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Compliance monitoring: The University of Auckland approach

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FOREWORD

“Compliance Monitoring: The University of Auckland Approach” is the fourth paper in a series about the use of animals in research, testing and teaching published from time to time by the Ministry of Agriculture and Forestry (MAF) under the auspices of the National Animal Ethics Advisory Committee (NAEAC). The objective is to disseminate to a wider audience articles that appear in academic journals and in the proceedings of conferences, or papers prepared for a particular purpose that are considered to be of interest to a more general readership.

Compliance monitoring is a topic of considerable significance to NAEAC. The integrity of the regulatory system in place under Part 6 of the Animal Welfare Act 1999 depends on the commitment of Animal Ethics Committees to rigorous processes ensuring compliance with the conditions on which projects are approved.

The willingness of AECs to share experience has been a characteristic of the AEC workshops organised by NAEAC in recent years. The diversity of animal use across more than 100 code holders is also a feature of the New Zealand system. The University of Auckland is a leading research institution and the range of its activities is clearly not shared by all other code holders. Nonetheless, the account by Dr Justine Stewart, NAEAC member and Animal Welfare Officer at the University, of the new programme of compliance monitoring in place in Auckland since 1 July 2007 will be of interest and value to other AECs. It is, as Dr Stewart says, a personal reflection of the Animal Welfare Officer’s experience of being involved with designing and implementing the new programme.

NAEAC is grateful to Dr Stewart for her work in preparing the paper and to The University of Auckland for permission to publish.

John Martin
Chair, NAEAC

October 2009

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Compliance monitoring: The University of Auckland approach

By Justine Stewart, BVSc

Animal Welfare Officer, The University of Auckland

National Animal Ethics Advisory Committee member

The main purpose of this paper is to outline the compliance monitoring programme that has been implemented at The University of Auckland. A secondary purpose is to make this approach known to other committees for their consideration in determining their own compliance monitoring programmes, but not to proclaim The University of Auckland way the best or the only way to do things. The programme that has been implemented at The University of Auckland is very much a local programme designed to meet the needs of The University of Auckland Animal Ethics Committee based on the types of research, number of protocols approved and the resources available. This is a personal reflection of the Animal Welfare Officer's experience of being involved with designing and implementing a new programme at The University of Auckland.

Background

Under the Animal Welfare Act 1999, section 99 (1), the functions of an Animal Ethics Committee (AEC) include monitoring compliance with conditions of project approvals and monitoring animal management practices and facilities to ensure compliance with the code of ethical conduct.

An ongoing programme to review approved animal protocols is an essential component of a comprehensive animal care and use programme. It provides an excellent method of ensuring institutional regulatory compliance, facilitating research activities and giving investigators an opportunity to discuss concerns or changes needed in active protocols.

During 2006 and 2007 The University of Auckland AEC reviewed and rewrote the procedures for compliance monitoring in preparation for the renewal of the University's code of ethical conduct, which came into effect on 1 January 2008. Section 6 of the new code of ethical conduct covers management of animal facilities and husbandry practice. The new compliance monitoring programme commenced in July 2007.

The University of Auckland has operated an Animal Ethics Committee since 1981. The committee has continued under a MAF-approved code of ethical conduct since the implementation of the Animal Welfare Act 1999. The AEC is a committee of Council, the University's ruling body, and is independent from faculty structure, reporting to Council annually. The AEC covers all work with animals for the purposes of research and teaching undertaken by University staff and students. In addition, the AEC currently acts for five external organisations (parented organisations).

Every year The University of Auckland AEC considers a large number and wide variety of protocols. The MAF "Purposes" of AEC-approved animal use for the purposes of research and teaching covers species conservation, animal husbandry, basic biological, medical and veterinary research. Nearly every animal type (according to MAF codes) is used in research approved by The University of Auckland AEC, except for hamsters, deer and amphibia. Currently, there are approximately 250 approvals held by 116 responsible investigators. Work varies in location geographically: whilst most of it is centred around Auckland, field work using wild animals ranges across the country.

In light of the number of protocols considered, the variety of research types and breadth of animal types used the membership of the committee has been broadened from the minimum requirements of the Animal Welfare Act 1999. The University believes this is appropriate in order to consider fully the scientific justification of protocols (i.e. the ethics of using animals) and appropriateness of manipulations proposed by investigators.

The committee is comprised of at least 10 members:

1. Chairperson nominated by the Office of the Vice Chancellor (the Chief Executive Officer of the University)
2. One lay member nominated by the territorial or regional council
3. One veterinarian nominated by the New Zealand Veterinary Association
4. One nominee of the Royal New Zealand SPCA
5. Dean of Faculty of Medical and Health Sciences or his/her nominee
6. Dean of the Faculty of Science or his/her nominee
7. An animal facilities manager
8. Two representatives of the Faculty of Medical and Health Sciences
9. One representative of the Faculty of Science.

The AEC Secretary is in attendance at every meeting (non-voting) along with the Animal Welfare Officer (non-voting, advisory capacity only). Other members may be co-opted for a period of three years as required in order to provide the AEC with expertise.

What is monitoring?

Monitoring includes a range of activities undertaken by various members of the committee and/or the Animal Welfare Officer (who serves as veterinary expert for the committee).

The code of ethical conduct states:

- i. *The members of the AEC and the Animal Welfare Officer shall have the right at any time to inspect the facilities in which the animals are housed, the procedures used, and the condition of the animals; and where there is concern they shall be required to investigate and take appropriate action. All members of the University or other persons may bring to the attention of the AEC or the Animal Welfare Officer any concern regarding compliance with this code.*
- ii. *Approvals shall be subject to post-approval monitoring in order to ensure compliance with any conditions of approval.*
- iii. *The AEC shall be responsible for ensuring compliance with approvals and can require a University member through their Head of Department to either modify (as directed by the Committee) or to stop their teaching or research programme involving live animal usage.*

This has been interpreted to include the following monitoring activities:

1. Observations at unscheduled times i.e. not premeditated for compliance monitoring. This could be conducted by any member of the AEC who happens to be visiting animal holding facilities and observes animal practices as an unintended consequence of their primary activity. Examples of this type of visit include, but are not limited to, a visit to an animal facility by an AEC member in their capacity as an investigator undertaking their own manipulations, the animal facilities member during their management activities or the Animal Welfare Officer (AWO) during a scheduled training session. Veterinary visits and facility checks (see points 3 and 4) lead to the most frequent unplanned observations as the AWO walks past investigators performing manipulations.

2. AEC facility visits

Ongoing monitoring of compliance with conditions of approvals is performed by the AEC. The AEC makes regular facility visits to each animal holding area at least once in every 12 month period in order to monitor animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct.

All committee members and the AWO are invited to each visit. There are currently 12 holding facilities within the University and another three holding facilities belonging to parented organisations. University facilities are each visited by the AEC once a year. The University facility visits are supplemented by more frequent visits by the AWO (see point 3). Parented organisations are visited by the AEC at the time of implementing the parenting agreement and then once every three years.

3. AWO facility checks

The AWO conducts regular visits to all facilities to monitor animals, husbandry and management of facilities. These visits are at variable frequencies according to the research being conducted: the grading of manipulations, experience of investigators and management history of the facility are taken into account when deciding visit frequency. Most facilities that conduct regular research performing manipulations of “little” through to “moderate” impact will be visited at least once a month by the AWO to review all animals and support rooms.

4. Veterinary care

Animals are vet checked by the AWO as required. Each facility has an approved procedure for reporting of sick (ill, injured, distressed) animals – conditions which the investigator may not have anticipated during the planning phase and do not have covered by their approved monitoring and contingencies in their approved protocol. The AEC has a standard condition on all approvals “All deaths which occur prior to the planned end of experiment must be notified to the AEC so that a postmortem may be performed if required by the Animal Welfare Officer. This includes all animals that are found dead or moribund, or killed due to abnormalities which make them not fit for purpose”.

Veterinary care of animals with conditions which have not been anticipated during the planning phase ensures that information on models is transferred back to the AEC and can, often, be “fed back” into the model to improve and refine the model, reduce variability and ultimately perhaps animal usage.

5. Post-approval review of procedures relating to protocols – welfare review and ethical review

A structured post-approval review of procedures relating to protocols is conducted. This includes conditions set by the AEC at the time of approval (welfare review) for new models, new procedures and new personnel. This aspect of post-approval review focuses more on individual procedures or components of an approval, rather than review of the whole protocol. It ensures that new models have been set up properly and that personnel are trained appropriately for the work at hand, especially for new models.

The AEC also schedules whole protocol review (ethical review), including review of the written protocol, planned practical procedures and records held by the responsible investigator. This is undertaken by a primary reviewer (a member of the AEC) as well as the AWO or a suitable secondary reviewer. The AWO usually supports the primary reviewer but may suggest a suitable alternative where there is a potential conflict of interest or where the AWO is unavailable for logistical reasons such as illness or annual leave.

Welfare and ethical reviews have all been arranged with investigators in advance. By their very nature, welfare reviews are often a training opportunity as much as a “review” and cannot be done without prior arrangement between investigator and AEC.

During the reviews, attention is given to animal care and welfare, maintenance of health and welfare monitoring records plus a check that appropriate techniques are used during surgical or other manipulative procedures. Post-operative care and methods of pain control are also reviewed when surgical manipulations are performed. Proposed euthanasia methods may also be discussed with the researcher if this is not viewed at the time of the review. The appropriateness of the equipment and facilities used to perform the observed manipulations are judged at this time.

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. Where the appropriate experience is not available from within the AEC (e.g. absence from sick/annual/conference leave, distance to the review site, lack of experience) outside experience may be contracted in as necessary.

Welfare reviews are undertaken according to the experimental situation and conditions imposed by the AEC at the time of approval. Reviews include (but are not limited to) protocols and experiments where:

- there is involvement of new responsible investigators;
- there are new procedures that the committee has concerns about or where welfare implications are unknown at the time of approval;
- new models are proposed, especially those with unknown welfare implications;
- new manipulations that are graded high or very high impact.

Ethical reviews include (but are not limited to) protocols and experiments where:

- numbers of animals for which approval is given are greater than 1000 per research group;
- the number of approved protocols for a research group is five or more. Reviews rotate through the protocols or experiments in a group where multiple protocols have been issued;
- the responsible investigators have been liable for welfare incidents or breaches of approval. If any such incidents occur this will prompt immediate review as part of the non-compliance procedure detailed below and then followed up in 12 months.

The review schedule also takes into account the grading of the manipulations approved and will be automatic for those graded “high” or “very high” impact. There is no limit to the number of welfare reviews that the AEC may request. The AEC aims to conduct ten ethical reviews per year, often covering multiple approvals at each ethical review. Approvals for teaching activities are audited by teaching department (rather than the course co-ordinator who holds the approval) once every three-year period.

6. Reporting of Animal Welfare Incidents

“Anyone who identifies an Animal Welfare Incident should report the incident. Any urgent welfare concerns must be acted upon immediately by contacting a team leader or facility manager”. There is a reporting form that anyone may use, although reports can also be made by email or verbally.

The form is forwarded to the AEC Secretary, the AEC Chairperson or the AWO and an investigation is undertaken according to the procedure outlined in the AEC Process document that supplements the code of ethical conduct.

7. Animal facility staff act informally as “eyes and ears” for the AEC. Observations by animal carers are often passed on to the AWO if animal care staff believe animal welfare is compromised or conditions of AEC approvals are breached. This may lead to an animal welfare incident being registered with the AEC.

Scheduling reviews – Planned or surprise?

Ethical reviews usually involve at least three people. Reviewers often have commitments such as teaching and research as well as needing to be involved in the AEC review process. The AEC Secretary organises these reviews, usually beginning the process months before the review actually happens. The date of the review is often organised according to the schedule of manipulations – viewing manipulations is essential for welfare reviews and desirable for ethical reviews (the ethical review has a paperwork and a manipulation component). Many manipulations may not commence for some time after approval, and work may only take six months (for example) of the three-year approval period. Ethical reviews may also be split so that the paperwork and manipulation reviews are undertaken on separate dates – especially for wildlife work. Surprise visits for reviews and facility visits are a possibility but to date the AEC has not considered the need to undertake an unscheduled ‘surprise’ review.

Facility checks by the AWO are usually planned in advance, but occasionally the AWO does unscheduled visits when in the vicinity for some other reason. Veterinary visits to sick animals are usually at very short notice and arranged with the carer of the animal under observation, either an animal care staff member if the animal is part of the husbandry programme or the investigator if the animal is on protocol.

Outcomes of compliance monitoring in the first 12 months of the new programme

The AEC conducted 12 facility visits, 11 ethical reviews and nine welfare reviews from July 2007 to June 2008. Nine non-compliance reports were issued as a result of these activities.

Welfare Reviews

In the 12 month review period featured in this paper, manipulations on nine protocols were reviewed over 36 visits. Four protocols were reviewed as a result of the AEC placing a condition of approval for use of a new model. One protocol was reviewed because it involved a new manipulation graded as high impact. Three protocols had welfare reviews to establish experimental endpoints that were more severe than the welfare endpoints normally used e.g. greater weight loss than usual for that model. One protocol had a manipulation review as a result of a reported animal welfare incident. The nature of these reviews was such that no non-compliances were generated, instead good practice was established.

Ethical Reviews

Eleven ethical reviews were undertaken across eleven research groups undertaking research under multiple protocols. As part of the ethical review animals were observed either at the time of manipulation or whilst still on experiment, however it was not always possible to view animals in association with every ethical review. Approximately half of the ethical reviews included review of surgical manipulations, two included wildlife manipulations in the field, two reviewed the teaching of students who subsequently performed the manipulations. Five of these reviews generated nine non-compliance reports. Some findings were not major and did not require non-compliance reports so retraining was undertaken instead e.g. to upgrade surgical procedure.

What non-compliances were found?

Two investigators were issued with non-compliance reports as a result of not performing monitoring according to approved protocol. Another two investigators were not recording monitoring checks as required by their approval. One investigator was using Elizabethan collars¹ on some animals post-operatively without AEC approval. One investigator kept an animal alive beyond the approved period of experiment (no experiments were performed and there was no compromise of welfare) for good scientific reasons, but without AEC knowledge or approval. One investigator had not accurately recorded the number of animals used on their protocol.

In the first 12 months of the new programme there were also six animal welfare incidents investigated by the AEC and AWO. These ranged in severity from misunderstandings between investigators and animal care staff through to deaths of animals that were on experiment. There have been no further animal welfare incidents since the end of the first 12 months, partly due to the use of the non-compliance procedure (see next section). The AWO also believes the welfare review system has had a real benefit, especially relating to training of investigators in new models so that there is shared knowledge (between investigator, animal care staff and AWO) of expected welfare outcomes, appropriate welfare endpoints, adequate pain relief and good surgical procedures (e.g. use of aseptic technique and gentle tissue handling). The AEC have also introduced the policy on dead animal reporting which has led to increased knowledge regarding reasons for deaths.

Non-compliance procedure

Where non-compliance is found during a review then a non-compliance report (NCR) is issued. This takes the form of a one page document that details the observation (i.e. the non-compliance), an immediate action (essential if animal welfare is at risk) and a longer term action as a final remedy for the situation (e.g. apply to the AEC to amend the protocol). This is issued at the time of a review.

Non-compliances identified outside the review process (e.g. overuse of animals, use of animals without approval) are dealt with in the first instance by the Chairperson of the AEC. If considered a serious compromise of animal welfare or breach of conditions, the Chairperson of the AEC notifies the responsible investigator within one working day of receiving the complaint. The responsible investigator has two working days to respond. A meeting with the Chairperson of the AEC, the Animal Welfare Officer and at least one other AEC member is held within a reasonable timeframe.

All NCR are signed by both the AEC member (e.g. primary reviewer, Chairperson) and the responsible investigator, so that both parties are in agreement about both the non-compliance and the solution. These NCRs are target-dated and reported back to the AEC at the next monthly meeting. The AEC Secretary registers the NCR on a post-approval activities spreadsheet for follow up and tracking. Each month a report is prepared for the AEC meeting that details all unresolved NCRs. This is then recorded in the minutes for the AEC meeting. All non-compliances are reported to the Office of the Vice Chancellor.

Sanctions imposed by the AEC may include changes in condition of approval (e.g. change to technical procedures), suspension of all work (with work to recommence when certain conditions have been met such as retraining, change in supervision requirements for individual personnel), suspension of part of the approval, termination of an approval or transfer of the approval to a new responsible investigator. The Office of the Vice Chancellor may also impose sanctions that are outside the jurisdiction of the AEC via the institutional disciplinary procedures, but this has not been required to date.

¹ An Elizabethan collar is a bucket-type device (imagine a 10L bucket with the bottom taken out) that is placed over the head of an animal, anchored around the neck loosely with a normal collar so that the animal can still see ahead, drink and eat but cannot chew wounds or itchy spots (the bucket gets in the way). For smaller animals such as rabbits they are made out of smaller plastic devices than buckets, such as x-ray film cut to size and taped together to form a funnel. This is considered normal veterinary care but when used as a regular contingency The University of Auckland AEC requires it to be included in the AEC protocol.

How have investigators taken this?

Some resistance and confusion was anticipated in the planning stages for this new programme of monitoring. Two meetings were held for investigators at which the programme was outlined. The meetings were well attended and there has been no objection to the process at any stage since these meetings.

In the unlikely event that an investigator disagrees about non-compliance (and to date they have not) then discussion would continue until the real issue is agreed upon. If after discussion there was still no agreement the issue would either be raised with the AEC at the next monthly meeting, for all members to discuss and resolve, or there would be a move to the Complaints Procedure. Reviews have not been adversarial to date. This is perhaps because the AEC and the AWO believe all reviews and facility visits need to be conducted in a friendly, collegial manner with opportunity for feedback on AEC processes as well as investigator processes. The reviews and any resulting non-compliances have been conducted with the intent of discovering good practice and elevating poor practice to the level of good practice.

The Complaints Procedure is written into the Code of Ethical Conduct as follows:

“Complaints regarding the Animal Ethics Committee will be dealt with by the Chairperson of the AEC in consultation with at least one other member of the AEC. Written complaints will receive a written acknowledgement from the Chairperson, and the complaint and the acknowledgment will be tabled as correspondence at the next scheduled AEC meeting. The full committee will discuss the complaint and the Chairperson will write to the complainant stating the action(s) that will be taken.

If further clarification is sought by the complainant then a meeting will normally be arranged within 10 working days of the receipt of written request for clarification. Those attending this meeting shall comprise the complainant (and up to two support persons), the AEC Chairperson, Animal Welfare Officer and one other AEC member. The resolutions of this meeting shall be recorded by the Chairperson and copies forwarded to the complainant and all members of the AEC.”

Conclusion

The University of Auckland AEC embarked on a major change in the monitoring programme during 2006 to ensure and enforce compliance with the code of ethical conduct. As well as achieving compliance, the programme was also designed to be more transparent and maximise chances of investigator acceptance and education whilst balancing the workload of the AEC and the Animal Welfare Officer. Findings in the first year highlighted the benefits of the programme and these have been instrumental in supporting good practice. Examples of recurrent non-compliances have been incorporated into the training programme that is run by the Animal Welfare Officer, as have examples of good practice. The review programme has been well accepted by members of the AEC and investigators. Importantly, communication between investigators and the AEC has improved, and procedures within the AEC have improved as a result of feedback from investigators.

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