

National Animal Ethics Advisory Committee



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Ensuring regulatory compliance in
the use of animals in science in
New Zealand – the review process

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FOREWORD

The ninth in NAEAC's Occasional Paper series, this paper is based on a presentation given at the 7th World Congress on Alternatives and Animal Use in the Life Sciences in Rome in 2009, and its origins in Alternatives to Animal Experimentation (ALTEX), a quarterly journal for new paths in biomedical science, are acknowledged.

The paper details the review process that institutions undertaking research, testing or teaching (RTT) using animals must undergo at a maximum of every five years to ensure they are complying with both their own code of ethical conduct and Part 6 of the Animal Welfare Act 1999. This review process adds another level of scrutiny to a system that requires that any such use of animals must not proceed without the approval of an animal ethics committee, whose members must include at least three from outside the institution concerned – nominees from the New Zealand Veterinary Association, the Royal New Zealand SPCA and local or regional councils respectively.

It is important to NAEAC that the systems in place to govern the use of animals in RTT are robust and credible, and it is pleasing to members that the results of this analysis of reviews carried out in 2009 indicated that the system appears to be working well, and should provide confidence in the overall regulatory system for this use of animals in New Zealand.

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Chair, NAEAC
August 2012

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Ensuring regulatory compliance in the use of animals in science in New Zealand – the review process

Introduction – the regulatory system

The use of animals in research, testing and teaching (RTT) in New Zealand is governed by a self-contained set of provisions contained within Part 6 of the Animal Welfare Act 1999 (the Act). The main focus of the Act is to impose a “duty of care” on owners or those in charge of animals, requiring that the physical, health and behavioural needs of the animal are met and, where practicable, that when the animal is ill or injured it receives treatment that alleviates any unreasonable or unnecessary pain or distress. Part 6, however, stands alone, because it provides a process that, in some circumstances, sanctions manipulations that have the potential to cause suffering, distress, or compromised care in recognition that the procedures on a small number of animals may result in significant benefits to a wider group of people or animals, to society generally or to the environment.

However, society, in allowing this use of animals, has required that there are safeguards in place to ensure that such use is only undertaken under close scrutiny. Any individual or organisation wanting to use animals for RTT purposes is subject to a comprehensive set of requirements. Firstly, they must hold a code of ethical conduct (CEC) approved by the Director-General for Primary Industries (D-G) or be employed by a person or organisation that holds an approved CEC, or has a notified arrangement to use another organisation’s animal ethics committee (AEC). Secondly, each individual project must first be approved by an AEC appointed by the code holder: the composition of AECs is specified in Part 6 of the Act.

As a further layer of scrutiny of the animal ethics system in New Zealand, code holders and their AECs must undergo reviews at least every five years by independent reviewers who are accredited by the Ministry for Primary Industries (MPI). These reviews assess compliance by a code holder, and by each AEC appointed by the code holder, with the requirements and standards of the Act, the Animal Welfare (Records and Statistics) Regulations 1999, and the CEC. Any approval of a CEC for a second or subsequent period depends upon the D-G’s satisfaction with the reported findings of the review.

The review process

Where a code holder holds an approved CEC for the first time, or where a person did not carry out RTT in the two years prior to obtaining their current CEC approval, the first independent review must take place within two years of the approval. Subsequent reviews must be completed before the term of approval of the current CEC has expired. For example, where the CEC was approved for the maximum term of five years, an independent review must be carried out within the first two years and again three years later. After that, expiry reviews take place at an interval determined as part of the approval – usually every 5 years.

The code holder is responsible for contracting an accredited reviewer to carry out the review, a list of reviewers being maintained on the MPI website. Reviewers are accredited by the D-G, with due regard to their competency, their character or reputation, and their ability to maintain an appropriate degree of impartiality and independence when conducting reviews.

Standards for the review are set out in MPI documents that specify terms of reference and include a detailed checklist of policies, procedures and processes that must, as specified in the Act, be contained in the CEC. There are two stages to a review: a desktop audit of documents and a visit to the institution.

During the desktop audit, the reviewer assesses the implementation of the CEC by reviewing a sample of project applications covering the entire period since the code was approved, or since that last review, with an emphasis on those entailing higher impact. As a guide, a 10% sample size is suggested, with, depending on the number of projects the AEC processes, a minimum of five applications and a maximum of 15. Other documents scrutinised include minutes of AEC meetings, and reports of monitoring conducted by the AEC on animal facilities and specific projects.

The reviewer's visit to the institution would normally include attendance at an AEC meeting if feasible, and interviews with individual AEC members, particularly the external members. These interviews may be conducted by phone if they cannot be held on the day of the visit. The reviewer uses such interviews to establish how well the AEC functions in terms of participation by members, particularly those members not associated with the institution. The reviewer will also interview researchers and animal carers as well as assessing the adequacy of animal facilities in relation to the standards contained in the MPI checklists.

Collectively, the desktop audit and visit to the institution give the reviewer a comprehensive overview of the functioning of the code holder, AEC, and staff in relation to the requirements of the CEC and the Act. This then enables the reviewer to write a report to a specified format. The report may notify a "critical situation", "key issues", "key topics" and/or "recommendations".

A "critical situation" is any situation which, in the judgement of the reviewer, places the code holder's, the AEC's or the D-G's credibility at risk. If a critical situation is identified during a review, this must be immediately notified to the D-G, and could potentially lead to the suspension or revocation of the approval of a code of ethical conduct. To date, there have been no critical situations identified.

A "key issue" is defined as a non-compliance that, in the opinion of the reviewer, demonstrates a major non-compliance of the institution's procedures and policies with the Act, its regulations, or the CEC. The issue may be a specific non-compliance or a systemic fault with multiple non-compliances having a cumulative effect. Key issues may be created by escalation of outstanding issues from previous reviews. Any key issues found will be discussed during the review, and will appear in the review report. The D-G will require these to be resolved within an agreed time frame and may require extra reviews, during which the effectiveness of corrective actions will be measured.

A "key topic" is defined as a point of interest, which is discussed in the report. It may include positive and negative findings and may give rise to key issues or recommendations. Once again, these will be discussed both during the review and within the review report, with corrective actions necessary for perceived failings.

A recommendation is a suggestion aimed at improving the procedures and policies.

Recommendations are non-binding. Examples include suggestions for:

- a review of meeting frequency;
- an internal audit process;
- an improvement in the clarity of the application form.

The reviewer's draft report is initially sent to the code holder for comment, and may result in changes to the proposed CEC. The final report, along with any code holder comments, is then distributed to the code holder, the D-G, and the National Animal Ethics Advisory Committee (NAEAC), an advisory committee to the Minister for Primary Industries on matters relating to the use of animals in RTT.

The D-G, having received the final report, must then inform the code holder in writing whether the review indicates that a satisfactory level of compliance has been achieved. If compliance is unsatisfactory, the D-G must inform the code holder of the actions that must be taken in order to achieve a satisfactory level of compliance. As well as remedying any shortcomings, this may include a requirement for more frequent reviews over a given period of time. If the code holder does not subsequently comply, or if the response is unsatisfactory, the D-G can decline approval of a new CEC or can revoke the existing CEC, a power that has not been necessary to date.

The regulatory system in practice

An analysis¹ of all reviews between 2002 (the first year of reviews under the 1999 legislation) and 2008 was undertaken in 2009 to assess the performance of the regulatory process.

The major key issues identified during the analysis included:

- failings in the procedures of the AEC, such as members not being appointed in accordance with the CEC;
- a failure to adequately monitor compliance with approved protocols;
- inadequacies in animal facilities.

The main key topics identified in past reviews included:

- commendation of the focus on animal welfare;
- inadequate documentation of monitoring by the AEC;
- inadequate attendance at AEC meetings of some members.

The analysis covered a period during which some institutions were reviewed twice. Given that the first round of reviews was seen as an educative as well as an assessment process, a higher level of compliance was to be expected at the second review. This proved to be the case, with 81% of institutions achieving satisfactory compliance at their second review compared to 72% at the first.

Given that there are a number of reviewers, emphasis is placed on ensuring consistency of the review process. Procedures to improve consistency include:

- provision of performance standards for reviews;
- provision of a template for a checklist based on information provided to code holders in two documents: the *Guide to the Preparation of Codes of Ethical Conduct* and the *Good Practice Guide for the Use of Animals in Research, Testing and Teaching*;
- in years where more than two or three reviews are carried out, a teleconference is held including reviewers, MPI staff and members of NAEAC. This provides a forum for discussion of the previous year's reviews including any new issues raised as a result of those reviews;
- regular update of reviewer documents as a result of the annual meetings as well as any other issues that have arisen;
- three-yearly audit of the performance of the reviewers themselves. To date, all audits of reviewers have shown them to be meeting the required standards.

In summary, the 2009 analysis of compliance by code holders, their staff and AECs demonstrated that, in the majority of cases (24 from 34 organisations), a satisfactory level of compliance with the Act and CEC had been achieved. For those where compliance was found unsatisfactory, subsequent follow-up reviews showed that a satisfactory level of compliance had

¹ Williams V, Carsons L. Reviewing the reviews: an analysis of the process of ensuring regulatory compliance in the use of animals in science in New Zealand. ALTEX 27, Special Issue, 2010

been achieved. Given these results, the review system would appear to be working well and should add confidence to the overall regulatory system for the use of animals in RTT in New Zealand.

National Animal Ethics
Advisory Committee

New Zealand Government