

Appendix 6: Reviewer Checklists

Introduction

The following checklist provides templates for questions that reviewers are encouraged to ask when carrying out reviews to aid NAEAC and MPI in their decision making. The checklists are based on questions from the previous *Template for Checklists for the Review of Code Holders and Animal Ethics Committees* and NAEAC's *Code of Ethical Conduct Template*. The recording of metrics also provides a quantifiable measure that can be used to track and assess code holder and AEC compliance with their code and the Act.

This revised checklist has been developed in collaboration between MPI, NAEAC and accredited reviewers.

1. Introduction/Background on the Activities of the Applicant

Scope of Activity	
Is the description of the general nature and extent of the RTT activities in which the applicant is engaged, or proposes to be engaged, appropriate?	<input type="checkbox"/>
RTT and 3 Rs	
Is the organisation's philosophy towards RTT and the 3 Rs explicit and adequate?	<input type="checkbox"/>
Responsible Persons	
Describe the individuals in the organisation who will be responsible for administering the CEC.	<input type="checkbox"/>
Persons/Organisations under the CEC	
Describe the person(s) and/or organisation(s) to whom the CEC applies.	<input type="checkbox"/>
Do all AEC members and researchers/investigators have access to a copy of the CEC?	<input type="checkbox"/>

2. Establishment, Functions, Powers and Membership of the Animal Ethics Committee

Functions, Duties and Powers of the Committee	
Is the AEC clear on its functions, duties and powers under the Act?	<input type="checkbox"/>
Membership of the AEC	
Is the code holder a member of the AEC? If not: – Is the senior representative of the company/organisation appointed by the chief executive? and; – Does that representative have the capability of evaluating the scientific or teaching value of every proposal? and; – Is the senior representative endorsed by the AEC?	<input type="checkbox"/>
Have the statutory external members been nominated appropriately by the respective organisations (Royal New Zealand Society for the Prevention of Cruelty to Animals (RNZSPCA), a territorial authority or regional council and the New Zealand Veterinary Association (NZVA)) and do they meet the requirements of the Act (Section 101)?	<input type="checkbox"/>
Are statutory external members remunerated fairly?	<input type="checkbox"/>
Additional Members	
Are there any additional members/organisational members?	<input type="checkbox"/>
Is the actual membership of the AEC in accordance with the CEC?	<input type="checkbox"/>

Vacancies	
Have there been any unexpected/prolonged absences during the current period of the CEC?	<input type="checkbox"/>
Induction and Training of New Members	
Do AEC members appointed during the current CEC approval period consider that the induction and training was adequate?	<input type="checkbox"/>
Terms of Appointment	
Do the terms and conditions for appointed members of the AEC align with the CEC?	<input type="checkbox"/>
Is the appointment of the Deputy Chair in accordance with the CEC?	<input type="checkbox"/>

3. AEC Procedures

AEC Meetings	
Has the AEC determined its own procedures?	<input type="checkbox"/>
Frequency of Meetings	
How many times has the AEC met during the current CEC approval period?	<input type="checkbox"/>
How many of the meetings were face to face?	<input type="checkbox"/>
Use of Tele/Video Conferencing	
Did the AEC use video/teleconferencing during the current CEC approval period? If so: - How many times and how does this compare to face-to-face meetings? - Did the tele/videoconferencing adhere to the policy and procedures described in the CEC?	<input type="checkbox"/>
Timing for Circulation of Agenda Items	
How much notice was given to AEC members of meeting time and place?	<input type="checkbox"/>
Do AEC members consider that meeting documents were circulated with sufficient time and in a manner to allow adequate preparation and consideration?	<input type="checkbox"/>
Were adequate records of meetings kept?	<input type="checkbox"/>
Quorum	
Was every meeting (including tele/video) quorate? If not: - How often was the meeting inquorate and what practices were put in place to deal with AEC business?	<input type="checkbox"/>
Decision Process	
Were all decisions made by the AEC in accordance with the CEC?	<input type="checkbox"/>
Conflicts of Interest	
Have conflicts of interest been sought and documented?	<input type="checkbox"/>
How were perceived or real conflicts of interest handled by the AEC?	<input type="checkbox"/>
Effective Input of Committee Members	
Do all AEC members consider that they were sufficiently supported/resourced to ensure they could provide effective input into the performance of the AEC during the current CEC approval period?	<input type="checkbox"/>
Confidentiality	
How did the AEC manage the confidentiality and protection of confidential information?	<input type="checkbox"/>
Consideration between Meetings	

Did the AEC consider any matters that arose between scheduled meetings?	<input type="checkbox"/>
How many items were considered between scheduled meetings?	<input type="checkbox"/>
What proportion of AEC decisions were made between scheduled meetings?	<input type="checkbox"/>
Did the decision processes adhere to the policy and procedures described in the CEC?	<input type="checkbox"/>
Did the AEC utilise sub-committees to consider matters between scheduled meetings? If so, were the processes in accordance with the CEC?	<input type="checkbox"/>
Use of Subcommittees	
Does the AEC make use of subcommittees?	<input type="checkbox"/>
Public Presence at Meetings	
Was there any public presence at AEC meetings?	<input type="checkbox"/>
Applicant Presence at Meetings	
Were applicants allowed to be present at AEC meetings?	<input type="checkbox"/>
Secretariat Support	
Do members of the AEC consider that the AEC has had adequate secretarial support during the current CEC approval period?	<input type="checkbox"/>
Record Keeping and Information Management	
Has the AEC maintained documentation in order to meet the requirements of the CEC and the Act?	<input type="checkbox"/>
Reporting of Statistics to MPI	
Has the code holder forwarded statistics on animal use and impact of use to MPI each year as required?	<input type="checkbox"/>
Process to Amend the CEC	
Has the AEC recommended to the code holder that the CEC be amended during the current CEC approval period?	<input type="checkbox"/>

4. Consideration of Projects by the AEC

Criteria for Consideration	
The AEC must ensure that approved proposals meet the following criteria as set out in the Act (Section 100).	
Does the proposal meet the purposes of Part 6, including the 3 Rs?	<input type="checkbox"/>
Were the scientific or educational objectives clearly identified?	<input type="checkbox"/>
What harm and distress will the animals experience and how will this be alleviated?	<input type="checkbox"/>
Will the experimental design or demonstration meet the objectives?	<input type="checkbox"/>
What factors have been considered regarding the choice of species?	<input type="checkbox"/>
What statistical justification was provided for the proposed number of animals?	<input type="checkbox"/>
What measures were in place to ensure the health and welfare of the animals?	<input type="checkbox"/>
Will suitably qualified persons be involved in this project?	<input type="checkbox"/>
Does the application provide information on the multiple use of animals and the effects on the welfare of those animals?	<input type="checkbox"/>
Is there a commitment to ensure the findings will be adequately used, promoted or published?	<input type="checkbox"/>
If any additional criteria were imposed, were they considered by the AEC?	<input type="checkbox"/>

Outcomes for Consideration	
Did the AEC utilise all potential outcomes as described in the CEC?	<input type="checkbox"/>
What were the numbers for each outcome?	<input type="checkbox"/>
Maximum Approval Period	
How did the AEC manage projects that spanned longer than the maximum approval period described in the CEC?	<input type="checkbox"/>
Changes to Approved Applications	
Has the AEC made changes to approved projects, including minor modifications during the current CEC approval period? If so: - Were the processes in accordance with the CEC?	<input type="checkbox"/>
Use of non-human hominids	
Did the Director-General give approval for use of non-human hominids?	<input type="checkbox"/>
Power to Suspend, Revoke and Vary Approvals	
Has the AEC exercised the power to suspend or revoke approvals or set, vary or revoke conditions of project approval during the current CEC approval period? If so: - Was there adequate documentation? - Is there evidence that a documented process has been followed?	<input type="checkbox"/>

5. AEC Post-Approval Responsibilities

Compliance	
Have all manipulations performed during the current approval period adhered to the AEC approval conditions? If not: - Has the non-compliance been documented adequately? - Have referral procedures been followed for follow-up action?	<input type="checkbox"/>
Appropriate Qualifications	
Have all manipulations been undertaken by appropriately qualified personnel, or under the direct supervision of appropriately qualified personnel?	<input type="checkbox"/>
Adverse Events	
Is there adequate documentation for adverse events?	<input type="checkbox"/>
Were adverse events dealt with promptly and appropriately in accordance with the Act?	<input type="checkbox"/>
Were adverse events reported to the AEC, and how were the outcomes of these events managed by the AEC to prevent any other such incidents?	<input type="checkbox"/>
Grading	
Does the AEC have a clear understanding of impact grading of proposed and approved projects?	<input type="checkbox"/>
Euthanasia for tissue collection/dissection	
Does the AEC have adequate policies and procedures in place regarding euthanasia for the purposes of tissue collection/dissection?	<input type="checkbox"/>

6. Conduct of Experiments

The AEC should consider 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?	<input type="checkbox"/>
Were pilot studies carried out (for example, where the manipulation was to be carried out for the first time, or to confirm new techniques, or to refine humane endpoints)?	<input type="checkbox"/>
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? (for example, 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?	<input type="checkbox"/>
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")	<input type="checkbox"/>
Were study endpoints developed that minimised pain or distress? (See section 7.4.3 of the Good Practice Guide for suggestions.)	<input type="checkbox"/>
Was the method of euthanasia appropriate?	<input type="checkbox"/>
Surgery	
Was there evidence of careful planning for surgical procedures? - Was there pre-operative examination? - Was there pre-operative fasting? - Was administration of pre-operative antibiotic or analgesic considered? - Was there evidence of use of experienced surgeons? - Was there evidence of aseptic technique for recovery surgery? - Was there appropriate post-operative care, with duties of staff clearly defined, emergency procedures established and records maintained?	<input type="checkbox"/>
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?	<input type="checkbox"/>
If animal models of human diseases are used was the most appropriate species selected, and was care taken to minimise pain and distress?	<input type="checkbox"/>
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?	<input type="checkbox"/>
For toxicological testing proposals were <i>in vitro</i> methods used for initial screening tests, and did the procedures involving animals follow internationally accepted methods?	<input type="checkbox"/>
For work involving hazards, was the advice of the organisation's biohazards committee sought, and were appropriate procedures for containment, disposal and decontamination established?	<input type="checkbox"/>

Is work involving the manipulation of animals' genetic material carried out in accordance with MPI requirements?	<input type="checkbox"/>
Is there evidence that where tumours were induced, the site was chosen carefully, animals monitored carefully, and the endpoint was appropriately observed?	<input type="checkbox"/>
Where lesions of the CNS are a feature of a project, have special caging and animal care been provided as specified?	<input type="checkbox"/>
For work involving the withholding of food or water, was the monitoring and care provided within those limits specified and approved by the AEC?	<input type="checkbox"/>
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?	<input type="checkbox"/>
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?	<input type="checkbox"/>

7. Animal Facilities

Management of Animal Facilities	
Does every facility (including those of parented organisations) have appropriate policies and procedures approved by the AEC to ensure that all animal facilities and practices are in accordance with good practice and scientific knowledge (as recommended by NAEAC in its Good Practice Guide for the Use of Animals in Research, Testing and Teaching) and to the relevant codes of welfare issued under section 75 of the Act?	<input type="checkbox"/>
The following should be considered for each animal facility.	
Person-in-charge	
Name of Supervisor/Manager:	<input type="checkbox"/>
Qualifications and 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?	<input type="checkbox"/>
Do they contribute to the development and maintenance of the organisation's animal care policies and procedures?	<input type="checkbox"/>
Do they ensure that there is reliable monitoring of the well-being of all animals?	<input type="checkbox"/>
Do they 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?	<input type="checkbox"/>
Do they ensure that staff wear protective clothing and maintain high standards of personal hygiene in animal areas?	<input type="checkbox"/>
Do they receive information from the AEC regarding project work? (for example, copies of applications and approvals)	<input type="checkbox"/>
Do they maintain liaison with investigators regarding all issues relating to animals involved in project work?	<input type="checkbox"/>
Staff	
What are the number and qualifications/experience of animal care staff?	<input type="checkbox"/>

Are the staff numbers sufficient for the numbers and types of animals?	<input type="checkbox"/>
Are these staff: - Trained? - Competent?	<input type="checkbox"/>
Development of SOPs	
Is every facility and its standard operating procedures fit for purpose?	<input type="checkbox"/>
Small Colony Procedures	
Are there documented procedures for the management of holding and breeding facilities?	<input type="checkbox"/>
Is there a regular schedule of cage, equipment and facility sanitisation?	<input type="checkbox"/>
Are there adequate records for the source, care, allocation, movement between locations, use and disposal of all animals?	<input type="checkbox"/>
Are there adequate records of the genetic constitution, fertility, fecundity, morbidity and mortality of animal breeding groups?	<input type="checkbox"/>
Are there adequate records of the health status and disease diagnosis (that is, frequency of testing/observation, and comprehensiveness)?	<input type="checkbox"/>
Immediate Environment of Animals	
Are cages/pens or containers suitable for the animals housed in them?	<input type="checkbox"/>
Do cages/pens or containers allow for species-specific behavioural and environmental requirements?	<input type="checkbox"/>
Are animals kept in single housing, and if so, for what reasons?	<input type="checkbox"/>
Is food and water readily available?	<input type="checkbox"/>
Is there protection from spread of disease and pests?	<input type="checkbox"/>
Can animals be observed easily?	<input type="checkbox"/>
Are nesting materials provided, and are these appropriate?	<input type="checkbox"/>
Are the cages of smooth durable construction?	<input type="checkbox"/>
Are the cages clean and easily cleaned?	<input type="checkbox"/>
Are the cages well maintained?	<input type="checkbox"/>
Are the cages escape-proof?	<input type="checkbox"/>
Do the cages protect from climatic extremes?	<input type="checkbox"/>
Are the cages designed to prevent injury to animals?	<input type="checkbox"/>
Are the cages large enough for the animals to turn, lie down, stand up etc.?	<input type="checkbox"/>
Is the population density appropriate for the species, age, environment etc.?	<input type="checkbox"/>
Are wire-floored cages in use? If so: - Are these used only when essential to the project? - Is a solid resting area available?	<input type="checkbox"/>
Enrichment	
Are animals provided with opportunities/stimuli to promote expression of normal behaviour (for example, is recompense made for unnatural environments)?	<input type="checkbox"/>

Husbandry Procedures	
Do animals receive appropriate, uncontaminated and nutritionally adequate food in sufficient quantities?	<input type="checkbox"/>
If animals are fed in groups, are there sufficient feeding points to avoid undue competition for food?	<input type="checkbox"/>
Is suitable drinking water constantly available?	<input type="checkbox"/>
Are husbandry procedures, which are not part of project work, such as immunisations, carried out by competent personnel?	<input type="checkbox"/>
Animal Identification	
Are all animals identified?	<input type="checkbox"/>
Is the identification method reliable?	<input type="checkbox"/>
Does the identification method cause minimal stress?	<input type="checkbox"/>
Disposal of Animal Carcasses and Waste	
Is appropriate provision made for the prompt and sanitary disposal of animal carcasses and waste material?	<input type="checkbox"/>
Environmental Factors	
For either indoor or outdoor facilities, consider the following environmental factors for the species housed there.	
Is the ventilation appropriate for the species?	<input type="checkbox"/>
Are the temperature and humidity appropriate for the species?	<input type="checkbox"/>
Is the odour control appropriate for the species?	<input type="checkbox"/>
Is the noise level appropriate for the species?	<input type="checkbox"/>
Is the light intensity and/or light cycles appropriate for the species?	<input type="checkbox"/>
Outdoor Holding Facilities	
For each outdoor holding facility, consider the following aspects and their compatibility with the needs of the species housed there.	
Is the facility the appropriate size for the species?	<input type="checkbox"/>
Is there shelter provided?	<input type="checkbox"/>
Is there water provided?	<input type="checkbox"/>
Does the facility meet species-specific needs?	<input type="checkbox"/>
Is the facility compliant with established best practice for the species (that is, does it conform to the code of welfare for that species)?	<input type="checkbox"/>
Indoor Housing	
For each indoor housing facility, consider the following aspects and their compatibility with the needs of the species housed there.	
Is the building maintained in good repair?	<input type="checkbox"/>
Is the building kept clean and tidy?	<input type="checkbox"/>
Is the building compatible with the needs of the animals to be housed there?	<input type="checkbox"/>
Is the building compatible with the projects to be undertaken?	<input type="checkbox"/>
Is the building designed and operated to control environmental factors appropriately?	<input type="checkbox"/>
Is the building designed and operated to limit contamination associated with the keeping of animals, delivery of food, water and bedding, and the entry of people and other animals?	<input type="checkbox"/>

Is there a pest control programme to exclude vermin?	<input type="checkbox"/>
Are there adequate storage areas for food, bedding and equipment?	<input type="checkbox"/>
Is the choice of detergents, disinfectants and pesticides appropriate?	<input type="checkbox"/>
Are cleaning practices monitored to ensure effective sanitation? Explain: - what parameters are monitored? - what records are kept?	<input type="checkbox"/>
Is there a reticulated water supply?	<input type="checkbox"/>
Is there adequate waste-water control and drainage?	<input type="checkbox"/>
Are there contingency plans for emergencies such as flooding, fire, or a breakdown in lighting, heating, cooling or ventilation?	<input type="checkbox"/>
Monitoring Animal Facilities	
Does the AEC undertake annual monitoring of all animal facilities for approved projects, including the monitoring the approved projects of parented organisations?	<input type="checkbox"/>
Acquisition of Animals	
Are any animals collected from their natural habitats? If so: - Have measures consistent with s.6.7 of the NAEAC Good Practice Guide been followed?	<input type="checkbox"/>
Are any animals obtained from other countries? If so: - Have the measures consistent with s.6.8 of the Guide been followed?	<input type="checkbox"/>
Are any of the animals transported? If so: - Have the measures consistent with in s.6.9 of the Guide been followed?	<input type="checkbox"/>
On admission of new animals, are quarantine provisions undertaken consistent with s.6.16 of the Guide? - Are animals quarantined? - Is animal health evaluated and treatment provided if necessary? - Are animals acclimatised to the new facility? - Is commencement of experiments delayed until the completion of quarantine?	<input type="checkbox"/>
Transportation of Animals	
Have animals been transported under species appropriate, humane and hygienic conditions at all times?	<input type="checkbox"/>
Has the code of welfare for Transport within New Zealand been followed?	<input type="checkbox"/>
Housing of Animals	
Have the policies and procedures that ensure that where animals are housed, their health is safeguarded and that undue stress is avoided been followed? If not: - Has the non-compliance been documented adequately?	<input type="checkbox"/>
Standard Operating Procedures (SOPs)	
Has the AEC approved SOPs relating to procedures, care and use of animals? If so: - Does the AEC undertake a scheduled review of SOPs?	<input type="checkbox"/>

Sick and Injured Animals	
Have any animals become sick or injured during the current CEC approval period? If so: - Has the non-compliance been documented adequately?	<input type="checkbox"/>

8. Monitoring of AEC Approvals

Appropriate Training	
Has the AEC ensured that all people manipulating animals are trained and competent to carry out the procedures?	<input type="checkbox"/>
Is there an appropriate training programme for the types of manipulation that are used?	<input type="checkbox"/>
Frequency of Monitoring	
Has the AEC kept adequate records detailing the frequency of monitoring visits by the AEC or its nominee during the current CEC approval period?	<input type="checkbox"/>
Are these records in accordance with the CEC?	<input type="checkbox"/>
Monitoring of Manipulations Grade C-E	
Has the AEC kept adequate records detailing the frequency of monitoring visits by the AEC or its nominee during the current CEC approval period?	<input type="checkbox"/>
Are these records in accordance with the CEC?	<input type="checkbox"/>
Monitoring by Nominated Veterinarians	
Did the AEC utilise the expertise of a veterinarian nominated as representing the AEC during the current CEC approval period?	<input type="checkbox"/>
Are these monitoring visits documented and outcomes recorded following the visit?	<input type="checkbox"/>
End of Approval Reporting	
Is the AEC informed of the outcome of approved projects at the completion of the project?	<input type="checkbox"/>
Was an appropriate End of Approval report received for every approved project during the current CEC approval period?	<input type="checkbox"/>
End of Approval Grading	
Was it necessary for the AEC to reassess the impact gradings of approved projects at the completion of the project?	<input type="checkbox"/>
End of Approval Statistics	
Did the AEC receive animal use statistics at the completion of every project during the current CEC approval period?	<input type="checkbox"/>
Non-Compliance	
Were any incidences of non-compliance detected/reported during the current CEC approval period? If so: - Was there adequate documentation, consideration by the whole AEC and appropriate escalation processes?	<input type="checkbox"/>

9. Arrangements for External Parties to Use the CEC and AEC

Parenting Arrangements	
Did the AEC undertake any parenting agreements during the current CEC approval period? If so: - Is this in accordance with the CEC and was MPI notified?	<input type="checkbox"/>

Were all processes for the parented organisations with regard to approval, monitoring and compliance equal to the processes applied to other projects?	<input type="checkbox"/>
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10. Complaints Procedures

Reporting of Complaints	
Were any complaints made during the current CEC approval period? If so: - Were the procedures for dealing with the complaints appropriate?	<input type="checkbox"/>
Animal Welfare Complaints	
Were any animal welfare complaints made during the current CEC approval period? If so: - Was there appropriate escalation to MPI and/or RNZSPCA?	<input type="checkbox"/>

11. Process to Amend, Suspend or Revoke the CEC

CEC Amendments, Suspension or Revocation	
Were any requests made during the current CEC approval period for amendment, suspension or revocation of the CEC?	<input type="checkbox"/>