

NAEAC GUIDELINES FOR ANIMAL ETHICS COMMITTEES ON ADEQUATE MONITORING

Introduction

The Animal Welfare Act 1999 requires AECs to monitor:

- i) compliance with the conditions of project approvals (section 99(1)(d));
- ii) animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct (section 99(1)(e)).

A survey in New Zealand has shown that, in general, most of the general public accept the use of animals in RTT (i.e. research, testing and teaching), with conditions, such as ensuring no unnecessary suffering (Williams et al. 2007). Because such animal use can (and should) only continue with public support, it is essential that it can be demonstrated transparently that the manner in which approved animal use is conducted does actually meet the standards expected by the AEC, as representatives of the community.

The Act and its associated regulations do not specify the types of monitoring activities that should be undertaken: rather, it is expected that AECs will develop monitoring processes that are appropriate to the scope and nature of research, testing or teaching carried out under its approval. A variety of approaches (summarised in Table 1 on page 6) are suggested to meet the requirements of the Act. Not all methods will be appropriate for all AECs.

Monitoring methods

Ensuring compliance with AEC approvals

1. Scheduled observation of manipulations

The most obvious and direct means of assessing whether animal use meets the protocol and conditions approved by an AEC is to arrange visits to coincide with scheduled manipulations. This often requires some flexibility on the part of the AEC and is more easily achieved by the use of a subcommittee of perhaps two or three committee members. It is advisable that subcommittees should always include a veterinary member and one other 'external' member. Committees should consider the need for monitoring when applications are reviewed. Monitoring should be focused on manipulations that have the greatest impact on animals, and those that involve new procedures or personnel (especially contracted or 'parented' work – see below). Routine, well-established manipulations may warrant only periodic monitoring.

In large institutions with a dedicated animal welfare officer (AWO), it can be advantageous to have such visits conducted by this person, and examples of the animal manipulation recorded on video for the AEC to observe later.

A report should be prepared on completion of the visit: this is necessary to inform other AEC members (where subcommittees conducted visits) of the findings; to support any recommendations that the AEC may make to the project leader or host institution; and to provide, for future statutory reviews, evidence of the monitoring that was undertaken.

2. Non-scheduled observation of manipulations

Monitoring reports from non-scheduled (i.e. surprise) visits hold the attraction of being highly transparent and objective. On the face of it, this would appear to be an admirable way of assuring the general public that RTT is being conducted justifiably and to acceptable standards. However, the approach suffers a significant disadvantage in that it may engender a defensive attitude amongst the RTT community that may, to a degree, obstruct the real intent of animal welfare legislation as it applies to RTT. It is advisable for an AEC to discuss the use of surprise visits with the managers of a host institution before using this monitoring approach. Use of the AWO to make surprise visits on behalf of the AEC is less likely to have negative consequences as it is presumably less surprising for project staff to have the AWO make an unannounced visit.

3. Review of completed projects

Reviews by the AEC of completed projects should be retrospective, detailed assessments of the conduct of a piece of work, from beginning to end, against the specifications of the AEC-approved protocol. There are a number of potential benefits to be gained by AECs periodically selecting a range of completed projects for review. Firstly, reviews provide an overview of the work and contribute to a fuller assessment of whether it was conducted as approved than is possible from simply observing the actual animal manipulations. Importantly, the committee is more likely to be able to assess whether animal suffering was outweighed by the benefits accruing from the work once it is completed, thus aiding evaluation of future proposals. Secondly, unanticipated difficulties may sometimes arise that, with hindsight, may change the balance of costs and benefits; knowledge of this can be helpful to both project leaders and AECs in refining methods in future proposals to use animals for similar purposes. Thirdly, project reviews are useful in assessing the adequacy of the processes used by the AEC itself in regulating RTT. This is a particularly valuable benefit as it can form a regular, systematic means by which the appropriateness of AECs' codes and processes are assessed and gradually improved. Fourthly, the 5-yearly code-compliance reviews carried out by independent reviewers will be helped by such 'internal' project reviews; they provide concise but comprehensive 'case-studies', and enable reviewers to assess how well AECs both regulate and monitor RTT.

4. Reports to the AEC

It is often difficult for AECs to remain familiar with work once the approval process has been completed, especially if no on-site monitoring of manipulations is undertaken, or if projects are being conducted off-site at remote locations (especially in wildlife studies). Under such circumstances, it is recommended that AECs should require project leaders to submit interim reports at least annually, and a final report on completion. Well-designed reporting formats should focus on succinctly gathering information on the achievements of the work in relation to the objectives, and whether any animal welfare issues (positive and negative) have arisen. Where a large number (e.g. more than 20) of reports are being received periodically by an AEC, the most efficient means of gaining the most value from them is to apportion them equally to individual AEC members for careful consideration and reporting back to the whole committee.

5. Presentations to the AEC

Another way in which an AEC can maintain familiarity with a project, or a more general area of work, is to invite project leaders to AEC meetings to give presentations on their work. This could form a regular part of the agenda of committee meetings, and provides an opportunity for presentation and discussion of proposed new work, work in progress, or completed work. As

with written reporting, the emphasis of the presentation should be on the ethical costs and benefits of the work, and the animal welfare issues it entails.

6. Compliance reporting

AECs should make provision for any staff members within the host institution to raise a concern over the conduct of work. This provides a structured means of informing the AEC and key staff when things do not go to plan. Sometimes the non-compliance may be considered justifiable in hindsight; on other occasions there may be a need to make changes to how work is conducted. The aim should be to firstly consider the action that may be needed to address any animal welfare concerns, and secondly to address procedural and personnel matters based on a clear understanding of the nature of and reasons for non-compliance. Serious cases of non-compliance should be addressed by disciplinary procedures, as determined by management of the host institution in conjunction with the AEC.

7. Monitoring of contracted or parented work

In some cases, an AEC may approve work that will be carried out for the host institution by a third-party animal facility under separate management. Similarly, there may be instances where an AEC is asked by another institution to 'parent' work where the institution does not maintain its own AEC. Where such arrangements are made, the AEC will have the same statutory responsibilities that apply to work carried out within the host institution, and it is therefore important in both cases that high standards of monitoring are applied. Difficulty may arise where the work is to be conducted at a distance that makes normal site visits impractical, and in such cases the AEC should consider contracting the services of consultant veterinarians or auditors to carry out monitoring as prescribed by the AEC.

8. Monitoring of animal welfare by researchers

Where applications to the AEC anticipate significant impact on animal welfare, the AEC should ensure that this is monitored through the use of a purpose-designed monitoring schedule and appropriate monitoring sheets (examples given in National Research Council 2008). In certain cases the AEC may have a particular interest in evaluating such monitoring data, and could therefore require that the information should be provided as a condition of approval. For practical purposes, it may be adequate for the AEC to receive a summary of such data.

9. Statutory reviews

Statutory reviews of code-compliance in New Zealand are ultimately the most important forms of monitoring undertaken of the conduct of institutions using animals for scientific purposes; this is because they are the main mechanism by which public accountability can be demonstrated. The reviews are conducted 5-yearly by MAF-accredited reviewers with subsequent evaluation by NAEAC to establish consistency. While the AECs do not undertake this monitoring, it forms a very important part of the system being reviewed. Evidence of AEC activities (e.g. minutes of meetings and monitoring information) provides a tangible basis on which code-compliance can be partly assessed, and consequently contributes to the process by which regulators, and in turn Ministers and the public, are assured of the ethical scientific use of animals.

AEC monitoring of animal management practices and facilities

1. Scheduled visits

The purpose and scope of AEC inspections of animal facilities needs to be defined clearly and may vary from, for example, inspection of a specific aspect of animal husbandry practice or the adequacy of a particular building, to a complete assessment of all practices and facilities. Complete assessments are probably most beneficial at a point midway between scheduled statutory reviews, and AECs are encouraged to use the comprehensive checklists used by accredited reviews during statutory reviews. AEC inspections of animal facilities should be preceded by familiarisation with the relevant documents (e.g. livestock codes, standard operating procedures (SOPs)) that describe the physical conditions under which animals are kept, and the routine husbandry practices and experimental techniques that are used. Reference to these documents enables AEC members to judge the adequacy of facilities and practices, and may result in suggested improvements or, alternatively, modifications to SOPs.

2. Non-scheduled visits

As in the case of surprise visits to monitor approved work, there is the possibility that non-scheduled visits to monitor animal facilities and routine practices may have negative consequences. AECs often include in their membership an animal carer from the host institution. This has often proved useful in forming a close linkage between the AEC and the operation of animal facilities, such that high standards are reinforced and incremental improvement is encouraged. Non-scheduled monitoring visits are likely to erode this collaborative approach, with the relationship becoming increasingly adversarial the more visits occur. However, the AEC and institutional managers need to consider whether these disadvantages are outweighed by, for example, a greater degree of public accountability in the use of animals.

3. Routine monitoring of animal health

All animal facilities should routinely monitor animal health. This is essential to prevent unnecessary impact on animal welfare, to ensure that the quality of scientific data is not compromised by animals behaving or functioning abnormally, and to avoid costly and disruptive disease outbreaks. It is expected that animal carers will have been appropriately trained and capable of designing and implementing such a health monitoring programme. There is a large body of literature to assist this process.

4. Adverse incident reporting

Adverse incidents are unanticipated or atypical events that occur to an animal as a result of routine husbandry, experimental manipulation, or diseases. Where unexpected adverse incidents or outcomes occur during RTT, rapid reporting is essential, primarily from the point of view of animal welfare. Understanding of incidents and how to respond to them may require specialised knowledge, so it is important that key information is recorded and reported promptly to those responsible for the work and the AEC, and a collective response made. This may be, for example, isolation of affected or potentially affected animals, closer monitoring, changes to routine husbandry or experimental procedures, or suspension or termination of the work.

5. Periodic review of SOPs

As the scientific body of knowledge underpinning animal management practices is constantly expanding, there is a need to periodically review the adequacy of SOPs being used by animal carers and users. Typically, review of SOPs at 3-year intervals would be appropriate, but in rapidly evolving areas of scientific knowledge, more frequent review should be considered.

6. Animal carer on the AEC

The most direct means for the AEC to monitor the day-to-day operation of an animal facility is through the membership of an animal carer of the host institution on the committee. This enables the AEC to gain insight into the culture, commitment, capability and effectiveness of the staff responsible for animal welfare. Many AECs have a regular part of meetings devoted to discussion of items raised by the animal care representative.

7. Collection of animal use statistics

MAF collects data annually from AECs on the numbers of animals used in RTT, the purposes for using them, and the degrees of impact involved. The data are collated in the annual report of NAEAC, and provide a means of informing the general public of the overall situation and trends relative to usage in previous years.

References

- National Research Council 2008: Tools to monitor and assess health status and well-being in stress and distress. Pp. 95–112 *in*: ‘Recognition and alleviation of distress in laboratory animals’, National Research Council of the National Academies, Washington, USA. ISBN-13: 978-0-309-10817-1.
- Williams, V.; Dacre, I.T.; Elliott, M. 2007: Public attitudes in New Zealand towards the use of animals for research, testing and teaching purposes. *New Zealand Veterinary Journal* 55: 61–68.

Table 1: Summary of the monitoring approaches discussed

Purpose of monitoring	Type of monitoring
Compliance with AEC approvals	1. Scheduled observation of manipulations by site visits
	2. Non-scheduled observation of manipulations by site visits
	3. Reviews of completed projects
	4. Annual reports on AEC-approved projects
	5. Project presentations to the AEC
	6. Compliance reporting
	7. Monitoring of contracted or parented work
	8. Monitoring of impact on animal welfare 'in study' by score sheets or checklists
	9. Statutory reviews
Animal management practices and facilities	1. Scheduled visits to facilities
	2. Non-scheduled visits to facilities
	3. Routine animal health monitoring by animal carers and AEC oversight
	4. Adverse incident reporting by facility staff
	5. Periodic review of Standard Operating Procedures by AEC vet
	6. Animal carers on the AEC reporting regularly on animal welfare
	7. Collection of animal use statistics