

NAEAC GUIDELINES FOR ANIMAL ETHICS COMMITTEES ON ADEQUATE MONITORING

These guidelines have been drafted in response to a number of Animal Ethics Committee (AEC) inquiries regarding the statutory requirements for monitoring. The National Animal Ethics Advisory Committee (NAEAC) has a legislative role in providing information and advice to AECs. The Animal Welfare Act 1999, in force on 1 January 2000 requires monitoring. This is detailed in two key sections:

- 1) Section 88(1)(c): “Make provision for adequate monitoring of compliance with the conditions of project approvals to be carried out...”
- 2) Section 99(1)(e): “To monitor animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct”

The Act details a number of powers and functions expected of each AEC. These are listed in Table 1.

It is recognised that each institutional AEC will deal with different animal models and facilities; these can range from small rodent colonies to large herds of domestic livestock at pasture. NAEAC believes these guiding principles can be applied to the use of all animals used in research, testing or teaching.

In these guidelines the word “monitor” is defined to mean a device used to observe/ to keep watch over/ to test or control the operation / working of animals manipulated in research, testing or teaching.

Monitoring of animal production, holding and use facilities:

An annual inspection of all animal production, holding and use areas is recommended, including indoor and outdoor areas. Buildings should be compatible with the needs of the animals, be maintained in good repair, kept clean and tidy, and operated to achieve maximum possible hygiene. Outdoor holding areas should be compatible with the needs of the species, provide adequate shelter and water, and protect animals from predation. The AEC should be informed in writing of the inspection findings, in order that it can make recommendations to the institutional code holder regarding any concerns, such as repairs and maintenance work.

Monitoring of animal manipulations:

It is recommended that the monitoring of compliance with the conditions of project approvals is best performed by a site visit to observe how animals are used. This usually requires a visit scheduled in advance. It is essential that the AEC representatives are familiar with the approved project and have appropriate training and experience that qualifies them to evaluate the manipulations they observe. During the visit attention should be given to animal care and welfare, maintenance of health monitoring records,

and a check that appropriate techniques are used during surgical or other manipulative procedures; for example, to check that aseptic techniques are being used if indicated in the approved project. Post-operative care and methods of pain control should also be reviewed when surgical interventions are performed. Proposed euthanasia methods should also be discussed with the research personnel. The visit is a good opportunity to review any changes that have been made to the project since its approval. The appropriateness of the equipment and facilities used to perform the observed manipulations can be judged at this time.

To assist the researcher, it is advisable that the site visitors discuss any concerns at the time of the visit, whenever possible. Recommendations for improvements can be considered and the researcher given the opportunity to clarify issues. This should be followed by a written report to the AEC, with a copy to the researcher. These visits are in the best interests of the researcher, because they can confirm compliance with approved projects and support the scientific use of animals, in the face of public challenge. Alternatively, they can identify strategies to assist the researcher gain compliance with the approved project.

The frequency of visits will vary with the nature of the manipulation, the committee workload and the training and experience of the researchers involved. Routine non-invasive sampling procedures without any animal welfare risk are less likely to need monitoring when compared with highly invasive survival surgeries which require intensive post-operative care, when personnel resources are limited. It is recommended that all new staff members performing manipulations for the first time, which potentially have a high animal welfare risk, should be evaluated during a site visit. When substantive changes to the protocol occur, a site visit may be required. Other possible reasons for a site visit are detailed in Table 2.

Monitoring of AEC record systems:

It is recommended that once a year, the AEC review the institutional policies and procedures in place to monitor animal usage: a system to ensure that the numbers of animals used does not exceed the number of animals approved by the AEC.

Procedures to notify the AEC of adverse effects that significantly compromise the health and welfare of animals on study should be in place. The provision of veterinary care for such animals should be reviewed to ensure appropriate treatment has been administered, or the animal euthanased.

Changes in personnel, including their training and experience, should be documented with the AEC.

Table 1. Functions and powers of the AEC (Animal Welfare Act 1999: section 99)

A	To consider and determine on behalf of the code holder applications for the approval of projects
B	To set, vary, and revoke conditions of project approvals
C	To monitor compliance with conditions of project approvals
D	To monitor animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct
E	To consider and determine applications for the renewal of project approvals
F	To suspend or revoke, where necessary, project approvals
G	To recommend to the code holder amendments to the code of ethical conduct
H	Each Animal Ethics Committee has such powers as are reasonably necessary to enable it to carry out its functions

Table 2. An AEC site visit is recommended when:

1	A new Principal Investigator is appointed and seeks approval to use animals
2	A current PI seeks approval to perform a new manipulation s/he is unfamiliar with
3	Manipulations involve high animal welfare costs
4	Undergraduate or graduate students are scheduled to perform manipulations
5	The AEC application lacks sufficient detail for a definitive decision on the animal welfare costs involved
6	The proposed endpoint of the study is of questionable animal welfare cost
7	The proposed euthanasia method is unconventional and may compromise animal welfare
8	The PI indicates that analgesics are contra-indicated and the AEC insists on a trial to assess the justification for withholding pain medication
9	Any other matter of concern to the AEC such that a visit would give them assurances of compliance