

Part III Template for Checklists for the Review of Code Holders and Animal Ethics Committees

1.0 INTRODUCTION

The following checklists provide possible templates for questions that reviewers may ask when carrying out reviews. The checklists are based on 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*. They are intended as guides only and provide possible questions that reviewers could ask code holders and AECs. Since all CECs and AECs will not be identical in their content and procedures, it is not intended that the following checklists provide a complete list of questions. Not all questions will be pertinent to every situation and there may be additional questions that a reviewer asks that have not been included here.

Comments on the checklists are invited at any time and should be addressed to the Principal Adviser Animal Welfare, MAF, PO Box 2526, Wellington 6140.

Name of Code Holder/Institution.....
Name of AEC(s):.....
Name of AEC chairperson(s):.....
Contact details:.....
Reviewer:.....
Date:.....
Location:.....
Observers:.....

2.0 CEC ADEQUACY AND CURRENCY, AEC FORMATION BY THE CODE HOLDER

- Has the CEC been approved by the Director-General of MAF, when was it approved, and is it still current?
- Does the code accurately describe the type and range of work undertaken by the institution?
- Do all AEC members and researchers/investigators have access to a copy?
- Is the number and category of persons constituting the AEC, as stated in the code?
- Does the CEC have a stated process for
 - appointment;
 - reappointment; and
 - replacement of AEC members?
 - Is this being followed (especially for Chair and Deputy Chair)?

- When external members' terms expire are nominations sought from the appropriate body?
- Are new AEC members offered training and given an outline of the expectations of them, in accordance with the CEC?
- Are there policies and procedures in place to ensure that external members have an effective input into the working of the committee,
 - What are these?
 - And how is this effectively evaluated or measured?
- Is there provision for adequate monitoring of compliance with the conditions of project approvals to be carried out?
- Are there policies and procedures to deal with non-compliances?
- Is there provision for the code holder to collect the information and to maintain the records required by the Animal Welfare (Records and Statistics) Regulations 1999?
- Does the CEC specify animal management practices and facilities that are such as to enable the purposes of Part 6 of the Animal Welfare Act 1999 to be met adequately?
- Are there policies and procedures to ensure that if any member of the AEC makes a complaint, the complaint will be dealt with fairly and promptly by the AEC or the code holder?
- Are there policies and procedures to cover parenting arrangements?

3.0 AEC ADHERENCE TO STATED PROCEDURES

- Has the AEC determined its own procedures?
- Do these procedures cover the following items, (not all items are applicable to all AECs), and is there evidence that the procedures are being followed?
 - Purpose of the AEC
 - Meeting frequency
 - Quorum for meetings
 - Preparation and distribution of the agenda
 - Secretarial support for minute taking
 - Distribution of project applications and other information to AEC members

- ❑ The method of setting, varying or revoking conditions of project approvals
- ❑ The conditions for renewal of projects
- ❑ The power to suspend or revoke project approvals
- ❑ Method of decision making
- ❑ Management of conflict of interest by AEC members
- ❑ Provisions for approving projects between meetings (fast-track provisions)
- ❑ Use of subcommittees
- ❑ Handling of commercially sensitive information
- ❑ Use of teleconferencing
- ❑ Information and document control and storage
- ❑ Internal auditing
- ❑ Recommending to the code holder amendments to the CEC.
- ❑ Are there procedures in place to deal with complaints from
 - ❑ AEC members?
 - ❑ applicants?
 - ❑ staff?
 - ❑ the public?
- ❑ If there have been any complaints, were these procedures followed?
- ❑ Where applicable, is public attendance at AEC meetings enabled within the parameters set out in the CEC and the Local Government Official Information and Meetings Act 1987?

4.0 AEC ADHERENCE TO CRITERIA IN APPROVING PROJECTS

- ❑ If non-human hominids are being used, did the Director-General give approval?
- ❑ Does the AEC:
 - ❑ Provide guidance for applicants for completing applications?
 - ❑ Does this include the criteria used in accepting project applications?
 - ❑ Are there deadlines for the submission of applications?
- ❑ The reviewer is expected to view a sample of project applications. The sample must cover the entire period since the code was approved, or since that last review, and should cover applications of all grades of severity, and include applications from parented organisations (where applicable). As a guide, a 10%

sample size is suggested, with a minimum of 5 applications and a maximum of 15.

- ❑ What number of applications was sampled? What was the total number that the sample was selected from?
- ❑ Did the sample cover applications involving all degrees of severity of manipulation?
- ❑ Are the impact gradings used by the investigators and the AEC appropriate according to the guidelines in *Animal Use Statistics*?

4.1 Criteria for approval

- ❑ When considering applications is there evidence that the AEC has had regard for the following matters?
 - ❑ the purposes of Part 6, including the Three Rs?
 - ❑ whether the scientific or educational objectives were clearly identified?
 - ❑ the harm and distress and whether alleviated by any means?
 - ❑ will the experimental design or demonstration meet the objectives?
 - ❑ include the details of the choice of species?
 - ❑ was there statistical justification for the proposed numbers to be used?
 - ❑ whether there were measures in place to ensure the health and welfare of the animals?
 - ❑ whether suitably qualified persons were involved?
 - ❑ whether any duplication of the experiment is proposed?
 - ❑ does the application provide information on the multiple use of animals and the effects on the welfare of those animals?
 - ❑ whether there is a commitment to ensure the findings will adequately used, promoted or published?
- ❑ If any additional criteria were imposed, were they considered by the AEC?

4.2 Changes to protocols

- ❑ Is there a procedure in place to make changes to projects after approval?
 - ❑ is this within the constraints specified by the CEC, or AEC procedures?
- ❑ Is there a procedure in place to renew projects and
 - ❑ is there evidence that this has been followed?

- Is there a procedure in place to suspend or revoke approvals?
 - is there evidence that this has been followed?

5.0 AEC COMPLIANCE WITH ITS POLICIES AND PROCEDURES FOR MONITORING APPROVED PROJECTS

- Is there a policy for monitoring:
 - approved projects;
 - animal management practices and facilities; and
 - standard operating procedures?
- Do the records show that the AEC adhered to this policy?
- Has the AEC ensured that all people manipulating animals are trained and competent to carry out the procedures?
- Is there an appropriate training programme for the types of manipulation carried out?
- Are applicants required to report back to the AEC:
 - if an unexpected adverse outcome arises from manipulation?
 - at the conclusion of project work, or at any other time?
 - Is there evidence that this reporting has occurred?
- Has the AEC collected data on animal usage in compliance with the Animal Welfare (Records and Statistics) Regulations 1999?

6.0 AEC COMPLIANCE WITH ITS POLICIES AND PROCEDURES FOR PARENTING ARRANGEMENTS

- Does the CEC state any policies and procedures in respect of any parenting arrangements?
- Do the parenting arrangements comply with the:
 - CEC?
 - Act? (Notification to MAF)
- View applications from a selection of parented organisations to ensure these comply with the requirements of the code of ethical conduct and AEC procedures.
- Does the AEC monitor parented organisations? What is monitored and are there records of the monitoring?

7.0 CARE OF ANIMALS (SEE THE GOOD PRACTICE GUIDE FOR THE USE OF ANIMALS IN RESEARCH, TESTING AND TEACHING)

The Act requires the AEC to monitor animal management practices and facilities, to ensure compliance with the CEC. The reviewer should visit a range of experimental situations to verify that findings are in accord with those found during AEC monitoring and to meet with staff responsible for animal management. It is expected that the *Good Practice Guide for the Use of Animals in Research, Testing and Teaching* (the Guide) will provide a benchmark for the care of animals used in research, testing and treatment.

Checklists used by the reviewer may be developed:

- based on approved projects or
- from notes prepared by the AEC on the basis of previous visits, or
- reviewers may utilise sections of these checklists as a guide to investigating the level of care that is being provided in these facilities.

Specific project issues will need to be added.

The following checklists list questions that the reviewer could ask during the review. The checklists are based on the Guide.

Section 7.1 addresses compliance by facility staff with good practice for animal care. Section 7.2 addresses the extent to which investigators have complied with good practice for animal care.

It is suggested that a list of animal facilities is obtained at the time of arranging the review so a selection can be made to visit during the review.

7.1 Facility staff, compliance with the Guide

7.1.1 Acquisition of animals

- Are any animals collected from their natural habitats?
 - If so, have measures consistent with s.3.1 of the Guide been followed?
- Are any animals obtained from other countries?
 - If so have the measures consistent with s.3.2 of the Guide been followed?
- Are any of the animals transported?
 - If so have the measures consistent with in s.3.3 of the Guide been followed?
- On admission of new animals, are quarantine provisions undertaken consistent with s.3.4 of the Guide?
 - quarantined?
 - animal health evaluation and treatment if necessary?

- ❑ acclimatised?
- ❑ participation in experiments delayed till completion of quarantine?

Facilities

Outdoor holding facilities

- ❑ Are outdoor holding areas compatible with needs of species:
 - ❑ size
 - ❑ shelter
 - ❑ water
 - ❑ meet species-specific needs?
- ❑ Compliant with established practice for that species, eg does care conform to the code of welfare for that species?

Indoor housing

- ❑ Is the building:
 - ❑ compatible with the needs of the animals to be housed, and?
 - ❑ the projects undertaken?
- ❑ Is the building designed and operated to:
 - ❑ control environmental factors appropriately?
 - ❑ exclude vermin, and
 - ❑ limit contamination associated with the keeping of animals, delivery of food, water and bedding, and the entry of people and other animals?
- ❑ Is the building maintained in good repair?
- ❑ Is the building kept clean and tidy?
- ❑ Is there a pest control programme?
- ❑ Are there adequate storage areas for food, bedding and equipment?
- ❑ Is the choice of detergents, disinfectants and pesticides appropriate?
- ❑ Are cleaning practices monitored to ensure effective sanitation?
 - ❑ What parameters are monitored?
 - ❑ Are records kept?
- ❑ Is there a reticulated water supply?
- ❑ Is there adequate waste water control and drainage?

- ❑ Are there contingency plans for emergencies such as flooding, fire, or a breakdown in lighting, heating, cooling or ventilation?
- ❑ Is access to the building controlled to prevent the entry of unauthorised persons?

Environmental factors

- ❑ Are the environmental conditions appropriate for the species?
 - ❑ ventilation
 - ❑ temperature and humidity
 - ❑ odour control
 - ❑ noise
 - ❑ light intensity and light cycles.

Immediate environment of animals

- ❑ Are cages/pens or containers suitable for the animals contained?
 - ❑ Do they allow for species-specific behavioural and environmental requirements?
 - ❑ Are animals kept in single housing, and if so, for what reasons?
 - ❑ Is food and water readily available?
 - ❑ Is there protection from spread of disease and pests?
 - ❑ Can animals be observed easily?
 - ❑ Are nesting materials provided, and are these appropriate?
 - ❑ Are the cages of smooth durable construction?
 - ❑ Are they clean and easily cleaned?
 - ❑ Are they well maintained?
 - ❑ Are they escape-proof?
 - ❑ Do they protect from climatic extremes?
 - ❑ Are they designed to prevent injury to animals?
 - ❑ Are they large enough for the animals to turn, lie down, stand up etc?
- ❑ Is the population density appropriate for the species, age, environment etc?
- ❑ Are wire-floored cages in use?
 - ❑ Are these cages used only when essential to the project?
 - ❑ Is a solid resting area available?

Enrichment

- Are animals provided with opportunities/stimuli to promote expression of normal behaviour (e.g. is recompense made for unnatural environments)?

7.1.3 Management factors

Person-in-charge

- Name of Supervisor/Manager:.....
- Qualifications:.....
- Experience:.....
- Is a veterinary consultant used? Name:.....

- Does the person-in-charge:
 - Have responsibilities for the management of the day-to-day animal care, including weekend coverage?
 - Contribute to the development and maintenance of the organisation's animal care policies and procedures?
 - Ensure that there is reliable monitoring of the well-being of all animals?
 - Ensure that all ill or injured animals are treated promptly, that the cause of death is investigated for animals that die unexpectedly, and that unexpected death or illness is documented?
 - Ensure that staff wear protective clothing and maintain high standards of personal hygiene in animal areas?
 - Receive information from the AEC regarding project work e.g. copies of applications and approvals?
 - Maintain liaison with investigators regarding all issues relating to animals involved in project work?

- For small animal colonies are there:
 - Documented procedures for the management of holding and breeding facilities?
 - A regular schedule of cage, equipment and facility sanitisation?

- ❑ Adequate records for the source, care, allocation, movement between locations, use and disposal of all animals?
- ❑ Adequate records of the genetic constitution, fertility, fecundity, morbidity and mortality of animal breeding groups?
- ❑ Adequate records of the health status and disease diagnosis (i.e. frequency of testing/observation, and comprehensiveness)?

Staff

- ❑ Number and qualifications/experience of animal care staff
- ❑ Are the staff numbers sufficient for the numbers and types of animals?
- ❑ Are these staff:
 - ❑ Trained?
 - ❑ Competent?

Husbandry procedures

- ❑ Do animals receive appropriate, uncontaminated and nutritionally adequate food in sufficient quantities?
- ❑ If animals are fed in groups are there sufficient feeding points to avoid undue competition for food?
- ❑ Is suitable drinking water constantly available?
- ❑ Are husbandry procedures, which are not part of project work, such as immunisations, carried out by competent personnel?

Animal identification

- ❑ Are all animals identified?
- ❑ Is method reliable?
- ❑ Does method cause minimal stress?

Disposal of animal carcasses and waste

- ❑ Is appropriate provision made for the prompt and sanitary disposal of animal carcasses and waste material?

7.2 Compliance with the Guide by investigators and teachers

It is expected that those factors required to be considered by investigators and teachers, as covered in section 6 of the Guide, with respect to the planning and submission of projects, will have been reviewed by the AEC at the time of approval of the project.

- ❑ Do investigators and teachers understand that they have direct and ultimate responsibility for all matters related to the welfare of the animals under their control (ideally they should have signed a statement to this effect when they submitted their project application)? This includes supervision of students.

Conduct of experiments

The following items are given as a guide. The AEC should have considered these as part of the project approval process. Application forms that guide applicants by asking the appropriate questions will be of assistance to both the applicant and the AEC.

Limiting pain and distress:

- ❑ Did the investigator consider any potentially adverse effects of a manipulation, and have a plan for managing these?
- ❑ Were pilot studies carried out (e.g. where the manipulation was to be carried out for the first time, confirm new techniques, refine humane endpoints)?
- ❑ Is there evidence that animals were adequately monitored during the experiment for evidence of pain and distress?
 - ❑ Were score sheets used to document these observations?
 - ❑ Were appropriate indicators used? (e.g. abnormalities in: behaviour, movement, sound, heart and respiration rate, appetite, body weight, temperature, defaecation and urination, reproduction etc)
 - ❑ Were unexpected outcomes of manipulation reported to the AEC?
- ❑ Were the anaesthetics/analgesics and or tranquillising agents used appropriate to the species? (Refer to “Analgesic Best Practice for the Use of Animals in Research and Teaching”).
- ❑ Were study endpoints developed that minimised pain or distress? (See section 6.4.3 of the Guide for suggestions.)
- ❑ Was the method of euthanasia appropriate?

Surgery:

- Was there evidence of careful planning for surgical procedures?
 - Pre-operative examination?
 - Pre-operative fasting?
 - Administration of pre-operative antibiotic or analgesic considered?
 - Evidence of use of experienced surgeons?
 - Evidence of aseptic technique for recovery surgery?
 - Appropriate post-operative care, with duties of staff clearly defined, emergency procedures established and records maintained?

More severe or controversial manipulations:

- If the AEC approved the use of neuromuscular blocking agents or electroimmobilisation, was special care taken to prevent pain or distress?
- If animal models of human diseases are used was the most appropriate species selected, and was care taken to minimise pain and distress?
- If procedures have been approved that involve modifying an animal's behaviour was positive reinforcement used? If noxious stimuli were used were these as mild as possible and used for the minimum time necessary?
- For toxicological testing proposals were in vitro methods used for initial screening tests, and did the procedures involving animals follow internationally accepted methods?
- For work involving hazards was the advice of the organisation's biohazards committee sought, and were appropriate procedures for containment, disposal and decontamination established?
- Is work involving the manipulation of animals' genetic material carried out in accordance with MAF requirements? Have investigators kept the AEC informed of any adverse effects on the well-being of animals as a result of these manipulations?
- Is there evidence that where tumours were induced, the site was chosen carefully, animals monitored carefully, and the endpoint was appropriately observed?

- ❑ Where lesions of the CNS are a feature of a project, has special caging and animal care been provided as specified?
- ❑ For work involving the withholding of food or water, was the monitoring and care provided within those limits specified and approved by the AEC?
- ❑ For work in which a foetus is affected, was cognisance taken of the requirements, pain and distress of both the mother and foetus? Where new born or newly hatched animals are used, were appropriate care and facilities provided?
- ❑ For research work on pain and its relief, was the use of painful stimuli limited to levels which do not distress humans, limited to the minimum time necessary, and were the animals given pain relief, or able to escape from the painful stimuli?