratory Animal Science* 37(special issue): 145-147.

NAL call number: 410.9 P94

Descriptors: animal welfare, research institutes, public opinion, ACUC.

Williams, J.F. (1987). **Investigator concerns: Animal care and use committees.** *Laboratory Animal Science* 37(special issue): 113-114.

NAL call number: 410.9 P94

Descriptors: animal welfare, animal experiments.

Useful World Wide Web Sites

The University of Arizona Institutional Animal Care and Use Committee Handbook

<http://www.ahsc.arizona.edu/uac/iacuc/member.shtml>

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<http://iacuc.tennessee.edu/>

IACUC Membership--a very complete description of the composition, officers and their responsibilities, terms and appointments, and member responsibilities.

Instructions for Principal Investigators

<http://www.research.fsu.edu/contractsgrants/documents/larinstructions.pdf>

This site is provided by the Florida State University Laboratory Animal Program.

Responsibilities: Investigator

<http://research.unl.edu/orr/docs/policiesandprocedures.pdf>

This site is provided by the University of Nebraska at Lincoln Institutional Animal Care and Use Committee.

U.S. Department of Agriculture, Animal and Plant Health Inspection Service

<http://www.aphis.usda.gov/regulations/index.shtml>

Viewers are able to comment on an open proposal or read comments made by the public on proposed USDA rules or regulations.

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Updated June 18, 2014

Alternatives and Database Searching

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IACUCs and AWIC The Search for Alternatives

Tim Allen and D'Anna Jensen
U.S. Department of Agriculture, Animal Welfare Information Center
Beltsville, MD USA

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"Do we see some veterinarians still pursuing the methods of the ancients and perpetrating pain on a helpless subject... The result has been, and the feeling still exists, largely among the laity, that we are a hard-hearted profession..."

A modern day diatribe by animal activists. Not really. Those words were written by Dr. J.P. Turner in the Proceedings of the American Veterinary Medical Association in 1899. He was lamenting the fact that many of his colleagues were resisting the use of anesthetics to restrain animals during surgery in favor of hobbles and rope tie-downs, "the accustomed way, or the methods we were taught." While things have certainly changed, it is still not uncommon to hear "that's the way we've always done things." However, with the passage of the Improved Standards for Laboratory Animals Act in 1985, Congress let it be known that it is concerned about the use of animals in painful procedures. Under this law, scientists performing painful experiments on animals must document if there are alternative methods to the painful procedure and report this information to the Institutional Animal Care and Use Committee (IACUC) when

they submit their animal use protocol form for approval. It is then the responsibility of the IACUC to determine if the alternative methods should be used. To assist IACUCs and investigators in complying with this portion of the law, Congress established the Animal Welfare Information Center (AWIC) at the National Agricultural Library. In the next few pages, we will look at the critical role that IACUC's play in the animal use approval process, especially the problems associated with documenting whether or not alternatives exist, and how AWIC can assist members of an IACUC and/or scientists.

The U.S. Department of Agriculture views alternatives with an eye to the 3R's concept so eloquently described by W.M.S. Russell and R.L. Burch in *The Principles of Humane Experimental Technique*--reduction of animal numbers, refined procedures to minimize or avoid pain, and replacement of animals with non-animal models. According to the Animal Welfare Act (AWA) regulations (9 CFR ' 2.31(d)), "the IACUC shall determine that the principle investigator has considered alternatives to procedures that may cause more than slight pain or distress to the animals, and has provided a written narrative of the methods and sources used to determine that alternatives were not available." The IACUC is also responsible for ensuring that the proposed research does not *unnecessarily* duplicate other research. Along with several other items, AWIC considers these the information requirements of the act (the other sections being scientific justification for withholding anesthetics or analgesics, or using animals in more than one major operative procedure from which s/he is allowed to recover).

While the regulations seem fairly straight forward, it has been our observation that many people are unsure exactly what an alternative is and are confused as to what information is required to show compliance. There are many opportunities to incorporate alternatives into an experimental procedure; however, many IACUCs and scientists mistakenly assume that only non-animal methods satisfy the definition of an alternative. Although outside the scope of this paper, some alternatives might include pair-housing of rodents to alleviate the distress of isolation, proper use of analgesics in a post-procedural period, or reducing the volume of a receptor binding assay thereby reducing the amount of animal tissue needed to quantify the reaction and ultimately reducing the number of animals. The point is that IACUC's and investigators need to fully understand that identifying viable alternatives requires more than looking for non-animal models.

Animal welfare regulations require, as a minimum, that an investigator perform a search of the literature in an attempt to identify alternatives to painful procedures. Cynthia Smith, an AWIC staff member, wrote a method paper on searching for alternatives that is an excellent overview of this type of searching. But what is important to realize is that a multidatabase approach is necessary, as an alternative procedure or method may come from outside the specific discipline being studied. For example, if you concentrate on mammalian models for studying Parkinson's disease or diabetes, emerging fish models may be overlooked.

It is also important to conduct the literature search on a case by case basis. AWIC staff often are asked by an IACUC to perform a literature search on a painful procedure outside of the context of an experiment. It is impossible to look for alternatives to something as general as thoracotomies in dogs. Some of the questions that need to be addressed are why is the procedure being performed? What is the expected outcome? Is the procedure terminal? Only with complete information can a search be performed, and the IACUC properly evaluate the literature search.

Some IACUC's require attaching a literature search to the protocol with a list of the databases and strategy used to show that a good-faith effort was made to find alternatives. Many others require only that a box be checked indicating that alternatives are not available or may simply ask for a few key words and the database searched. Still others list AWIC as a source of information on the protocol form leading to many requests for information. Regardless of the system used all are fraught with problems. When an investigator contacts AWIC for help in completing an alternatives search, we commonly ask them to fax a copy of the protocol to us so that we will have all pertinent experimental information at hand. It is not uncommon to find the statement "AWIC was consulted and no alternatives were found" typed onto the protocol sheet that we are seeing for the first time. Oftentimes it is plain to see that the alternatives search is clearly an afterthought, being performed simply to comply with the law. The most common refrain is, "I'm turning in my protocol tomorrow, and I see that I have to have a literature search, can you fax that to me?" In our roles as members of Federal IACUC's, we routinely see protocol forms filled out stating that a literature search was performed, but, when we ask the investigator to provide us with a copy of the search, it usually has not been conducted. In other cases, the entire concept of alternatives is simply ignored by both the IACUC and the investigator. Are these examples the norm? Maybe not,

but they occur often enough that there clearly is a problem with IACUC oversight of this particular part of the regulations. Comments made to us at meetings or workshops reveal that many scientists and IACUC members view the alternatives search as unnecessary government intrusion into the research process, and not as a resource that might enhance or improve their research. Not surprisingly, a Department of Agriculture report on enforcement of the AWA by the Animal and Plant Health Inspection Service, Regulatory Enforcement and Animal Care (ed. note: this unit is now called Animal Care), found that IACUC's do not always meet the standards of the act and that this is attributable to the fact that committee members are not always aware of the act's requirements. Two of the major deficiencies noted are failure to properly address the use of alternatives and failure to provide written assurance that activities are not unnecessarily duplicative.

With these problems fresh in mind, what can or does AWIC do to help animal care committees comply with the law? AWIC was established to provide information pertinent to employee training, to prevent unintended duplication of animal experimentation, to reduce or replace animals used in painful experimentation, or on refined methods to minimize pain to animals when no other model can be found. To help IACUC's, investigators, and animal research support people understand the alternatives section of the regulations, AWIC staff developed a two-day workshop called "Meeting the Information Requirements of the Animal Welfare Act." The workshop provides an overview of the Animal Welfare Act looking specifically at the information requirements, Federally mandated IACUC functions, criteria for granting IACUC approval for animal research, and the required contents for an institutional training program. A representative from the U.S. Department of Agriculture's REAC staff is also available for a question and answer period. The workshop also provides an overview of the "alternatives concept," multiple database resources, concepts involved in developing search strategies (but no magic formulas), and, finally, the opportunity to gain hands-on searching experience using the DIALOG database system.

The success of the workshop is measured not only by the fact that every class held at the National Agricultural Library is booked months in advance but also by the number of requests we receive to bring the workshop to offsite facilities. Even more importantly, however, are the comments received from people who have taken the training class. The most common sentiment is that the class should be required for all members of IACUC's as it addresses many of the problems common to successful IACUC functioning.

If it is true as Ben Franklin said that an investment in knowledge pays the best interest, then perhaps AWIC's greatest utility to the scientific community is the capability of providing comprehensive literature searches or other information on alternatives, animal husbandry, animal models, philosophical issues, and many other topics related to animal research. When AWIC is requested by an IACUC or an investigator to perform a literature search, the package of information they receive includes the search strategy, the databases searched, and the literature information that documents whether alternatives are available and if the research is duplicative. We may also include a copy of one or two pertinent articles. Many IACUC's, working through institutional libraries, also maintain collections of bibliographies produced by AWIC on topics from anesthesia and analgesia to zoonoses. The AWIC staff also produces a newsletter that covers topics such as environmental enrichment, IACUC communications, alternatives, etc.

How is AWIC able to provide such a breadth of information to such a diverse audience? We owe this ability to a much underutilized resource, the National Agricultural Library (NAL), as well as new technology such as the World Wide Web, and the numerous databases available through services such as DIALOG. The NAL houses one of the largest collections of veterinary literature in the world, and is developing one of the most comprehensive collections of laboratory animal literature. These materials include NAL's AGRICOLA database, more than 400 videos and slide programs that can be used in institutional training programs, most relevant journals, codes of practice, newsletters, texts, and other published materials such as conference proceedings and abstracts relating to laboratory animals and farm animals used in biomedical research. Because of international exchange agreements, AWIC and NAL also work closely with other agencies providing information or regulatory oversight to animal care committees throughout the world. In this way, we are able to bring a broader perspective to many issues.

In 1996, AWIC is celebrating its 10th anniversary. In its brief existence, AWIC and NAL have worked hard to develop a comprehensive resource to assist IACUC's in carrying out their enormous responsibilities. Animal care committees face many problems in assuring that their institutions are complying with the Animal Welfare Act and the Animal Welfare Information Center is available to help them.

For additional information contact the staff at: Animal Welfare Information Center, U.S. Department of Agriculture, Agricultural Research Service, National Agricultural Library, 10301 Baltimore Avenue, Beltsville, MD USA 20705-2351, Tel: (301) 504-6212, Fax: (301) 504-7125, Contact us: <http://awic.nal.usda.gov/contact-us> , <http://awic.nal.usda.gov>

References

- Allen, T. (1994). Meeting the information requirements of the Animal Welfare Act. A workshop. *Animal Welfare Information Center Newsletter* 5(3): 6.
- Byrnes, C. (1995). RRReaching the A-Zone. *Science and Animal Care* 6(4): 1-2,4.
- Code of Federal Regulations (1995), Title 9, Part 1, Subchapter A, Animal Welfare.*
- Russell, W.M.S. and R.L. Burch (1959). *The Principles of Humane Experimental Technique*. Universities Federation for Animal Welfare: Potters Bar, Hertfordshire, England, 238 pp.
- Smith, C.P. (1994). AWIC tips for searching for alternatives to animal research and testing. *Lab Animal* March 1994: 46-48.
- Stokes, W.S. and D.J.B. Jensen (1995). Guidelines for institutional animal care and use committees: consideration of alternatives. *Contemporary Topics* 34(3): 51-60.
- Turner, J.P. (1899). A plea for the more general use of anaesthesia in veterinary surgery. *Proceedings of the American Veterinary Medical Association* Session of 1899, p.103-111.
- U. S. Department of Agriculture, Office of Inspector General, *Audit Report No. 33600-1-Ch*, January 1995, 60 pp.

Bibliography

- Allen, T. (1997). **Online databases and the World Wide Web. What is available? What is missing?** In *Animal alternatives, welfare, and ethics, Proceedings of the 2nd World Congress on Alternatives and Animal Use in the Life Sciences, held in Utrecht, the Netherlands, 20-24 October 1996*, L.F.M. Zutphen and M. Balls (eds.), Amsterdam, New York: Elsevier, pp. 483-490.
NAL call number: QL1.D48 v.27
Descriptors: databases, animal testing alternatives, searching for alternatives, information retrieval, terminology, scientific writing.
- Allen, T. and D. Jensen (1996). **IACUCs and AWIC: the search for alternatives.** *The Johns Hopkins Center for Alternatives to Animal Testing Newsletter* 13(2): 1,3-6.
NAL call number: HV4701.J6
Descriptors: animal testing alternatives, information retrieval, information centers, committees.
- Balls, M., W. de Klerck, F. Baker, M. van Beek, C. Bouillon, L. Bruner, J. Carstensen, M. Chamberlain, M. Cottin, R. Curren, and J. Dupuis (1995). **Development and validation of non-animal tests and testing strategies: the identification of a coordinated response to the challenge and the opportunity presented by the Sixth Amendment to the Cosmetics Directive (76/768/EEC).** *Alternatives to Laboratory Animals: ATLA* 23(3): 398-409.
NAL call number: Z7994.L3A5
Descriptors: animal testing alternatives, cosmetics, European Union regulations, product development, animal welfare, eyes, skin, laboratory animals, mutagenicity, injection, European Union.

Bowd, A.D. (1994). **The role of animal care committees in fostering use of alternatives: A case study.** *In Vitro Toxicology* 7(2): 169.

Descriptors: committees, alternatives to animal testing.

Dawson, M. (1996). **Guidelines for the choice of an alternative to proposed animal experiments.** *Developments in Biological Standardization* 86: 329.

Descriptors: animal testing alternatives, animal welfare, Great Britain, licensing.

Gettings, S.D., D.M. Bagley, M. Chudkowski, J.L. Demetrullas, L.C. Dipasquale, C. L. Galli, R. Gay, K.L. Hintze, J. Janus, and K.D. Marenus (1992). **Development of potential alternatives to the Draize eye test: the CTFA evaluation of alternatives program. Phase II. Review of materials and methods.** *Alternatives to Laboratory Animals: ATLA* 20 (1): 164-171.

NAL call number: Z7994.L3A5

Abstract: The CTFA Evaluation of Alternatives Program is a multi-year effort, organised by the CTFA Animal Welfare Task Force, designed to evaluate the performance of currently promising in vitro (alternative) methods to the Draize eye irritancy test. The sole criterion for inclusion of a particular test is that it shows some initial promise as an alternative to the Draize eye test, and that it is under evaluation or development by a participating CTFA member company. Tests are evaluated for their ability to rank and discriminate the ocular irritation potential of prototype cosmetic and personal care formulations compared to the Draize eye test. Test materials and in vitro methods currently under evaluation in Phase II of the CTFA Program are described. Additional tests may be included in subsequent phases of the Program, should it be determined that they show particular promise as replacements for specific types of formulation. Conversely (at the discretion of sponsors), tests may be removed from the Program should initial promise be unfulfilled.

Descriptors: animal testing alternatives, evaluation, organizations.

Hart, L.A. (1995). **The animal subjects protocol process: Applying the 3Rs.** *Lab Animal* 24(5): 40-43.

NAL call number: QL55 A1L33

Descriptors: protocol preparation, protocol review, investigator's responsibilities, IACUC responsibilities, importance of animal wellbeing, alternatives, reducing sources of discomfort, approaches for the investigator, review of the literature, literature searching.

Hem, A., A.J. Smith, and P. Solberg (1998). **Saphenous vein puncture for blood sampling of the mouse, rat, hamster, gerbil, guineapig, ferret and mink.** *Laboratory Animals* 32(4): 364-368. This technique may be viewed at <http://www.uib.no/dyreavd/Vivarium-blood-sampling.pdf> (PDF 847KB)

NAL call number: QL55 A1L3

Descriptors: blood collection, techniques, animal welfare, alternatives to retroorbital bleeding.

Hendriksen, C.F. (1996). **A short history of the use of animals in vaccine development and quality control.** *Developments in Biological Standardization* 86: 3-10.

Abstract: Man has been using animals since early times to gain an insight into health, illness and death. The oldest known medical standard work, the Corpus Hippocraticum (circa 350 BC), contains descriptions of experiments on pigs. Although the first attempt at immunoprophylaxis dates as far back as the 6th century (variolation was practised in China to protect people against smallpox), it was not until the middle of the 19th century that animal experimentation acquired full scientific status in the development and quality control of immunobiological products. It was Louis Pasteur and Robert Koch who, through studies on animals, succeeded in underpinning the causal relationship between infectious diseases and micro-organisms, thus opening the way to the discovery of effective therapeutic and prophylactic agents for a number of these diseases. In several respects, the experimental animal work carried out in the last decade of the 19th century to find an effective and reliable way of treating and preventing diphtheria determined the use of animals. Many common routine animal tests in the quality control of immunobiologicals arose from diphtheria research. Conversely, diphtheria was one of the first diseases where experimental animal research laid the foundation for effectively reducing child mortality. This had a very profound impact on the attitude of society towards animal experiments in those days and almost completely eliminated the growing influence of the antivivisection movement. The interest in the possibilities of replacement, reduction and refinement (the Three-Rs concept) of the use

of laboratory animals is increasing for several reasons, including concern about animal welfare. The root of animal welfare can be traced back to the 18th century with the formulation of utilitarian ethics. One characteristic feature of these ethics was that the interests of any creature which is submitted to any procedure should be taken into consideration. This presentation sets out some major historical contributions of animal experiments to the development and quality control of immunobiologicals. Attention is also paid to the changing attitude of society towards animal experiments and its impact on the development of alternative methods. It is concluded that, although animal experiments have played an important part, a new area is now beginning in which increasing emphasis will be placed on in vitro methods.

Descriptors: animal welfare, diphtheria, poliovirus vaccine, quality control, animal testing alternatives.

Holden, F. (1997). **Alternatives committee established at Indiana.** *The Johns Hopkins Center for Alternatives to Animal Testing Newsletter* 14(3): 6-7.

NAL call number: HV4701 J6

Descriptors: subcommittee to IACUC, communications between researchers and campus animal protectionists, monthly round table, institutional support at highest levels, membership includes--information specialists, public relations/education representative, departmental representatives, IACUC liaison, animal protectionist, veterinarian, research assistant.

Huggins, J. (1998). **Co-occurring words: finding information about alternatives to animal testing.** *ATLA-Alternatives to Laboratory Animals* 26(6): 849-856.

NAL call number: Z7994 L3A5

Descriptors: databases, indexing, skin, literature searching, utilization of terms which co-occur can enhance information retrieval, toxicology, scientific methods, endpoints measured, informatics research.

Huggins, J. (1997). **Communication by keywords: Sharing information about alternatives to animal testing.**

Animal Welfare Information Center Newsletter 8(2): 9-11.

NAL call number: aHV4701

Descriptors: stresses need for defined vocabulary for alternatives to animal testing, need for scientists to incorporate keywords about the methods used during experiments, toxicology, endpoints, keywords for alternatives to skin irritation.

Irwin, M.H., R.J. Moffatt, and C.A. Pinkert (1996). **Identification of transgenic mice by PCR analysis of saliva.**

Nature Biotechnology 14(September):1146-1148.

NAL call number: QH442 B5

Descriptors: alternative to surgically obtaining samples, nested primers, gene integration, DNA purification.

Jackson, L.R., L.J. Trudel, and N.S. Lipman (1999). **Small-scale monoclonal antibody production in vitro: methods and resources.** *Lab Animal* 28(3):20-30.

NAL call number: QL55 A1L33

Abstract: Monoclonal antibodies (MAbs) are valuable research tools; however, MAb production via the mouse ascites method has come under recent scrutiny, due to the pain and distress it may cause the animal. The authors present a review of in vitro production of MAbs, as well as critical considerations in selecting the appropriate technique.

Jackson M.R. (1998). **Priorities in the development of alternative methodologies in the pharmaceutical industry.**

Archives of Toxicology 20(suppl): 61-70.

NAL call number: RA1190 A7

Abstract: Promotion of animal welfare is an underlying and laudable goal for toxicologists and there is good reason to adopt practical, focused, investigative approaches towards this aim. Pharmaceutical regulatory toxicology can be subdivided into the areas of systemic (target organ), reproductive, genetic and topical toxicology, as well as immunotoxicology and oncology. These areas can be assessed for prioritisation as to where adoption of measures to promote any or all of the 3 Rs (reduction, replacement, refinement) would lead to the most tangible benefit for animals. These measures can range, for example, from replacement of animal experimentation with alternative in vitro techniques, to adoption of regulatory protocols that reduce the number of animals required. This paper is confined to consideration of in vitro technology in terms of reducing/replacing laboratory animal use, and a suggested list of criteria

for prioritisation is potential for: - Regulatory acceptability, Reducing development cost, Reducing animal numbers, Promoting welfare aspects, Elucidating toxic mechanisms, Usefulness in compound selection, Advancing the science of toxicology. Clear messages emerge from such an analysis which could influence prioritisation of the application of in vitro toxicology from the standpoints of animal welfare, feasibility and resources.

Descriptors: alternatives, animal welfare, drug industry, toxicology methods, drug approval, drug screening, Great Britain.

Jennings, M., G.R. Batchelor, P.F. Brain, A. Dick, H. Elliot, R.J. Francis, R.C. Hubrecht, J.L. Hurst, D.B. Morton, A.G. Peters, R. Raymond, G.D. Sales, C.M. Sherwin, and C. West (1998). **Refining rodent husbandry: the mouse. Report of the rodent refinement working party.** *Laboratory Animals* 32(3): 233-259.

NAL call number: QL55 A1L3

Descriptors: animal husbandry, laboratory animals, animal welfare, animal housing, hygiene, mice.

Jennings, V.M. (1995). **Review of selected adjuvants used in antibody production.** *ILAR Journal* 37 (3): 119-124.

NAL call number: QL55.A1I43.

Descriptors: adjuvants, immunostimulants, antibodies, biological production, toxicity, adverse effects, pain, granuloma, arthritis, animal welfare, laboratory animals.

Johns Hopkins University Center for Alternatives to Animal Testing (CAAT) (1997). **Alternatives in monoclonal antibody production Technical Report No. 8.** Baltimore: CAAT, 41 p.

Available from <http://altweb.jhsph.edu/meetings/mab/proceedings.htm>

Descriptors: overview, hollow fiber reactors, comparison of in vitro and in vivo techniques, cost comparisons, quality comparisons, quantity comparisons, core laboratories, regulatory issues, European perspective, IACUC responsibilities, recommendations.

Johns Hopkins University, School of Hygiene and Public Health (1992). **Animal Care and Use Committees and Alternatives, a Symposium Sponsored by the Johns Hopkins School of Hygiene and Public Health, Office for Research Subjects, June 18, 1992.** Baltimore, Maryland: Johns Hopkins University, 110 p.

NAL call number: HV4704.A53 1992.

Descriptors: animal welfare, alternatives to animal testing, laboratory animals.

Kirchain, S. and R.P. Marini (1998). **A tissue harvesting program as a method for implementing the 3Rs of biomedical research.** *Lab Animal* 27(8): 37-39.

NAL call number: QL55 A1L33

Descriptors: reducing animal use, alternatives to animal testing, centralized database, information includes protocols, species, tissue donations and requests, sample forms, administration, IACUC approval, adoption program.

Koeter, H.B.W.M. (1993). **The science and the art of regulatory toxicology: how to deal with alternative tests.** In *Current Trends: in vitro skin toxicology and eye irritancy testing: proceedings of the symposium, April 21-23, 1993, Radisson Hotel, Ottawa, Ontario, Canada*, Ottawa : Joseph F. Morgan Research Foundation, p. 15-22.

NAL call number: RA1199.4.I5C87 1993.

Descriptors: animal testing alternatives, toxicology, regulations, guidelines, animal welfare.

Kreger, M.D. (1999). **The literature search for alternatives.** In *The Care and Feeding of an IACUC: The Organization and Management of an Institutional Animal Care and Use Committee*, M.L. Podolsky and V.S. Lukas, eds., Boca Raton, FL: CRC Press:, pp. 139-152.

Abstract: Describes the process of developing and executing a multidatabase literature search for alternatives.

Descriptors: alternatives, databases, literature search, evaluation, IACUC protocol.

Kreger, M.D. (1997). **Why conduct literature searches for alternatives?** *ASLAP Newsletter (American Society of Laboratory Animal Practitioners)* 30(3):19-23.

NAL call number: QL55 S97

Abstract: Describes the legal, ethical, and practical rationale for running a multidatabase search for alternatives. Explains the usefulness of the search and gives tips to reduce online fees.

Descriptors: literature search, Policy 12, Animal Welfare Act.

Langley, G., C. Broadhead, K. Bottrill, R. Combes, R. Ewbank, P. Hawkins, R. Hubrecht, M. Jennings, C. Newman, S. Rowe, J. Southtree, M. Todd, and L. Ward (1999). **Accessing information on the reduction, refinement, and replacement of animal experiments.** *ATLA-Alternatives to Laboratory Animals* 27(2): 239-245.

NAL call number: Z7994 L3A5

Descriptors: European regulations, information resources, problems with current resources, databases, websites, proposed solutions, recommendations.

Leenaars, P.P.A.M., M.A. Koedam, P.W. Wester, V. Baumans, E. Claassen, and C.F.M. Hendriksen (1998).

Assessment of side effects induced by injection of different adjuvant/antigen combinations in rabbits and mice. *Laboratory Animals* 32(4): 387-406.

NAL call number: QL55 A1L3

Abstract: We evaluated the side effects induced by injection of Freund's adjuvant (FA) and alternative adjuvants combined with different antigens. Rabbits and mice were injected subcutaneously, intramuscularly (rabbits) and intraperitoneally (mice) with different adjuvants (FA, Specol, RIBI, TiterMax, Montanide ISA50) in combination with several types of antigens (synthetic peptides, autoantigen, glycolipid, protein, mycoplasma or viruses). The effects of treatment on the animals' well-being were assessed by clinical and behavioural changes (POT and LABORAS assays) and gross and histopathological changes. In rabbits, treatment did not appear to induce acute or prolonged pain and distress. Mice showed behavioural changes immediately after (predominantly secondary) immunization. Injection of several adjuvant/antigen mixtures resulted in severe pathological changes, depending on adjuvant, type of antigen, animal species used and route of injection. Both rabbits and mice showed pathological changes ranging from marked to severe after injection of FA, and ranging from minimal to marked after Specol and Montanide injections. Pathological changes after RIBI injections were severe in rabbits, though slight in mice. After TiterMax injections, pathological changes were moderate in rabbits, though severe in mice. In conclusion, injection of FA according to present guidelines resulted mostly in severe pathological changes, whereas only very few clinical and behavioural signs indicated prolonged severe pain. Our findings indicate that Montanide ISA50 and Specol induce acceptable antibody titres, and cause fewer pathological changes than FA. Thus they are effective alternatives to FA.

Leeuw, W.A. de, P. de Greeve, H. Schoffl, H. Spielmann, and H.A. Tritthart (1997). **Experience with the Dutch Code of Practice for the immunization of laboratory animals.** *Ersatz- und Ergänzungsverfahren zu Tierversuchen: Forschung ohne Tierversuche 1996. Fourth Austrian International Congress on Replacement and Alternative Methods for Laboratory Animals in Biomedical Science, 24-26 September 1995, University of Linz.* Wien, Austria: Springer-Verlag Wien, pp.210-217.

NAL call number: HV4913 F672 1997

Descriptors: laboratory animals, immunization, ethics, animal welfare, monoclonal antibodies, alternatives to animal testing, Netherlands.

Martin, B.J., J.B. Watkins, 3rd, and J. Ramsey (1998). **Venipuncture in the medical physiology laboratory.** *American Journal of Physiology* 274(6 Pt 2): S62-7.

Abstract: Medical physiology laboratories, traditionally devoted to animal experimentation, face unprecedented difficulties linked to cost, staffing, instrumentation, and the use of animals. At the same time, laboratory experiences with living creatures play a unique role in medical education. In this article we describe the use of venipuncture and subsequent blood analysis, with medical students serving as both subjects and experimenters, in a sequence of first-year physiology laboratories. These experiments are safe, robust, inexpensive, and time efficient, and they teach the principles of cardiovascular, respiratory, renal, nutritional, and gastrointestinal physiology. In addition, they enhance medical education in several other important dimensions. First, they teach safe venous blood collection and handling, a training appropriate for students at this level. Second, by serving each week as subjects as well as experimenters, students experience aspects of both sides of the doctor-patient relationship. Third, the laboratories can be used to teach fundamentals of research design and analysis. Finally, because blood analysis is central to medicine, and because the student's own blood data are discussed, students are enthusiastic and cooperative, and the clinical relevance of the data is clear.

Descriptors: medical education, phlebotomy, physiology education, technology, medical laboratory education, glucose tolerance test, hematocrit, hemoglobins-analysis, hemostasis-physiology, kidney-physiology, metabolism-physiology, nutrition, respiration-physiology, teaching.

McArdle, J. (1998). **Alternatives to ascites production of monoclonal antibodies.** *Animal Welfare Information Center Newsletter* 8(3-4): 1-2, 15-18.

NAL call number: aHV4701 A9522

Descriptors: ascites, monoclonal antibodies, laboratory animals, animal welfare, methods, mice.

Morton, D.B. (1998). **The importance of non-statistical design in refining animal experiments.** *ANZCCART News* 11(2): 1-12(Insert).

NAL call number: SF405.5 A3

Descriptors: laboratory animals, animal experiments, animal welfare, ethics, pain, experimental design.

Orlans, F.B. (1996). **The three Rs in the research and education: a long road ahead in the United States.** *Alternatives to Laboratory Animals: ATLA* 24 (2): 151-158.

NAL call number: Z7994.L3A5.

Abstract: Attitudes toward the Three Rs concept of refinement, reduction and replacement in the United States in research and education are widely divergent. Positive responses have come from several sources, notably from four centres established to disseminate information about alternatives. Funding sources to support work in the Three Rs have proliferated. The activities of institutional oversight committees have resulted in the nationwide implementation of important refinements. In the field of education, student projects involving pain or death for sentient animals have declined, and the right of students to object to participation in animal experiments on ethical grounds has been widely established. However, there is still a long way to go. Resistance to alternatives is deep-seated within several of the scientific disciplines most closely associated with animal research. The response of the National Institutes of Health to potentially important Congressional directives on the Three Rs has been unsatisfactory. The prestigious National Association of Biology Teachers, which at first endorsed the use of alternatives in education, later rescinded this policy, because of opposition to it. An impediment to progress is the extreme polarisation of viewpoints between the biomedical community and the animal protectionists.

Descriptors: animal testing alternatives, animal experiments, education, animal welfare.

Pakes, S.P. (1990). **Contributions of the laboratory animal veterinarian to refining animal experiments in toxicology.** *Fundamentals of Applied Toxicology* 15(1): 17-24.

Descriptors: animal pain, psychology, measurement, research design, alternatives, trends, veterinarians, ACUC.

Pavletic, M.M., A. Schwartz, J. Berg, D. Knapp (1994). **An assessment of the outcome of the alternative medical and surgical laboratory program at Tufts University [School of Veterinary Medicine].** *Journal of the American Veterinary Medical Association* 205(1): 97-100.

Descriptors: animal welfare, cadavers, dogs, euthanasia, veterinary education, alternatives.

Purchase, I.F., P.A. Botham, L.H. Bruner, O.P. Flint, J.M. Frazier, and W.S. Stokes (1998). **Workshop overview: scientific and regulatory challenges for the reduction, refinement, and replacement of animals in toxicity testing.** *Toxicology Science* 43(2): 86-101.

Abstract: Public concern for animal welfare has been expressed through legislative control of animal use for experimental purposes since the first legislation was introduced in 1876 in the United Kingdom. Legislative control of animal use has been introduced in virtually every developed country, with major initiatives in Europe (1986) and the United States (1966 and 1985). Advances in scientific thinking resulted in the development of the concept of the three Rs--refinement, reduction, and replacement--by Russell and Burch in 1959. The field has expanded substantially since, with specialist scientific journals dedicated to alternatives, World Congresses organized to discuss the scientific and philosophical issues, and European and U.S. validation organizations being launched. Current scientific attention is focused on validation of alternative methods. The underlying scientific principles of chemical toxicity are complicated and insufficiently understood for alternative methods for all toxicity endpoints of importance in protecting human health to be available. Important lessons have been learned about how to validate methods, including the need to have prediction models available before the validation is undertaken, the need to understand the variability of the animal-based data which is to be used as the validation standard, and the need to have well-managed validation programs. Future progress will depend on the development of novel methods, which can now be validated through international collaborative efforts.

Descriptors: animal testing, alternatives, regulations, legislation, education, Europe, Great Britain, United States

reproducibility of results, toxicology.

Ray, S. (1998). **An alternative to water deprivation techniques in animal learning studies.** *Animal Technology* 49(3): 113-120.

NAL call number: QL55 I5

Abstract: Many laboratories use a period of water deprivation to motivate animals on a variety of water reinforced learning paradigms including aversive conditioning and maze learning tasks. Such procedures can lead to long periods without water and increase inter-animal variability in learning performance. Reported is an alternative procedure using sucrose rich drinks, or sucrose solutions, as a reward in maze and discrimination learning procedures with no prior water deprivation.

An initial experiment compares performance over trials of a water deprived group of rats learning to negotiate a Y maze, and a group of genetically matched animals running an identical maze with no water deprivation. Both groups negotiating the maze for a sucrose reward. Results show that non-deprived animals showed teaming that was equally as good as the water deprived animals. Similar results were confirmed in a Lashley jump stand discrimination task. The ability to study learning in non-deprived animals may be of great interest in studies of learned behaviour after lesion or other surgical interventions, when periods of dehydration may affect the animal's health. Further, the development of non-deprivation motivated techniques will reduce the severity of many commonly employed rodent learning paradigms.

These results may also offer a useful heuristic to explore learning paradigms without food or water deprivation schedules in other species.

Rowan, A.N. (1995). **The third R: refinement.** *Alternatives to Laboratory Animals: ATLA* 23(3): 332-346.

NAL call number: Z7994.L3A5

Abstract: This review attempts to provide an introduction to the complicated subject of refinement, the third R in the concept of alternatives. It starts with a brief discussion of what refinement means and the lack of specific attention paid to this third R. This is followed by an analysis of the conceptual underpinnings of pain, distress and suffering, and the problems of both definition and measurement which must be faced if we are to be objective and consistent in our search for refinement. The review then touches upon husbandry, care and handling issues as they affect animal discomfort and distress. Antibody production, both polyclonal and monoclonal, is discussed as an example of the refinement of research techniques. Finally, a few brief comments are offered on the refinement of a variety of other experimental techniques, including those used in toxicology, cancer research and behavioural research.

Descriptors: animal experiments, pain, anxiety, stress factors, animal welfare, mice, inflammation.

Schwetz, B and D. Gaylor (1998). **Alternative tests: carcinogenesis as an example.** *Environmental Health Perspective* 106(Suppl 2): 467-71.

NAL call number: RA565 A1E54 v.106 suppl.2

Abstract: Acceptance of new tests that are alternatives to currently used toxicology tests is a topic of considerable importance in the field of toxicology. Carcinogenicity testing today normally includes 2-year studies in rats and mice of both sexes, following widely accepted procedures for husbandry; selection of dose levels; pathology and toxicity observations; and statistical interpretation of tumor data. These studies are usually preceded by tests for genetic toxicity and subchronic toxicity studies to select dose levels for the 2-year studies. Although these data are used for quantitative risk assessment, the mechanistic basis for effects is usually unknown. The series of studies is very expensive and requires 5 years or more to conduct. Alternative approaches are being developed that would provide more mechanistic information and hopefully would permit decisions to be made about carcinogenic potential without the need to conduct 2-year studies in rats and mice of both sexes. Decisions could be based on a profile of data rather than on the result of one test. Procedures for regulatory acceptance of new approaches for carcinogenicity testing are critical to future progress.

Descriptors: alternatives, carcinogenicity tests, methods, toxicity, animal welfare, decision making, government, mice, public policy, rats, research design, trends, time factors.

Selection and use of replacement methods in animal experimentation. (1998). Herts, UK: Universities Federation for Animal Welfare, 32 p.

Copies are available from: FRAME, Russell and Burch House, 96-98 North Sherwood Street, Nottingham NG1 4EE,

UK, tel: +44 0115 958 4740, fax: +44 0115 950 3570, email: frame@frame.org.uk

<http://www.frame.org.uk> or UFAW, The Old School, Brewhouse Hill, Wheathampstead, Herts AL4 8AN, UK, tel: +44 0158 283 1818, fax: +44 0158 283 1414, e-mail: ufaw@ufaw.org.uk

<http://www.ufaw.org.uk>

Descriptors: legislative requirements (UK), introduction to the 3Rs, improved use of information, physical and chemical methods, mathematical and computer models, SAR, in vitro techniques, lower organisms, human tissues and volunteers, sources of tissues, sources of information, organizations, databases, on-line services.

Smaje, L.H., J.A. Smith, R.D. Combes, R. Ewbank, R., J.A. Gregory, J.A., M. Jennings, G.J. Moore, and D.B. Morton (1998). **Advancing refinement of laboratory animal use.** *Laboratory Animals* 32(2): 137-142.

NAL call number: QL55.A1L3

Abstract: Whatever view is taken of the morality of using animals in scientific research and safety testing, it can generally be agreed that so long as such use continues, every effort should be made to keep animal suffering to a minimum. This is the thinking behind the 'Three Rs' of refinement, reduction and replacement of laboratory animal use. This paper concerns refinement. We recognize that the Three Rs are taken very seriously in many countries of the world [see for example a recent editorial in the journal *Science* (Goldberg et al. 1996)] and, although we have written this paper from our own perspective in the UK, its principles are generally applicable.

Snow, B. (1990). **On-line searching for alternatives to animal testing.** *Online* (July): 94-97.

NAL call number: QA76.55 O6

Descriptors: developing search strategies, boolean operators, databases, category codes, terminology.

Stokes, W.S. and D.J.B. Jensen (1995). **Guidelines for institutional animal care and use committees: consideration of alternatives.** *Contemporary Topics in Laboratory Animal Science* 34 (3):51-55, 58-60.

NAL call number: SF405.5.A23.

Descriptors: animal testing alternatives, committees, guidelines, information services, training, regulations.

Van der Kamp, M.D.O. (1994). **Ways of replacing, reducing, or refining the use of animals in the quality control of veterinary vaccines.** Lelystad, The Netherlands: Instituut voor Veehouderij en Diergezondheid, 107 p.

NAL call number: HV4915 K36 1994

Descriptors: overview of veterinary vaccines, quality control, regulatory climate, alternatives to animal testing, feasibility of alternatives, recommendations.

Zeller, W., H. Weber, B. Panoussis, T. Burge, and R. Bergmann (1998). **Refinement of blood sampling from the sublingual vein of rats.** *Laboratory Animals* 32(4): 369-376.

NAL call number: QL55 A1L3

Descriptors: blood sampling, stress, laboratory animals, blood specimen collection, animal welfare, pain.

Zutphen, L.F.M.van and M. Balls (eds.) (1997). **Animal alternatives, welfare, and ethics, Proceedings of the 2nd World Congress on Alternatives and Animal Use in the Life Sciences, held in Utrecht, the Netherlands, 20-24 October 1996** Amsterdam, New York : Elsevier, 1260 p.

NAL call number: QL1.D48 v.27.

Descriptors: alternatives to animal testing, animal experimentation, animal welfare, laboratory animals, databases, literature searching.

Zutphen, B.F.M. van and J.B.F. van der Valk (1995). **Education and training: a basis for the introduction of the three Rs alternatives into animal research.** *Alternatives to Laboratory Animals: ATLA* 23(1): 123-127.

NAL call number: Z7994.L3A5

Abstract: Education is a highly effective way of promoting the introduction of alternatives into the everyday practice of biomedical research and testing. In some countries, specific requirement for the education of persons involved in animal experimentation have been made compulsory by law. In The Netherlands, young scientists must take a course on laboratory animal science as part of, or in addition to, their biomedical graduate programme. This course provides information on the proper design of animal experiments, but also covers alternatives animal welfare issues and ethical aspects of animal experimentation. The Three RB of Russell & Burch are the guiding principles of the course, during

which participants are challenged to seek methods or techniques that can replace, reduce or refine the use of animals. Since 1985 more than 2500 people in The Netherlands have taken the course, and evaluations have indicated that a large majority of the participants appreciated this education as a contribution to both the quality of experiments and the welfare of the animals, and considered the course to be indispensable for those who are responsible for the design and performance of animal experiments.

Descriptors: animal testing alternatives, animal experiments, educational courses, training, laboratory animals, animal husbandry.

Useful World Wide Web Sites

Altweb

<http://altweb.jhsph.edu/>

A site for news, information, discussion, and resources from the field of alternatives to animal testing. This site is a collaborative effort funded by the Alternatives Research & Development Foundation, the Doerenkamp-Zbinden Foundation, the Humane Society of the United States, the Office for Protection from Research Risks at the National Institutes of Health, and the Procter & Gamble Company. It is being developed by the Center for Alternatives to Animal Testing at Johns Hopkins University, in collaboration with the Altweb Project Team (which includes AWIC), to serve academic, industrial and government scientists, educators, the media, and the general public.

Animal Welfare Information Center

<http://awic.nal.usda.gov/alternatives>

Articles and other resources concerning alternatives

Association of Veterinarians for Animal Rights

<http://www.avar.org>

This site will give you access to Alternatives in Education Database, a comprehensive listing of videos, computer simulations, and other media that can be incorporated into educational curricula from high school on through medical, veterinary, or graduate school.

Center for Alternatives to Animal Testing (CAAT)

<http://caat.jhsph.edu/>

The Johns Hopkins Center for Alternatives to Animal Testing (CAAT) is a global resource for the development of replacement, reduction and refinement alternatives for research and testing.

ECVAM : European Centre for the Validation of Alternative Methods

<http://ecvam.jrc.it/index.htm>

Validating methods and strategies to reduce or replace the use of live animals in laboratory studies.

Fund for the Replacement of Animals in Medical Education

<http://www.frame.org.uk/>

FRAME advocates the Three Rs approach to animal experimentation through the development, validation and acceptance of replacement alternative methods.

Guide to Searching for Alternatives to the Use of Laboratory Animals

http://www.frame.org.uk/page.php?pg_id=139

This guide assumes no previous knowledge of search techniques nor of the facilities available for obtaining information from the Internet.

ICCVAM: Interagency Coordinating Committee for the Validation of Alternative Methods

<http://iccvam.niehs.nih.gov/>

ICCVAM and its supporting center, NICEATM (the National Toxicology Program Interagency Center for the

Evaluation of Alternative Toxicological Methods), coordinate the development, validation, acceptance, and harmonization of alternative toxicological test methods throughout the U.S. Federal government. Another great resource provided by the U.S. Government.

The Netherlands Centre Alternatives to Animal Use

<http://www.nca-nl.org/>

The Netherlands Centre Alternatives to Animal (NCA) is the central point in the Netherlands for coordinating research and disseminating information on alternatives to animal experiments. One of its important tasks is to support the Alternatives to Animal Experiments Platform, in which the Dutch government, industry, and animal protection organizations collaborate.

The Norwegian Reference Centre for Laboratory Animal Science & Alternatives

Knutepunktet for forsøksdyrlære og alternativer til dyreforsøk

<http://oslovet.veths.no/>

Links to the Norina database (Norwegian Inventory of Audiovisuals (NORINA) <http://oslovet.veths.no/NORINA>) of alternatives and other alternativesdatabases

University of California Center for Animal Alternatives

http://www.vetmed.ucdavis.edu/Animal_Alternatives/main.htm

The Center places special emphasis on disseminating information concerning models, computer programs, and other animal alternatives in education through every level of public and private education.

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