



Department of
Primary Industries

ANIMAL RESEARCH REVIEW PANEL

Common issues encountered during inspections of animal research establishments

Animal Research Review Panel Guideline 25
January 2017

Introduction

The NSW Department of Primary Industries / Animal Research Review Panel inspections of Accredited Animal Research Establishments and Licensed Animal Suppliers have shown that most Animal Ethics Committees (AECs), facility staff and investigators are focused on animal welfare issues and have good intentions to follow the *Australian code for the care and use of animals for scientific purposes* (the Australian Code). Despite this, some common non-compliance issues have been encountered relating to the 8th Edition of the Australian Code.

To improve compliance with the Australian Code here is a brief summary of these issues.

Numbers bracketed in italics refer to relevant sections of the Australian Code.

Common issues and recommendations

Common issues relate to:

1. Out-of-session approval of projects
2. Chair alone approving out-of-session applications for minor amendments
3. Conflict of interest
4. Formal agreements between accredited institutions collaborating with research
5. Three yearly review of standard operating procedures by the AEC
6. Annual project reports
7. Projects expiry dates
8. 12 monthly issuing of Animal Research Authorities
9. Animal monitoring and record maintenance
10. AEC inspection documentation
11. AEC monitoring of remote research sites
12. AEC consideration of animal transport during projects
13. Documentation maintained with animals

1. Out-of-session approval of projects

“The AEC must consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, only at quorate meetings of the AEC” (2.3.6).

Some AECs have been using email correspondence between members as a method of forming a quorum to approve new projects or major amendments out-of-session.

Email not acceptable: Email correspondence does not allow sufficient discussion between AEC members regarding a new project or a major amendment of a project. It does not constitute a quorate meeting.

Videoconferencing and teleconferencing: Where a face-to-face meeting is not possible, quorate AEC meetings may be conducted through the use of videoconferencing and web-conferencing or, in special circumstances, teleconferencing.

Decisions made out-of-session must be ratified at the next quorate face-to-face AEC meeting (2.2.26(ii)).

2. Chair alone approving out-of-session applications for minor amendments

The Chair alone cannot approve amendments applications: In some AECs the Chair alone has been traditionally approving **minor** amendments to approved projects, such as a changing staff members, animal numbers and drug doses.

All out-of-session minor amendments to previously approved projects must only be approved by a quorum of AEC members or a properly constituted Animal Ethics Committee Executive. This includes the Chairperson and at least one member from Category C or D. These decisions must then be ratified at the next quorate AEC meeting (2.2.23).

Executive committee communication: Communication between Executive Committee members can be by any means the AEC considers appropriate, such as via email or telephone.

What constitutes a minor amendment: It is helpful for an AEC to develop a policy regarding what constitutes a **minor** amendment. A minor amendment would be a change that, in comparison to what has already been approved, has a minor or positive impact on:

- animal welfare and
- the anticipated scientific or educational value and the likelihood of meeting the project's objectives.

Some examples of minor amendments:

- changes in staff where they are appropriately qualified or supervised
- additional tissues or samples collected post mortem
- additional tests performed on samples approved to be collected when the amount collected does not need to change
- changes in numbers of animals used below a certain percentage of the number originally approved (e.g. 5-10%)
- addition of a new research location but using the same project methodology.

Final approval of conditionally approved project or amendment: When the AEC has conditionally approved a new project or amendment at a quorate meeting, pending a satisfactory response from the investigator regarding certain issues, the AEC may delegate the Chair or Executive Officer or other AEC members with relevant expertise to confirm final approval. The approval is given by confirming that the requirements, concerns or modifications requested by the AEC have been met.

3. Conflict of interest

Who needs to declare a conflict of interest: Most AECs are aware that if an AEC member is a principle investigator on a project that is being reviewed, a conflict of interest exists and the person must withdraw from the AEC meeting for the final decision making on that project. (The review might be for a new project application, amendment application, annual, final and unexpected adverse incident reports, inspections and inspection reports).

However, the Australian Code states that procedures for declaration of interests need to be developed for management of perceived or actual conflicts of interest involving AEC members, *and experts whose advice is sought by the AEC*, and must require people with a conflict of interest to remove themselves from the AEC's decision making on matters that relate to the conflict of interest (2.2.21).

This means that any AEC members or non-members attending a meeting who are named on a project application (such as some facility managers named on breeding or training projects), regardless of whether they are a principle or associate investigator, must declare a conflict of interest and remove themselves from the AEC's decision making on matters that relate to the conflict of interest.

How to manage conflicts of interest: Clause 2.3.6 states that "For decision making, members with a conflict of interest must withdraw from the meeting. Once such members have withdrawn, the remaining members must constitute a quorum as defined in Clause 2.2.25—that is, one member from each of the membership categories A, B, C and D, with Categories C and D together representing at least one-third of members present."

The management of the conflicts of interest can vary. The AEC should be aware that some AEC members may feel uncomfortable or inhibited in discussions with the person present but do not admit or speak up about this. It is worthwhile having conflicts of interest declared at the start of the meeting to bring the issue to people's attention. In some AECs the person with the conflict of interest remains in the room while initial discussions about their project are held to answer questions and then temporarily leaves the room during final discussions and decision making. In other AECs the person leaves the room for initial discussions then re-enters the room to answer questions if required, then leaves again during AEC final discussions.

Also of note:

- It is essential that the AEC operates with a quorum in accordance with the Australian Code even when the person has temporarily withdrawn (2.2.25).
- Where category A or B members of the AEC are frequently named as investigators on projects considered by the AEC, then additional members should be appointed to the committee in those categories. This will ensure a quorum is maintained throughout the meeting.

For further information please see Animal Research Review Panel (ARRP) Policy 16:

<http://www.animaethics.org.au/policies-and-guidelines/operation/conflict-of-interest>

4. Formal agreements between accredited institutions collaborating with research

The Australian Code states that for projects involving more than one institution and/or Animal Ethics Committee arrangements between institutions should be as a formal agreement. Institutions should avoid unnecessary duplication of processes (2.6.6).

What is a formal agreement: the nature of these agreements can vary with different AECs and different projects. They range from legal agreements between institutions to email exchanges between the institution's AECs regarding individual projects. The reason for requiring an agreement is to:

- avoid animals being unintentionally neglected by ensuring the AECs of both institutions are aware of the project
- establish who is responsible for what (e.g. approval, animal care, transport, monitoring) and
- ensure that clear communication channels are established between all AECs and all investigators on the project (2.6.4).

Responsibility of institutions for employees: where an employee of one institution proposes to carry out animal research at another institution, the AEC of the "host" institution has a supervisory role over the research, but the employing institution continues to have authority over the employee's actions and is responsible, in terms of vicarious liability, for any acts of its employee that contravene the Animal Research Act.

For further guidance please see ARRP Guideline 3 Collaborative Research - <http://www.animaethics.org.au/policies-and-guidelines/collaborative-research> and the Australian Code clauses 2.6.4 - 2.6.7

5. Three yearly review of standard operating procedures by the AEC

Standard operating procedures (SOPs) that are referenced in, but not provided with AEC project applications, must be approved and reviewed by the AEC every 3 years in accordance with the Australian Code clauses 2.2.33 – 2.2.36.

If SOPs are not referenced in applications or the SOP has not been reviewed by the AEC within 3 years then details of methodology must be provided within the application itself.

The titles and numbers of the SOPs listed in applications should also match the current title/number of the SOPs.

The version and date of the last review of the SOP by the AEC should be documented on the SOP.

6. Annual project reports

Some AECs have been unaware that annual project reporting is required, regardless of the length of time a project is approved for, in accordance with the Australian Code clauses 2.2.32(ii)(b), 2.2.32(iii), 2.3.2 (iii), & 2.4.34 (i).

Why annual reports are required: Annual reporting allows the AEC to conduct a follow-up review of approved projects and activities to allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code (2.3.2(iii)).

The information to be provided in these reports is determined by the AEC requirements and may include what progress has been achieved; any problems that may have interfered with progress of the project; how many animals have been used; whether the wellbeing of the animals is consistent with that anticipated in the proposal; whether any changes are envisaged and whether the project is meeting its aims. The use of templates for these reports is an option.

7. Project expiry dates

On a number of inspections it has been noted that some investigators have submitted their annual project report to the AEC after the Animal Research Authority has expired or it is due to expire prior to the next AEC meeting date when the report will be reviewed.

Investigators must submit annual reports on time: investigators should be reminded of the requirement to submit annual reports in time for the AEC to review prior to the Animal Research Authority expiry date. Conducting research without a current Animal Research Authority is an offence under the *Animal Research Act 1985* which is punishable by a penalty or imprisonment.

8. 12 monthly issuing of Animal Research Authorities

The *Animal Research Act* states that “Unless sooner cancelled, an animal research authority remains in force for the period of **12 months** from the date on which it was issued or, where a shorter period is specified in the authority in that regard, for the shorter period so specified.”

Animal Research Authorities should be issued by the institution once a project is approved by the AEC and reissued upon receipt of and approval by the AEC of a satisfactory annual project report.

For further information please see –

Animal Research Authorities (Fact sheet 5) at:

<http://www.dpi.nsw.gov.au/content/agriculture/livestock/animal-welfare/research-teaching/factsheets/awfact05>

and

<http://www.animaethics.org.au/animal-ethics-committees/animal-research-authorities>

9. Animal monitoring and record maintenance

During a number of inspections it was noted that some investigators had not:

- monitored animals as described in the project application and approved by the AEC
- maintained records as required by the AEC and the institution – including not documenting monitoring as described in the project application and not keeping the records with the animals when this is required by the institution.

Investigators should be reminded of their responsibilities for maintaining records as required by the AEC and the individual institution and that the Australian Code states in part that Investigators must “follow relevant policies and procedures established by the institution and the AEC” (2.4.4(ii)).

Additionally, it is an offence under the Animal Research Act 1985, to carry out animal research “otherwise than with the approval, in accordance with the directions, of the animal care and ethics committee specified in the authority.”

10. AEC Inspection documentation

AECs are required to monitor the care and use of animals by inspecting animals, animal housing and the conduct of procedures, and/or reviewing records and reports (2.3.17).

Additionally, the AEC must maintain records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes (2.2.30(iii) & 2.3.22).

Required inspection records: some AECs have not been maintaining records of inspections or not recording sufficient detail regarding inspections.

Records may vary from a detailed inventory of animals, procedures and facilities to documentation that an inspection was conducted and including any significant findings. As a general guide, significant findings (good and bad) and problem areas should be documented. Where problems are encountered, documentation should be kept of how these have been followed up and solved.

For more information please refer to ARR Policy 13 ‘Inspections by animal ethics committees’:

<http://www.animaethics.org.au/policies-and-guidelines/operation/inspections>

11. AEC monitoring of remote research sites

The Australian Code clause 2.3.23 states:

“AEC procedures should cover the delegation of authority to suitably qualified people to monitor animal care and use, including projects and activities conducted at remote sites (e.g. fieldwork). Procedures should include how reports of such monitoring are to be provided to the AEC (e.g. using still or video images).”

Inspection of remote research sites continues to be problematic for many AECs, especially those that approve field research and wildlife surveys.

Examples of methods used by some AECs include:

- field trips by members of the AEC to inspect sites when plausible, at times coinciding with an AEC meeting
- delegating an experienced/qualified person to conduct the inspection on the AEC's behalf
- use of video cameras to capture procedures and trapping when research is being conducted to send back to the AEC on a regular basis. Video cameras can be hand held or hands-free GroPro® type cameras fixed to the body
- requesting investigators attend AEC meetings to make presentations regarding the progress of projects, including photos and video footage.

12. AEC consideration of animal transport during projects

The AEC is responsible for approving and monitoring all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the AEC (2.3 (ii) & 2.3.18).

When animals need to be transported from one institution to another or a long distance within a facility during the life of a project, this information needs to be provided to the AEC in the original project application or an amendment application for approval of the details.

13. Documentation maintained with animals

During a number of inspections of rodent housing facilities it has been found that there has been:

- no or outdated versions of Animal Research Authorities easily accessible where the animals are being housed
- no documentation of Animal Research Authority number and expiry date on cage labels
- incorrect details of animals being listed on the cage labels

- a mismatch between identification information recorded on cage labels and monitoring records.

Animal Research Authorities in research facilities: For the benefit of facility management, animal care staff, the AEC and external inspectors it is recommended that the most recent version of Animal Research Authorities for projects are readily available, either in paper form or electronically, in or just outside all animal holding rooms

Example of ARRP guidelines for cage labels:

Mouse Cage Labels

All cages should have labels attached to them that provide the following information, or cross reference to a central record in the same room containing this information:

- * Mouse identification (strain, sex, number of mice);
- * Age (date of birth) of litters or of individual mice;
- * Approval number of project in which mice are being used;
- * Name, location and contact numbers of the chief investigator/teacher and, if applicable, other investigators/teachers using mice;
- * Name, location and contact details of staff associated with the housing and care of the mice;
- * Treatments / procedures;
- * Date arrived.

For further information please refer to page 18 of:

http://www.animaethics.org.au/_data/assets/pdf_file/0004/249898/Guideline-22-mouse-housing.pdf

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