**

**Scientific Procedures License Audit**

Project review

# Audit details

|  |  |
| --- | --- |
| **Details** | **Details required** |
| License name and number |       |
| Date of interview with principal investigator  |       |
| Name of auditor(s) |       |
| Names of any additional persons at interview  |       |

# Project details

|  |  |
| --- | --- |
| **Project details** | **Details required** |
| Title of application |       |
| Name of principle investigator |       |
| AEC project # |       |
| Names of other interviewees  |       |
| Dates of approval  |       |
| Species approved |       |
| Number of animals used  |       |

# Part A Checklist – Application to the AEC

## Institutional responsibility

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| Does the institution establishing an AEC develop documentation (an application form) for applications for AEC approval to: * commence a project or activity?
* amend an approved project or activity?
 |       |       |
| Does the design of the form allow for the provision of information required by the AEC to assess the ethical acceptability of the proposed use of animals? |       |       |

## AEC responsibility

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| Is this project or activity ethically acceptable to the AEC and does it conform to the requirements of the Australian code? |       |       |
| Was this application approved at a quorate meeting? |       |       |
| Was there appropriate consideration and approval for any requested modifications or subsequent amendments?* Where this was considered by an executive was the modification minor in nature?
 |       |       |
| Did members with conflict of interest withdraw from the meeting for decision making?* If yes, was there a quorum remaining?
 |       |       |
| Did the AEC clearly communicate its decisions, the reasons for its decisions and any conditions attached (note wording of conditions) to an approval to investigators in writing as promptly as possible? |       |       |

## Investigator responsibility – Information provided to the AEC

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| Information provided in plain English |       |       |
| The scientific or educational aims of the project. * An overview of how the project is designed in relation to its aims
 |       |       |
| Evidence to support a case to use animals.* the project has scientific or educational merit, and has potential benefit for humans, animals or the environment, and
* the use of animals is essential to achieve the stated aims, and suitable alternatives to replace the use of animals to achieve the stated aims are not available, and
* the project involves the minimum number of animals required to obtain valid data, and
* the project involves the minimum adverse impact on the wellbeing of the animals involved
 |       |       |
| Evidence the purpose of the project is to:* obtain and establish significant information relevant to the understanding of humans and/or animals, or
* maintain and improve human and/or animal health and welfare, or
* improve animal management or production, or
* obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment, or
* achieve educational outcomes in science, as specified in the relevant curriculum or competency requirements
 |       |       |
| Information to support the AECs consideration of the standard of scientific integrity:* regardless of the potential benefits of a project, the methods used must be scientifically valid, feasible, well designed and carefully conducted so that there is a reasonable expectation that the aims of the project will be achieved.
* projects that are not scientifically valid must not be performed, no matter how mild the impact on the wellbeing of the animals
 |       |       |
| The potential benefits of the outcomes, and the evidence that supports the use of animals(For teaching projects, justification must include an outline of how the attainment of educational outcomes will be assessed, including, as applicable, national educational outcomes, required Vocational Education and Training (VET) package competency achievements, endorsed program outcomes, and other curriculum-related outcomes). |       |       |
| Details of:* why the use of animals is essential to achieve all the stated aims
* potential alternatives that are available to replace the use of animals in all or part of the project
* why these alternatives are not suitable
 |       |       |
| Information to support the case for ethical acceptability of the proposed use of animals, based on: * whether such use demonstrates the principles of the Australian code
* balancing whether the potential effects on the well-being of the animals involved is justified by the potential benefits
 |       |       |
| Particular justification for activities that involve severe compromise to animal well-being, and for which the 3Rs cannot be fully applied, including:* unrelieved pain and distress, including where the planned endpoints will allow severe adverse effects to occur
* death as the endpoint
* reuse and repeated use of animals
* prolonged restraint or confinement
 |  |  |
| Where applicable - Requirement for ministerial approval for death as endpoint scientific procedures prior to commencement of the project |       |       |
| Particular justification for activities that involve use of non-human primates |       |       |
| Where applicable - Requirement for ministerial approval for scientific procedures on non-human hominids prior to commencement of the project |       |       |
| Where the aim(s) of the project involves the animals experiencing pain and distress that will not be alleviated, the planned endpoint of the project must be as early as feasible to avoid or minimise pain and distress in the animals. |       |       |
| Details of species, strain or breed of animals chosen, and the reason for this choice |       |       |
| Details of source of animals* Source of specified animals is consistent with licence conditions
 |       |       |
| Factors that may contribute to variability of results are taken into account, including the biological status of the animals and their living conditions (e.g. physical, environmental and social conditions) |       |       |
| Unintended adverse impacts on animal well-being that may confound experimental data are avoided or minimised |       |       |
| The proposed methods and procedures accord with current best practice and are appropriate for the purpose of the project, and if not * details and justification for care and management of animals that does not accord with current best practice
 |       |       |
| A clear description of the steps taken to consider and apply the 3Rs |       |       |
| Reduction:* the number of animals required
* the justification for this number
* requirement for experimental design and statistical considerations (using the minimum number to obtain valid data)
 |       |       |
| Reduction - teaching projects:* the number of animals required
* the justification for this number
* information provided on the ratio of students to animals, and the number of times that each animal will be used in each class, and/or handled per day and/or per week for teaching projects; (using the minimum number to achieve educational objectives)
 |       |       |
| Opportunities for sharing of tissues and other biological material (from animals being killed at the conclusion of the project) |       |       |
| Details of:* housing
* husbandry
* care of the animals
 |       |       |
| Living conditions and management that are appropriate for the species are available, including suitable housing facilities |       |       |
| Any special requirements for the care and management of the animals are met |       |       |
| Procedures are in place for monitoring and managing animal health during the project |       |       |
| Details of the locations:* where animals will be housed
* where procedures will be conducted
 |       |       |
| Assessment of the potential adverse impact on animal well-being for the duration of the project, including:* a step-by-step description of what will happen to each animal, or group of animals, for the duration of the project,
* provisions for the animal at the conclusion of their use
 |       |       |
| Assessment of the potential adverse impact on animal well-being for the duration of the project, including where applicable, procedures that apply to breeding programs that are integral to a project (such as the creation of a new line of animals, including genetically modified or cloned animals, or that are integral to the maintenance of a line of animals in a facility |       |       |
| * Assessment of the potential adverse impact on animal well-being for the duration of the project, including identification of known and potential causes of adverse impacts on the well-being of an animal and how such impacts will be avoided or minimised?
* Experimental and non-experimental factors addressed?
 |       |       |
| Details of how the well-being of animals will be monitored and assessed throughout the project, the frequency of monitoring and assessment, the actions to be taken if problems are identified, and the criteria for intervention points and humane endpoints?  |       |       |
| * For any standard operating procedures:
* the SOP must have current approval from the AEC
* the SOP must include in its title the date of approval or last review by the AEC
* investigators named in the application must be competent to implement the SOP
* any variation to an SOP must be described in the application and should be considered as a prompt for review of the SOP.
 |       |       |
| Has the SOP been reviewed by the AEC within three years of its approval? |       |       |
| Are referenced SOPs available to all relevant people, including AEC members? |       |       |
| Identification of the person with ultimate responsibility for the conduct of the project and/or the care of the animals? |       |       |
| The name of the project, the people involved and their responsibilities? |       |       |
| The competence of people for all procedures they will undertake using animals, or details of their supervision by a person who is competent to perform the procedures? |       |       |
| Assurance that adequate resources will be available for the conduct of the project? |       |       |
| Details of any participation of staff from other institutions, and if and how the facilities of another institution will be used; or if project applicants are involved in collaborative studies using animals at another institution, or named in an application to the AEC of another institution? |       |       |
| Any actual or potential interest, including any financial interest or other relationship or affiliation, that may affect judgements and decisions regarding the well-being of the animals involved? |       |       |
| Any additional administrative details as required by the institution and the AEC e.g. details of collaborations, permits and licences, certification of the biological status of the animals, and work health and safety considerations? |       |       |
| Declaration by the responsible investigator(s) stating that they and all others involved in the project will comply with the requirements of the Australian code, and providing assurance that adequate resources will be available to undertake the project? |       |       |

# Part B Checklist – Investigator responsibilities

## Project management

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| How does the identified person with ultimate responsibility for animal care and use ensure that all people involved in the project understand and accept their roles and responsibilities? |       |       |
| How does the identified person with ultimate responsibility for animal care and use ensure that procedures and resources for meeting responsibilities are in place? |       |       |
| Is animal care is provided by an adequate number of competent people? |       |       |
| Are procedures performed either by competent investigators, or under the direct supervision of a person who is competent to perform the procedures? |       |       |
| For projects that involve hazards to other animals and humans, do investigators ensure that all personnel are aware of these hazards, and any potential pathogenic effects from these hazards? |       |       |
| For projects that involve hazards to other animals and humans, are appropriate procedures implemented for quarantining and handling animals that pose a risk to other animals and to humans because of naturally acquired or experimentally induced infectious disease? |       |       |

## Animal care and use under the project

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| Do investigators confirm animals are suitable for their proposed use at the time they are supplied or procured for that use? |       |       |
| Are animals used identified (individually or in groups)? |       |       |
| Are people involved in the care and use of animals in the project knowledgeable about the normal behaviour and signs of pain and distress for the species they will use? |       |       |
| For projects involving the use of privately-owned animals, how do investigators ensure that:* + all people involved in the care and use of such animals are aware of and accept their responsibilities relating to the animals
	+ people responsible for the daily management of the animals during the project are familiar with and understand the code, and are competent
 |       |       |
| For projects involving the use of privately-owned animals, do investigators provide the owner of the animal with a document, to be included in the application to the AEC, clearly stating the details and duration of the owner’s responsibilities? |       |       |
| For projects involving xenotransplantation, do investigators ensure that measures are in place to minimise the potential for xenosis, including the appropriate screening of source animals, management of biohazardous waste and emergency plans for the management of adverse outcomes? |       |       |

## Maintaining records

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| Do investigators maintain records of the care and use of animals, and make such records available to the institution, the AEC, and authorised external reviewers? |       |       |
| Do records include the origin/source of the animals and provisions for the animals at the conclusion of their use? |       |       |
| Do records include the number of animals used? |       |       |
| Do records include details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes? |       |       |
| Do records include the condition of the animal, any adverse impact on animal well-being and actions taken as a result? |       |       |
| Do records include any any additional information requested by the AEC |       |       |
| Do records include names of people performing the procedures and entering the records? |       |       |
| Do records include names and contact details of people responsible for monitoring and emergency incidents? |       |       |
| For activities involve genetically modified animals, do records include: * number of animals used for the creation and maintenance of genetically modified animals?
 |       |       |
| For activities involve genetically modified animals, do records include: * the lineage and health status of the animals?
 |       |       |

## Reporting

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| Do investigators report to the AEC as required: interim / pilot outcomes, annual, final reports? |       |       |
| Do investigators notify the AEC promptly of any unexpected adverse events? |       |       |

# Outcomes

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Y/N** | **Comment** |
| Do investigators only use animals: * when ethically acceptable
* effects on animals are justified by benefits based on governing principles in the Australian code
 |       |       |
| Do investigators apply principles of the Australian code in animal care and use* planning
* conducting
* reviewing projects
 |       |       |
| Do investigators conduct a project involving the use of animals in accordance with the conditions and requirements of the AEC approval, and cease the project if approval from the AEC is suspended or withdrawn? |       |       |
| Do investigators undertake education and training, and competency assessment, in accordance with institutional and AEC policies and procedures? |       |       |
| Do investigators ensure that procedures using animals are performed competently:* how?
* training register?
 |       |       |
| Do investigators follow institute and AEC policies and procedures? |       |       |
| Do investigators apply for and obtain written approval from an AEC before commencing a project that involves the use of animals, or an amendment to an approved project? |       |       |
| Do investigators conduct all aspects of a project in accordance with the conditions and requirements of the AEC approval and any subsequent amendments approved by the AEC? |       |       |
| Are animals monitored and assessed at all stages of the project at sufficient frequency for signs of pain and distress, including deviations from normal behaviour? |       |       |
| Is prompt action taken based on the monitoring and assessment of animal well-being, in accordance with intervention points and humane endpoints approved by the AEC?  |       |       |
| Does alleviating unanticipated pain and distress, and humane killing, if necessary, take precedence over project progress? |       |       |
| At all stages during the project, does the investigator ensure that the animal’s environment and management are appropriate for the species and support the animal’s well-being? |       |       |
| Do investigators take steps at all times to safeguard the well-being of animals by avoiding or minimising known or potential causes of harm, including pain and distress, to the animals? |       |       |