the Australian Society for Medical Research

Newsletters, News and Events
Submissions

August 1999

SUBMISSION to the NSW ANIMAL RESEARCH ACT REVIEW

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The Australian Society for Medical Research (ASMR) is the peak body representing medical researchers. The ASMR, a registered company (ACN 000599 235), was formed in 1961 with the goals to foster excellence in Australian health and medical research, and to promote community understanding and support for health and medical research in Australia. ASMR has approximately 1070 regular members and more importantly is affiliated with 37 specialist societies representing a further 14,800 members. Approximately 34% of these individuals are health and medical researchers based in NSW. The ASMR also has community and consumer representation through associate membership held by 11 disease focussed foundations such as the Arthritis Foundation, National Heart Foundation, etc.

As has been effectively argued in numerous public documents, and most recently in the Wills Review (Health and Medical Research Strategic Review) the economic and social returns of health and medical research are high. For Australia to continue to provide research outcomes to address the needs of the health and medical well being of Australians, it is imperative that no area of research investigation be selectively be not available to the research community or the public beneficiaries within the state of New South Wales. Thus, while many avenues of research can now be conducted in the test tube, using molecular or cellular techniques, the availability of animal experimentation, without jurisdicational impediments, is absolutley crucial in the endeavour to progress research in disorders such as arthritis, asthma, cancer, childhood and development disorders, dementia, diabetes, heart disease, infectious disorders, inherited genetic disorders, osteoporosis, pain research, etc. Any restriction that would impede ethical approval or the proper conduct of animal experimentation in NSW would therefore selectively disadvantage both the national and international competitiveness of NSW health and medical researchers and compromise the ability of these individuals to deliver benefit to the general community.

Thus, the provision of an effective legislative environment for the conduct of animal research in NSW is essential if we are to ensure:
? ethical evaluation of all proposed animal research
? proper consideration of animal welfare concerns
? meeting national and international agency requirements for review by an approved Animal Care and Ethics Committee of proposed research
? providing a balance between a highly regulated environment for the individual researcher and limited organisation freedom via the current enforced self-regulatory system.

In its detailed responses to the Discussion Document (see Appendix), the ASMR makes the following key points:

? the current system of enforced self-regulation provides considerable ethical review of projects and restricts investigators to the conduct of rigorously approved projects only

? the requirement of the National Health and Medical Research Council for the prescience of independent members, who are not involved in research, and non-researchers who have an involvement in Animal Welfare Organisations, on Animal Care and Ethics Committees together with an Organisations motivation to protect its reputation and good standing ensure that there is proper surveillance of Animal Experimentation

? the Animal Research Review Panel (ARRP, the Panel), by virtue of a diverse membership is able to represent both interest groups (eg researcher and animal welfare groups) and the broader community and provides necessary oversight of the organisational level Animal Care and Ethics Committees

? the Panel, which may conduct unannounced inspections of animal facilities, review Ethics Committee documents and has the power to recommend withdrawal of the license to conduct Animal Research, represents a very rigorous system for safe-guarding the welfare of animals used in research

? the requirements of the Act to ensure both benefit to the community and animal welfare could not be achieved by the Prevention of Cruelty to Animals Act (POCTAA)

In summary, the ASMR is of the clear view that the Animal Research Act serves both the community expectations in terms of improved health and medical outcomes and appropriately addresses animal welfare concerns. While some modifications and potential improvements are suggested in the attached Appendix any wholesale modifications would be unwarranted and place NSW at a substantial competitive disadvantage over the other Australian states.

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ASMR Director

Appendix

Detailed Responses by the
Australian Society for Medical Research
on the Discussion Paper on the Animal Research Act (1985)

3.1 Have the public policy objectives underlying the legislation been correctly identified? If not, what are they? Are these objectives still appropriate?

The stated objectives described in the Act (Section 2A) appear to neglect the Act's broader objectives of the act in terms of its impact on the community. In particular, one stated Objective of the Act (which is also relevant to the Competition Policy) should be to ensure that: 'there are no undue impediments to animal experimentation where the experiments have appropriate ethical approval under the Act'. This objective would protect the community interest in, and its right to have, continuing and improved access to the medical and health benefits of properly conducted animal experimentation. Since much of the State's health and medical research is supported by public funds eg ARC, NHMRC, researchers have a responsibility to the general public to discover and deliver the benefits of such research that utilises animal experimentation. Medicine has undergone a metamorphosis, in large part related to animal-based research, over the last century from a form of empiricism to a largely rational, and scientifically-based enterprise and, with that change, life expectancy has increased greatly and both human and animal health have improved enormously. If we are to extend this process into the 21st century we must ensure that the quest for new knowledge and enlightenment in these areas be fostered in the context of the now well-established sense of responsibility for the welfare of animals used in research.

The four listed implied objectives of the Code, namely; ethical review of animal research; animal welfare; public participation and accountability are appropriate.

3.2 How well does the NSW Animal Research Act 1985 currently achieve these policy objectives? Are some better achieved than others? How could achievement of the objectives be improved? How successful is the legislation in achieving the principles of reduction, refinement and replacement of animals in research?
The present Act achieves the Animal Welfare objectives in an admirable way that is regarded as a model of best practice by those familiar with practices in other countries, (e.g. the UK, the USA, continental Europe, and Asia) and in other States of Australia. However, in terms of the additional objectives, identified under Item 3.1, to ensure Competition Policy Guidelines are met and that the community in NSW has legitimate, competitive access to the benefits of animal research, the Act has been less successful.

The present operations of institutional ethics committees, the Animal Research Review Panel and NH&MRC Codes of Practice all ensure that the principles of reduction, refinement and replacement are put into effect wherever it is appropriate. Over the years there has been a steady and significant improvement in achieving the principles of reduction, replacement and refinement of animals through the work of ACECs. This has been stimulated by legislation and monitoring and also from the efforts of scientists seeking viable alternatives and new more sophisticated technologies. The Panel inspection process has enabled organisations to gain an external and sometimes differing perspective and has been a vehicle in which community views have been communicated to the scientist. However, it must be emphasized that the effectiveness of this cannot be evaluated by a simplistic count of whether fewer animals are being used for medical research in New South Wales each year. In particular, it must be recognized that New South Wales as a State has been historically well behind Victoria in its contributions to medical research and that recent NSW State Governments have been attempting to redress this imbalance, an exercise that quite appropriately will increase the use of animals in medical research.

The success with which the legislation meets its objectives is also dependent on the effectiveness of the ACEC and the organisational support it receives. The objectives of replacement, reduction, and refinement could be met more efficiently. Animal use has been steadily decreasing in NSW. If this is due to the use of effective in vitro alternatives, or due to more suitable animal environments, care, experimental design or via refinement of research which has led to reduced animal attrition rates and more significant research outcomes, then this is commendable. If restrictions placed on research have increased the cost of research in NSW compared to other States or countries and led to a movement of research out of NSW or the cancellation of projects, then the reduction of usage in this state has no net benefit to animal welfare nor met the obligation to provide a benefit to the community. Further, efforts to reduce the number of animals by banning the use of specific species or procedures may actually be deleterious to animal welfare. The banning of the supply of pound dogs for use in research in NSW has led to investigators purchasing and transporting dogs from other States. The net result is that the figures for dog usage in NSW will decline, they will increase in other States, the purchase cost will increase (freight cost) and the animals will be subjected to longer transport conditions and increased risk of misadventure. Attempts to force the use of alternatives, for example, the current draft recommendations released by the NHMRC which restrict the use of ascites to scale up monoclonal antibodies in mice, will result in these services being sourced overseas in countries with little or no animal welfare oversight. Reduction of animal numbers per se should not be used as a measure of whether the Act has met its objectives. It is only with refinement and replacement of animal use (with a cost effective and efficient in vitro alternatives) can any real gains in animal welfare be made and the performance of the Act be measured.

3.3 Is there a need for NSW to have legislation separate to POCTAA dealing with the protection of the welfare of animals used in research?
Yes. The welfare objectives of research animals versus companion and farm animals varies enough to justify different legislation. What may be considered acceptable treatment of a companion or farm animal may not be an appropriate standard for laboratory animals. Providing the basic requirements to lab animals (as would also apply to companion animals) eg food, water shelter and protecting them from overt cruelty falls short for animal research requirements. Lab animals need a much higher degree of control (environment, nutrition, care, husbandry etc) to ensure variability is minimised and the number of animals required to provide reliable data for a specific experiment is reduced.

Legislation for animals to be used in research has a more preventative approach based on best practice ie. the ACEC is compelled to ensure that environmental controls, housing, care and both research and animal care staff are appropriately skilled and trained and wastage is justified. Pet and livestock ownership requires no such licence/authority. ACEC inspections ensure compliance. Overall, this is a process which takes a more proactive approach to animal welfare- it prevents cruelty from occurring. Protection of Cruelty to Animals Act (POCTAA) provides a more reactive legislation based on punishment after the offender fails to meet fairly prescriptive (and basic) animal care guidelines.

The present multi-tiered system of regulation is proving very effective first, on animal welfare grounds and second, in terms of its cost to government and the taxpayer. A government-based inspectorate system would be a very substantial additional charge on the public purse and would bureaucratize an area where effective and efficient mechanisms are already in place.

Animal research falling under POCTAA would have a negative impact on animal welfare. In addition, the valuable communication channels and information exchange between the research community and ARRP (and the general community) would be lost.

3.4 Are there alternatives to the current legislative approach which will achieve or better achieve some or all of these objectives?
The support that legislation provides gives ACECs with the leverage to met their objectives and a direct means of ensuring that scarce resources are allocated to improve animal facilities and resources. The incentive to prioritise animal welfare is appropriately provided via legislation. The present legislation works extremely well, with a spirit of co-operation and common purpose on the part of both researchers and animal welfare representatives on most ACECs. It is also a very cost-effective mechanism that spares the government and taxpayers the financial burden of a government inspectorate bureaucracy.

The Australian community would not readily accept the development of rigid centralised control. Centralised systems tend to be costly and slow (the overseas experience) and a huge bureaucracy would be required to manage the system. It would remove, to some degree, the organisational responsibility to manage its own activities. An inspectorate would need to be established which would be based on the police and punish system. Policing would take resources away from training scientists and as such would be counter productive for animal welfare. Policing would increase the gap further between the scientists and animal welfare lobbyists and, unless common ground is established between the two groups, progress in animal welfare will be hindered. The appointment of independent members and members with animal welfare interests to ACECs ensures that organisational rubber stamping does not happen via the current system.

A further point to be emphasized is that any RSPCA-based inspectorate system as occurs under POCTAA would be entirely inappropriate as the RSPCA in NSW has declared itself to be completely against the use of animals in research. The RSPCA has, by declining to be represented on ACECs, failed to serve the interests of animal welfare. From this standpoint of declared opposing self-interest, the RSPCA has disqualified itself from consideration for such an inspectorate role.

4.1 Is a system of enforced self regulation appropriate for ensuring the welfare of animals used in scientific research and teaching?
Legislation based on enforced self regulation and the ACEC is the best alternative and is highly regarded throughout the world. However, enforced self regulation should not be confused with autonomy. The system of controls in place ensdure the individual scientist is strictly regulated directly via the ACEC, which is in turn regulated by the Panel. The present system also means researchers are given feedback from the ethics committee in monitoring and handling their animals. This provides a higher level of scrutiny than any alternate system. Self regulation makes the organisation responsible for it's actions both in financial terms (ie the cost of running an ACEC) and outcomes (the implications of non compliance). Scientific members of

an ACEC within an organisation who have the knowledge and expertise of the particular type of research are well placed to provide the scientific scrutiny required. Poor science and poor experimental design, factors which may be overlooked by an inspectorate or centralised committee, can lead to wastage of animals if experiments need to be repeated. The ACEC system ensures a group of informed scientists are on staff which, via peer pressure and example, educates others. The ACEC advice received from scientific peers would more readily lead to more positive organisational cultural change in attitudes.

NSW is better organised and better resourced through the Animal Research Review Panel (ARRP, the Panel) for both administration and inspection, than any other State or Territory. The implementation of the Act is monitored by the Panel which ensures the effectiveness of animal ethics committees within NSW. The ARRP ensures institutions have animal facilities that are in compliance with the Code of Practice. In addition, the NHMRC independently monitors compliance with the Code of Practice. To replace the present structure with a system of RSPCA inspectors would be to dismantle the most effective means of monitoring and influencing laboratory animal welfare that exists anywhere in the world. In addition, to being very appropriate for ensuring animal welfare the current system is vastly superior to an inspection regime where Inspectors will not be familiar with the scientific objectives of the projects in which the animals we involved or the ACEC review of the proposed research.

4.2 Should the animal Research Act 1985 or an alternative legislative mechanisms apply only to vertebrate animals? If not, which invertebrates should be included?
Any invertebrate suspected of having an integrated nervous system should be included. Cephalopods would meet this requirement.

4.3 Should dead animals be included? Should embryos/eggs/larval forms be included?
If the animal is killed primarily to provide tissues for use in research then, this must be fully scrutinised by the ACEC and included in the usage returns. If the animal tissues have been sourced from an animal killed for some other purpose eg abattoir specimens, then they should not be covered by the Animal Research Act.

Embryos and eggs should be included as for invertebrates ie. at the stage of development where it is suspected they may possess an integrated nervous system and likely to perceive pain.

4.4 Should there be restrictions on the research and supply of some species?
The supply for all traditionally used animal species (other than endangered species) should not be restricted as this may remove the most suitable model for research usage. The use of another less favoured species may result in sub-optimal outcomes and animal wastage.

4.5 Should there be specific consideration given in the Act of genetically modified organisms?
The Act should cover all animals and not distinguish between them. Under the Code, " The clinical status of animals in which the genetic material has been manipulated experimentally must be monitored for unusual or unexpected adverse effects. Investigators must report such effects to the AEC" (3.3.57). This should be included in the Act and should be extended to cover all animals undergoing research that may develop unexpected adverse side effects as a result of an experimental regime.

4.6 Should the definition of animal in the Animal Research Act 1985 include crustaceans as does the definition in the Prevention of Cruelty to Animals Act 1979?
Crustaceans should be included to provide consistency between POCTAA and Animal Research Act. The Act should cover all animals likely to experience pain and distress.

4.7 Which animal research activities should be covered by this or an alternative legislative scheme? Is the current definition too broad or too narrow?
The administration of veterinary treatment to an animal for the purpose of protecting the welfare of the animal should not be included. There should be no administrative barriers to deter such treatment.

4.8 Should there be a provision to exempt specific animal research activities?
It would appear that some studies such as wildlife observational studies could be excluded as: they do not impact on the welfare of the animal; they may give a false impression of the numbers of animals used in research (especially when the usage returns don't currently allow for a grading of invasiveness) and; their review by the ACEC consumes valuable resources. But, exempting certain activities may be removing the opportunity for the ACEC to use its expertise to assess whether potentially there is an actual threat to the animal's welfare and, to meet community expectations of science. Therefore, specific animal research activities should not be exempt.

4.9 If there is an argument to include a broad range of animal research activities, should all activities be treated in the same way by legislation? Are there non-legislative alternatives to meet the objectives for some classes of activities (for example, membership of a voluntary accreditation scheme such as the Australian Bird and Bat Banding Scheme)?
If they are included in the legislation then they must be treated in the same way. Unclear legislation with differing requirements for differing activities increases complexity and ambiguity and, as a result, risk a decrease in compliance. Regulations need to be reasonably black and white to ensure they are understood.

4.10 Is there a need for an Animal Research Review Panel to achieve the identified objectives of the Act? What would happen if there was no Panel?
The Panel is an essential component of the system of enforced self regulation as it monitors the effectiveness of the ACEC. The ARRP communicates, educates and monitors. Any attempt to undermine the ARRP would therefore decrease the effectiveness of the present system. The Panel membership, by including scientists ensures that policy is not made without consultation of the stakeholders. By including a range of membership, it should be able to ensure community concerns and objectives are considered and met. An appropriately constituted Panel has the expertise to develop policy documents with the aim of refining and reducing the numbers in animals and should have the credibility within the research community to provide valuable feedback during inspections. They provide the vehicle by which the Act is regulated.

Without the Panel, and in the absence of a replacement group or inspectorate, research would not be monitored, the Act would fail in its social objective of community accountability.

Potential reforms to improve the operations of the Panel could include:
? Members upon appointment to the Panel should have their responsibilities and what is expected of them clearly defined. This could include estimates of time committment, duration and frequency of meetings and inspections.
? The ARRP operating procedures should be reviewed by an independent consultancy to streamline efficiency to determine what administrative tasks can be delegated and what is the most appropriate role for ARRP versus the AWU.
? The inspection process could be improved by ensuring the inspection team is well balanced and a consultant, with expertise in the facilities and type of research being conducted at a specific organisation, attend the inspection.
? Findings from an inspection should be recommendations only unless data can substantiate a specific requirement or there is a direct breach of the legislation.
? The Panel should develop Standard Operating Procedures regarding inspections to reduce the variability in outcomes between inspection teams and over time. An organisation should have details of the inspection criteria in advance of an inspection and to permit self audit in between inspections.
4.11 If there is a need for an advisory group, does it need to have legislative status? What would happen in terms of achievement of the objectives of the Act if the Panel was replaced with an advisory committee?
The current role of ARRP fulfils this need.

4.12 If there is a need for the Panel, is its size and balance of membership appropriate? Are interest groups adequately represented? Should Panel membership be representational or functional? Does the current constitution ensure that there is adequate expertise on the Panel in science and ethics? Should there be an

independent community representative on the Panel (not aligned with research or animal welfare groups)? ARRP membership is drawn predominantly from science and animal welfare groups. As these categories combined could be considered to represent a minority community view, the Panel could be restructured. The Panel should be constituted as an ACEC is constituted, ie. veterinarians (with expertise in laboratory animal science), scientists, animal welfare representatives, community members and an ethicist.

The Panel, unlike the NHMRC animal welfare committee, is deficient in membership of veterinarians with expertise in the day to day management of animal research and/or production facilities ie. with laboratory animal science expertise. There are many veterinarians that work in the research environment that are intimately involved in both welfare and science and whose primary aim is to work within the system to optimise animal welfare. This group that can provide specific expertise to the Panel and a valuable contribution to policy but currently have no say due to a lack of representation on the Panel.

As a key aim of the legislation is accountability to the community, one or more community members, not aligned with either science nor animal welfare organisations, must be on the Panel . Increasing community representation may help bridge the gap between the polarised views of science and animal welfare representatives. A trained ethicist should be a member of ARRP. Legislation should be written with due consideration of the ethics of animal experimentation.

The wording of the question "Does the current constitution ensure that there is adequate expertise on the Panel in science and ethics? " reflects the poor understanding of the Act and members roles. For example, as there is not a trained ethicist on the Panel, does this question imply that only animal welfare members represent ethics? or that scientific members of the panel (or ACECs) do not represent animal welfare interests? The legislation requires all members to carry this responsibility, but greater involvement of non-aligned community members and ethicists would be of benefit.

4.13 Is the method of selection and appointment of members and the Chair appropriate?
The Chair should be selected based on: proven leadership skills (ability to obtain consensus from a diverse Panel membership), have no direct affiliation with research or animal welfare groups (to remove potential bias) and have a senior enough position in the community to influence change. They should be appointed by the Minister and this appointment should be endorsed by the Panel members. Term should be restricted to no more than 2 terms unless the Panel members unanimously support their extension of their term.

It is appropriate for industry (the listed nominating bodies) to nominate Panel members. To be added to this list should be a group, such as theology colleges, which could nominate an ethicist. The Minister should select from the nominees to ensure that each category (scientist, ethicist, community member, animal welfare and veterinarian) is represented. The Panel members should be required to endorse this selection. The term for members should be as for the Chair. The risk of losing Committee expertise must not outweigh the benefits of gaining the fresh perspective and enthusiasm of new members.

4.14 If there is a continuing need for a Panel, what should its functions be? Should they be operational or policy or a combination of both?
There is a need for ARRP. Functions should be both operational and policy with an emphasis on policy. More use could be made of external consultants to conduct inspections with ARRP to ease the load on Panel members. The inspection process is important for the Panel to receive feedback from the stakeholders and also for the scientific community to learn from the Panel.

4.15 Should Panel members carry out inspections? What would happen in terms of meeting the identified objectives if they did not?
Inspections are essential to ensure compliance with legislation. Providing the inspection team is balanced ie a scientist, an animal welfare representative and a veterinarian with expertise in laboratory animal medicine, then it is appropriate for the Panel to conduct inspections. The report should be forwarded to the organisation before the Panel recommendations are sent to the Minister to ensure inaccuracies are corrected before the report goes on record.

4.16 If Panel members have a role in carrying out inspections, what powers of access are required?
Panel members powers of access should be the same as members of ACECs. They should be permitted access to facilities and records without restriction provided: they are accompanied by a senior member of the organisation that can assure all animal facility procedures are followed correctly; who can contact specific investigators if required and who can provide the appropriate information on organisational research activities. They should not be permitted to take records off site, nor to make copies to remove off site, without the permission of the Head of the Organisation unless this is being undertaken as a result of a breach of the legislation, in which case legal redress is possible. Due respect for commercial in confidence and copyright restrictions must be maintained.

4.17 Is there a need for licensing schemes to achieve the objective of the Act? What would happen if there were no licensing arrangements?
Yes. The organisation in which animal research is conducted should be licensed as required by the current accreditation system. This would ensure there is appropriate infrastructure to support animal research, the appropriate staff to care for animals to be used in research and that there is a suitably structured ACEC in place to ensure self regulation. An inspection should be conducted prior to issuance of any licences.

It is assumed a no licensing system would be associated with an absence of inspections. This would remove the benefit of ARRP advice for organisations applying for accreditation for the first time. It would result in an increased variability in the quality of facility and animal research standards dependent on the expertise and strength of the ACEC and staff. This could actually compromise the reputation of the Australian scientist in the international community especially in the USA where accreditation systems and associated licences increase access to research funds.

Licenses imply that some standard has been attained which may be a way of demonstrating community accountability. Guidance documents provided by the AWU or Panel would help establish expectations in both facility standards and ACEC operational aspects.

4.18 Should fees be set for considering applications for accreditations, authorities and licences?
Yes. It is accepted that in the business world that licenses must be paid.

4.19 Are the current fees appropriate?
Yes It is inappropriate to add further financial impediments to the conduct of medical research in NSW.

4.20 Is there a need for Animal Care and Ethics Committees to achieve the identified objectives of the Act? What would happen if there were no Committees?
The ACEC provides constant and frequent organisational scrutiny of animal research and a valuable educational and monitoring role. The ACEC is thus the cornerstone of the Code of Practice.
The membership structure permits community and animal welfare members to provide input at the "coal face" which meets community objectives of the Code. Not having ACECs would mean input from the community and animal welfare groups would only be at the Panel level for policy and, at the organisational level, at inspections. It is the adoption of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes in Animal Research Acts across Australia that gives us national standards. NHMRC funding is only given to institutions that abide by the Code. Such an action could jeopardise eligibility for research funds in NSW and be an uncompetitive government restriction.

4.21 Would a system of review and monitoring by external ACECs meet the objectives of the Act more effectively that the existing system? What would the associated costs be?
No. External ACEC's are notoriously slow (ie. Germany, Britain and Sweden) and, even though they can be constituted appropriately, they would not have the organisational expertise for a specific type of research. External ACEC's would be less interactive with the scientist and their valuable training role would be lost.

4.22 Should research establishments and the Director-General, in the case of the Director-Generals ACECs retain the right to appoint and in effect remove individual as members of ACECs? If not, how should members of ACECs be appointed and removed?
Membership to an ACEC should be on the basis of category and nominations should come either from the organisation and/or its members. Appointment to the Committee should be first endorsed by the members of the Committee which can make the recommendation to the Head of the organisation. Removal of a member should be based on the same criteria.

4.23 Does the current constitution of ACECs ensure that there is adequate expertise in science and ethics? Is the balance of membership appropriate?
The balance as required by the Code ensures that members with different expertise contribute to a decision. This question correctly implies that a balance of science and ethics is required on the Committee but also suggests that some members are not considered ethical! The conduct of all members on an ACEC should be ethical and all should play a role in promoting animal welfare. The mix of membership should provide a broad range of input into how this should be done. The present balance recommended in the Code is fair and effective.

Some concerns have been raised that the Category C and D members are outnumbered by scientists on the Committee and that their numbers should be increased to ensure they have a voice. According to the Code (2.2.21 foot note 19) "Where two or more members oppose a proposal, it should not be approved until the AEC has explored ways of modifying the project that may lead to consensus". This is adequate to ensure all categories have a voice on the committee.

4.24 Is there a need for an inspectorate to meet the defined objectives of the Act?
Yes. Legislation must be enforced and monitored to ensure compliance. The inspectorate is the vehicle by which the requirements can be communicated

4.25 If the primary objective of the inspectorate is to ensure animal welfare, could this be achieved by extending the coverage of and subsequent enforcement of the Prevention of Cruelty to Animals Act 1979 by the existing POCTAA inspectorate?
No. The lack of experience in laboratory animal research or management and the lack of expertise of the existing POCTAA inspectorate in the scientific environment would make them unsuitable. The time delay in them gaining the appropriate experience could significantly impede developments in animal welfare. The RSPCA has had the opportunity to contribute to animal welfare via the ACECs yet has chosen not to by withdrawing its representatives from Committees. Since the RSPCA has publically stated their opposition to animal-based research, they would not be suitable agency to manage the inspectorate.

4.26 What qualifications should inspectors have and should they be appointed on a contract basis?
Inspectors should be appointed to the Animal Welfare Unit. They should have Veterinary qualifications and expertise in the species to be inspected. As veterinarians they would capable of assessing the health of the animal which a lay inspector is not qualified to make. This person should be experienced in laboratory animal science and should have experience in a research environment. This background would enable a greater level of scrutiny of research procedures and environmental factors which could otherwise be easily be overlooked. The inspections should be conducted in conjunction with a scientific and welfare representative from ARRP. More use could be made of consultants with specific expertise matched to the organisation to be inspected.

4.27 Should community animal welfare organisations e.g., RSPCA, Animal Welfare-League, Animal Liberation and Humane Society, be able to employ inspectors to enforce animal research legislation?
No, their publically stated agenda is to stop animal research. It would not be productive to use inspectors that are philosophically opposed to animal research in the policing of the Animal Research Act. Their responses would represent a narrow spectrum of community interest and as such the Act would fail to meet its objective of community participation. They should contribute at the Panel level and, as such, are able to participate as a member of the inspection team.

4.28 Should inspectors be appointed from the research industry?
An inspector appointed from the research industry who also has veterinary qualifications would potentially be suitable. However, because of perceived conflicts (which in effect are the reverse of issues raised in 4.27) it would be preferable that inspectors are independent individuals. More use of consultants with specific research and facility management is required to ensure inspections cover all aspects that can impact on animal welfare in a research environment.

4.29 Should inspectors have the power to issue directions and/or seize documents?
They should have the same powers as the ACEC providing they have the qualifications to make such decisions and be able to justify their actions. That is, they must be prepared to be held legally accountable for any actions they take.

4.30 Should POCTAA officers be given broader powers of entry to land or premises where research is being conducted?
No as POCTAA inspectors are not responsible for the Animal Research Act. The one exception to this would be if there was a breach of the Animal Research Act which was deemed as cruelty then this should be referred to POCTAA officers by either the AWU inspectorate or the ACEC. Only under these conditions should POCTAA inspectors should be permitted open access and then if accompanied by an AWU inspector and representative of the organisation.

4.31 Should some individuals be appointed as inspectors under both Acts?
No, the objectives of both Acts vary significantly as does the qualifications necessary for the inspectorate. The function is very different. AWU inspectorate has a preventative, advisory role rather than a police and punish role.

4.32 Is the complaints mechanism appropriate?
The fact that there have been few prosecutions under the Act does not necessarily imply the complaints and discipline mechanism is failing. It may indicate that improvements in animal welfare within the scientific community mean there are few breaches which warrant action.

To ensure community participation in decision making and a timely decision, the Panel, in conjunction with the AWU, should be able to investigate a complaint without prior referral to the Director-General.

4.33 Should the Director-General have the power to discipline an animal research authority holder through the formal complaints mechanism?
Yes if justified as this appropriately places some responsibility on the individual for their own conduct.

4.34 Is there a need for the Act to create offences to meet the defined objectives?
The present act identifies grounds for complaint, and under 1997 amendments, a detailed listing of offences. The offences act as a deterrent.

4.35 Is the current range of offences appropriate?
A simpler position would be that any breach of the Code could be listed in the Act as an offence.

4.36 Should the Act specify a longer period within which proceedings for offences may be commenced? If so, what would be an appropriate period?
Six months is considered appropriate to permit follow through and prosecution if necessary.

4.37 Is the penalties system appropriate? Should other forms of penalty be included? If so what types of penalties should be included?
The current penalties are appropriate at the organisational level. Penalties which require suspension of research, especially for the individual authority holder, would be a considerable deterrent.

4.38 Is the magnitude of penalties appropriate for the nominated offences?
Yes

5.1 Are there other competition restrictions in the Act which have not been identified?
Inconsistencies between states and the constraints placed on NSW researchers can prevent research being conducted in NSW (eg access to pound dogs).

5.2 What market failures or social objectives are being addressed by the competition restricting provisions of the Act?
The cost of bureacracy, the cost of reporting, the cost of inspections, the cost of species restrictions and the cost of running an efficient ACEC, add to the cost of research which is higher in NSW than other States. This may be hindering the provision of the benefits of scientific outcomes to the community.

The primary social objective is that animals used in research are treated in such a way that their welfare is optimised. This is being met.

5.3 What costs are imposed by these restrictions? Who bears these costs?
The restrictions impose time and opportunity costs which translate into dollar loss to both the researcher, the organisation, NSW and to Australia. A reduction, or delay in scientific output, which impacts on the reputation of Australia within the international research community can reduce overseas investment in Australian science. The general community may also accrue a cost due to diminished access to the benefits of medical research outcomes.

5.4 What are the benefits of these restrictions and who receives them?
Benefits are ethical treatment of experimental animals and in turn good quality animal care translates into good quality research outcomes and so ultimately all benefit.

5.5 Are there alternative less competition restricting approaches which would effectively achieve the policy objectives underlying the current legislation?
The current system is the most suitable. However, reforms to ARRP, streamlined procedures, more efficient inspections and more descriptive public reporting mechanisms would assist in more efficient attainment of the objectives of the Act. Some provisions, in particular those affecting access to pound animals, are excessively restrictive.

5.6 Is there a need for licensing and accreditation scheme to ensure that the identified objectives are met? If not, what alternatives are there?
Yes, the licensing of organisations is required for proper management but licensing of individual researchers is not necessary.

5.7 What are benefits and costs of restricting conduct of LD50 and Draize tests? What would happen if these procedures were left to the general deliberations of ACECs? What would happen if there was no legislation?
The LD50 requires approval of the Minister at present and I see no reason to change that. On certain occasions for serious public health issues the LD50 may be necessary. The Draize test falls into the same category. The existing legislation is entirely appropriate.

More generally, restricting research procedures, without a cost effective or viable alternative, will drive research off shore to those countries that have limited, or less restricted, animal welfare legislation. This will not enhance animal welfare. Further, it may be create a significant economic loss to Australia if industries relying on a specific technology are restricted.

5.8 If there is a benefit to these restrictions, should other specific procedures or the use of particular species be restricted?
No as per 5.7

5.9 Are the public accountability provisions in the Act adequate? If not, what changes should be made?
The public accountability provisions in the Act are adequate. How the information is presented could be improved. The regulation requiring accredited organisations to submit records on animal usage which are published annually could be implemented in a more useful manner. The returns do not give the opportunity to divide the type of research into categories of invasiveness ie. observational studies, tissue collection, treatments without surgical intervention, surgical intervention etc. would be more informative.

Community acceptance of research changes when a procedure conducted on an animal is associated with a specific outcome. The community wants to know why animal research is being conducted and what outcomes have been achieved. The provision of summary outcome information of animal research could be included in the annual returns, eg cancer research or preclinical testing .

Ensuring community members with no direct affiliation with scientific or animal welfare organisations are represented on the Panel must improve public accountability objectives.

5.10 What sort of information on animal research activities should the general public have access to?
General information only. It is not appropriate to reveal details of individual investigators nor the details of their experimental design. The present level of reporting is more than adequate.

5.11 What sort of information should be accessible only to ACECs, ARRP and inspectors?
All information involving the use of animals should be made available to the ACEC, ARRP and inspectors (providing the inspectorate is associated with ARRP). This view is based on confidentiality and safety grounds in view of potential threats to animal researchers.

5.12 Is there value in providing access of the public to information on areas of specific concern or should access (if provided) be general?
The public is entitled to general information on areas of specific concern and this information should come from a group such as the Panel so the information reflects a consensus. Detailed information may not be understood by the community and therefore not communicated accurately and subjected to distortion.

6.1 Are there alternative industry and/or statutory arrangements in other States that may be applicable in NSW?
No, the NSW Act provides an appropriate regulatory environment.

6.2 Are there any national or international agreements which impinge on alternative options for meeting public policy objectives in relation to animal research in NSW?
Any alternative that would result in the removal of the role of the ACEC could create problems nationally with those organisations receiving funding from the NH&MRC. Compliance with the Code is a requirement of funding and any legislative amendments in NSW that were in conflict with this Code could lose funding. Also a condition of USA funding (eg NIH and US Army grants) to Australia requires compliance with the philosophies of US legislation which is very much dependent on the ACEC.

6.3 What are the costs and benefits of alternative reform options?
There is no need to consider an alternative to the current system. The system works and responsibility for monitoring and compliance is placed quite appropriately on the organisation.

Acknowledgement
The ASMR wishes to thank Professors Mark Rowe, Michael Perry and David Tracey of the University of New South Wales and Dr Julie Ferguson of the Garvan Institute of Medical Research for their invaluable and extensive input into this submission.