

The Current Status of Laboratory Animal Ethics in South Africa

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An overview of the successes and current challenges in implementing and raising awareness of the Three Rs in South Africa

In South Africa, the humane care and use of non-human animals for scientific and teaching purposes is governed by the widely accepted ethical framework of the Three Rs – i.e. the *Replacement* of animals by non-animal models where possible, the *Reduction* of the number of animals used to the minimum required to yield valid scientific results, and the *Refinement* of scientific procedures and animal care standards in order to limit the potential for pain, suffering, distress or lasting harm, thus improving animal wellbeing.¹ This article outlines the successes and current challenges in implementing and raising awareness of the Three Rs in South Africa.

The South African National Standard

The South African Medical Research Council first published guidelines on ethical considerations for the use of animals in research in 1979,² and in subsequent revisions of this document in 1987,³ 1993⁴ and 2004,⁵ in order to sensitise biomedical scientists, research institutions, their Animal Ethics Committees (AECs) and animal care staff, to the interests and welfare of research animals.

The first national code for the use of animals for scientific and teaching purposes was produced in 1990 by the Department of Agriculture.⁶ This code was superseded in 2008 by the current South African National Standard (SANS) for the care and use of animals for scientific purposes (SANS 10386:2008).⁷ Produced by the South African Bureau of Standards, the SANS is primarily based on the Australian code of practice for the care and use of animals for scientific purposes (1997),⁸ and on the European convention for the protection of vertebrate animals used for experimental and other scientific purposes (1986).⁹

The purpose of the SANS is to ensure the ethical and humane care and use of all animals involved in scientific or teaching activities in South Africa, encompassing all aspects of the care and use of animals in medicine, biology, agriculture, industry, veterinary, wildlife, and other animal sciences, including animal use in research, teaching, field trials, product testing, diagnosis, the production of biological substances, and environmental studies.⁷ The SANS covers

all live non-human vertebrates and higher invertebrates (e.g. advanced cephalopods and decapods), including their embryonated eggs, and fetuses, where an integrated nervous system is evident.⁷

The aims of the SANS are: to establish uniform minimum national standards for animal care and use, based on international standards; to emphasise the responsibilities of researchers, teachers and institutions that use animals; to ensure that the use of animals is always appropriately justified by the formal review of all scientific and teaching protocols by institutional AECs; to ensure that animal welfare is appropriately considered; to ensure adherence to the core ethical principles of the Three Rs; and to promote the development of Three Rs methodology.⁷

Though not a legal prerequisite, the majority of South African research institutions have adopted the SANS. The responsibility to ensure compliance with the SANS rests with institutional AECs, whose members are required to regularly inspect all animal holding areas and laboratories, to ensure compliance.⁷ AECs are also responsible for ensuring that scientific studies and teaching activities are audited in relation to compliance with the submitted protocol.⁷

The establishment of the SANS has had a major impact on elevating the standards of animal care and use in South Africa. Major advances in the fields of animal science and welfare in recent years are reflected in the Australian code for the care and use of animals for scientific purposes (2013),¹⁰ and in the European directive on the protection of animals used for scientific purposes (2010).¹¹ As these represent the international standards on which the SANS is based, it is likely that the SANS will soon be updated, in order to continue to meet international best practice recommendations.

Institutional Animal Ethics Committees

Formal ethical review processes for the use of animals in research and teaching have been broadly implemented in South African universities and research institutions since the mid-1970s, as a result of the appointment of institutional AECs.⁵ AECs in

South Africa are decentralised, i.e. each institution's AEC operates according to its own policies. However, institutional AECs are required to establish formal terms of reference and standard operating procedures, in order to ensure that all animal care and use within their institution is conducted in compliance with the SANS, incorporates the principles of the Three Rs, and provides adequate welfare and proper justification for the use of the animals.⁷

The membership of AECs is defined by the SANS, with the requirement that each AEC should comprise at least four categories of members – i.e. veterinarians (or in special cases, persons with comparable expertise), persons with substantial recent experience in the use of animals in scientific studies or teaching, representatives from independent animal welfare organisations, and independent persons who have not conducted scientific studies or teaching that involved the use of animals.⁷ The balance between categories must be maintained. Staff members responsible for the breeding and care of animals are also required to attend AEC meetings. Additional members (e.g. bioethicists, statisticians, animal behaviour scientists, etc.) may also be appointed. Written proposals for scientific studies and teaching activities may be considered and approved only at quorate AEC meetings.⁷

Usually, the independent animal welfare representatives on South African AECs include members of the Animal Ethics Unit of the National Council of Societies for the Prevention of Cruelty to Animals (NSPCA). The NSPCA's Animal Ethics Unit, established in 2001, actively promotes the Three Rs in research and teaching, by: the involvement of their members in the review of research and teaching protocols by institutional AECs; performing routine inspections of animal facilities nationally; and identifying areas for improvement in legislation and national standards that govern animal research.¹²

All AECs that evaluate protocols where the research could impact on human health, must be registered with the National Health Research Ethics Council (NHREC).¹³ The functions of the NHREC include: setting norms and standards for conducting research on humans and animals; determining guidelines for the functioning of health research ethics committees; registering and auditing health research ethics committees; adjudicating on complaints about the functioning of health research ethics committees; instituting disciplinary action against persons who are in violation of any norms, standards, or guidelines for the conduct of research in terms of the *National Health Act*;¹³ and advising on ethical issues concerning research in South Africa.

Legislation

While there are currently no specific laws that regulate the care and use of animals for scientific or teaching purposes in South Africa, the SANS,⁷ though

itself not a law, must be read in conjunction with South African legislation that pertains to animals,¹⁴⁻²³ including the *Animals Protection Act*.¹⁸

Of special relevance to institutions that use animals for research and teaching are the *Veterinary and Para-Veterinary Professions Act*,¹⁵ and the *Rules* relating to the practising of the para-veterinary professions of laboratory animal technologists²⁰ and veterinary nurses,²³ which specify the professional services associated with these and other para-veterinary professions. All persons who are not registered with the South African Veterinary Council (SAVC) as veterinary or para-veterinary professionals, but who perform some of the services of these professions, e.g. general anaesthesia, clinical procedures or surgery on animals, are required to obtain authorisation from the SAVC in order to be permitted to do so. In such cases, a veterinarian is required to verify the competence of these persons, who, in turn, are required to work under the direct or indirect supervision of a veterinarian. The Chair of the AEC also needs to confirm that all personnel are competent. Institutions are responsible for ensuring, through their AECs, that their use of animals complies with these legal requirements.⁷ The *Medicines and Related Substances Control Act*¹⁹ governs the use of scheduled substances and drugs in research and teaching that involves animals.

The *National Health Act*¹³ prescribes that all animal research that could impact on human health, requires ethical approval from a research ethics committee in South Africa that is registered with the NHREC. This Act defines 'health research' to include any research which contributes to the knowledge of the biological, clinical, psychological or social processes in humans; improved methods for the provision of health services; human pathology; the causes of disease; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and related substances; or the development of new applications of health technology.¹³ In contrast to the stipulations of the SANS,⁷ there is currently no legal requirement to obtain formal ethical approval for scientific activities or teaching that involve animals in South Africa, unless the research could impact on human health.¹³

The NSPCA was founded in 1955, to provide a forum to bring uniformity to welfare legislation and standards in South Africa.¹² The NSPCA administers the *Societies for the Prevention of Cruelty to Animals Act*,²¹ with its inspectors authorised in terms of the *Animals Protection Act*,¹⁸ among others.²² The NSPCA Animal Ethics Unit identifies areas for improvement in the laws and standards that govern animal research.¹²

Teaching and training

In order to ensure the optimal implementation of the Three Rs, adequate training is required for all per-

sonnel involved in the care and use of animals for scientific and teaching purposes. These include persons who perform clinical or experimental procedures, breed and care for animals; scientists and teachers who use animals; AEC members; and those who set policy.

Laboratory Animal Technologists (LATs) are the para-veterinary professionals specifically trained in the theoretical and practical aspects of the humane care and use of animals for scientific purposes in South Africa.²⁰ National training courses for LATs were initiated in 1973, resulting in a three-year correspondence diploma course in laboratory animal technology, presented by the Technikon RSA from 1981 onwards, including practical training modules at accredited research animal facilities. Reduced government subsidy for animal facilities in the early 1990s led to a decreased demand for qualified personnel, with the subsequent discontinuation of the LAT diploma course in 1997.²⁴ While there are currently only 20 registered LATs in South Africa, the field of animal science is constantly expanding. The re-establishment of a national training course for LATs is being considered, in order to address this deficiency in trained personnel.

The South African Association for Laboratory Animal Science (SAALAS),²⁴ established in 1978, actively promotes education and training in laboratory animal science in South Africa. Links with the UK's Institute of Animal Technology (IAT) enabled many South Africans who perform the services of LATs, to enrol on the international IAT correspondence course. Following completion of the IAT course, practical training in required techniques enables such persons to be registered with, or authorised by, the SAVC to perform the services of a LAT. SAALAS aims to establish accredited national facilities for practical training, in order to promote recognised standards of proficiency for all laboratory animal personnel, including continuing education courses for LATs. The recent establishment of a veterinary Master's degree in laboratory animal science at the Faculty of Veterinary Science, University of Pretoria, presents a major advance in the field of laboratory animal science in South Africa.

The training of researchers who engage in animal research is conducted at the institutional level, with several institutions offering in-house training in animal ethics and care, such as the Introductory Course in Laboratory Animal Science at the University of Cape Town. The competency-based practical training of researchers in clinical and experimental techniques is similarly conducted at the institutional level, in order to meet legislative requirements for animal research.^{7,15,20,23} SAALAS aims to establish accredited national courses for the training of researchers, in order to promote recognised standards of competency in clinical and experimental techniques.

Training for South African AEC members is currently being planned by the Southern African Research and Innovation Management Association (SARIMA), an association for research and innovation managers in higher education, science councils, private research institu-

tions, and industry, thus aiding the implementation and raising awareness of the Three Rs in South Africa.

Courses aimed at increasing awareness of the Three Rs among researchers and AEC members are also presented at the national level by the NSPCA, e.g. the 2012 series of workshops on the use of non-animal models to replace the use of live animals in some research and teaching activities.

The national perspective

While it is estimated that at least 100,000 non-human animals are used annually for scientific and teaching purposes in South Africa, no formal reporting requirement or mechanism for compiling national statistics currently exists. It appears likely that the NSPCA's Animal Ethics Unit, whose members serve on the majority of South African AECs, could in future provide an avenue for collecting and collating such statistics, in order to objectively monitor national animal usage trends.

Though there is currently no systematic audit of institutional AECs in South Africa, the NHREC is in the process of registering and auditing all research ethics committees that evaluate protocols where the research could impact on human health,¹³ thus contributing toward standardising the nature and quality of animal ethical review processes in South Africa. Auditing mechanisms for the remaining AECs, i.e. those that do not evaluate protocols that pertain to human health, remain to be developed, in order to ensure compliance with the SANS⁷ and applicable legislation.

Due to its physical separation from developed countries and their closely-regulated standards for animal care and use, many South African institutions depend significantly on accessing international best practice recommendations for implementing the Three Rs, such as the information available on the websites of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs); the Federation of European Laboratory Animal Science Associations (FELASA); Digital Resources for Veterinary Trainers; the IAT; the Fund for the Replacement of Animals in Medical Experiments (FRAME); and Understanding Animal Research (UAR).

Conclusion

South Africa serves as an established reference point for the biomedical sciences in the African continent.²⁵ The highest ethical standards are thus paramount, in order to ensure the optimal implementation of the Three Rs in scientific activities and teaching involving animals across Africa.

Although South African laws and standards should be subject to further development, they are unambiguous in terms of setting the required norms for sci-

entific activities and teaching involving animals, based on internationally-accepted moral values. The primary challenge facing animal research in South Africa is confirming compliance with these laws and standards. The training of AEC members, biomedical scientists, animal care staff and policy-makers will help to address this challenge. It is contemplated that SAALAS will play an active role in the training and continuing education of laboratory animal science personnel.

There are currently no specific funding resources available for promoting research into the Three Rs in South Africa. The establishment of a South African equivalent to the UK's NC3Rs would present a major step toward improving the implementation of the Three Rs on the continent. Appropriate subsidy of research animal facilities remains critical, to maintain appropriate standards.

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