**

Scientific Procedures and Specified Animal Breeding Licence

Breeding project review checklist

#  Audit details

|  |  |
| --- | --- |
| **License and audit details** | **Details required** |
| Licence name and number: |       |
| Licence nominee: |       |
| Name person with ultimate responsibility for breeding project (principal investigator): |       |
| Name of project reviewed: |       |
| AEC approval number: |       |
| Approval dates: |       |
| Species: |       |
| Number of animals approved by the AEC within the project: |       |
| Auditor name(s): |       |
| Date(s) of project review: |       |

Contents

[**Part A**: Checklist – Assessment of the application to the AEC for approval to commence a project or activity related to breeding of animals 2](#_Toc527549341)

[**Part B:** Checklist – Person with ultimate responsibility for the project; conduct, record keeping and reporting where this person is the animal facility manager (AFM) or reports directly to the animal facility manager 9](#_Toc527549342)

[**Part C**: Checklist – Person with ultimate responsibility for the project; conduct, record keeping and reporting where this person is not the animal facility manager or a direct report 12](#_Toc527549343)

# Part A: Checklist – Assessment of the application to the AEC for approval to commence a project or activity related to breeding of animals

## Knowing and accepting responsibilities

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| 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 animalAs applicable, details of their supervision by a person who is competent to perform the procedures |       |       |
| Details of any participation of staff from other institutionsHow the facilities of another institution will be used |       |       |
| Any actual or potential interest, including any financial interest or other relationship or affiliation, that may affect judgments 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
* 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
* ensure adequate resources will be available to undertake the project
 |       |       |

## Presentation information

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| Information required by the AEC to assess the ethical acceptability of the proposed use of animals |       |       |
| Information is provided in plain English |       |       |

## Using animals only when it is justified

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| The scientific or educational aims of the project |       |       |
| The potential benefits of the outcomes, and the evidence that supports the use of animals |       |       |
| 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
* reuse and repeated use of animals
* prolonged restraint or confinement
 |       |       |
| Particular justification for activities that involve use of non-human primates |       |       |

## Applying high standards of scientific integrity

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| An overview of how the project is designed in relation to its aims |       |       |
| Details of species, strain or breed of animals chosen, and the reason for this choice |       |       |
| Details of source of animals |       |       |
| 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 are avoided or minimised  |       |       |
| The proposed methods and procedures accord with current best practice and are appropriate for the purpose of the project |       |       |

## Applying the three R’s

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| 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)
 |       |       |
| Opportunities for sharing of tissues and other biological material (from animals killed at conclusion of project) |       |       |

## Supporting the well-being of animals

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| 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 |       |       |
| Procedures for monitoring and managing animal health during the project |       |       |
| Details of the locations:* where animals will be housed
* where procedures will be conducted
 |       |       |
| Details and justification for care and management of animals that do not accord with current best practice |       |       |

## Avoiding or minimising harm, including pain and distress to animals

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| 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
 |       |       |
| Experimental or planned endpoint specifiedas early as feasible to avoid or minimise pain and distress in animals |       |       |
| Assessment of the potential adverse impact on animal well-being for the duration of the projectConsider, where applicable, procedures that apply to breeding programs that are integral to a project:* the creation of a new line of animals, including genetically modified or cloned animals
* 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
* how such impacts will be avoided or minimised

Addressing:* Experimental factors
* Non-experimental factors
 |       |       |
| 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
* the criteria for intervention points and humane endpoints
 |       |       |
| Consideration of the well-being of animals used in the project in terms of the cumulative effects of the animal’s lifetime experience? |       |       |

## Standard operating procedures

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| SOPs must:* have current approval from the AEC
* include in its title the date of approval or last review by the AEC
 |       |       |

# Part B: Checklist – Person with ultimate responsibility for the project: conduct, record keeping, and reporting

# where this person is the animal facility manager (AFM) or reports directly to the animal facility manager

## Project authorisation and conduct

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| Was written approval obtained from the AEC, for all activities, before commencing a project, 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? |       |       |

## New animal lines

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| Does the animal facility manager avoid generating a new animal line using genetic modification if a similar, suitable animal model is available? |       |       |

## Xenotransplantation

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| 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

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| Do records include details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes? |       |       |
| Do records include any additional information requested by the AEC |       |       |
| Do records include names of people performing the procedures and entering the records? |       |       |
| When activities involve genetically modified animals, do records include the number of animals used for the creation and maintenance of genetically modified animals? |       |       |
| When activities involve genetically modified animals, do records include the lineage and health status of the animals? |       |       |

## Reporting

|  |  |  |
| --- | --- | --- |
| **Is the following information provided to the AEC?** | **Yes/No** | **Comment** |
| As applicable, does the animal facility manager provide a final report to the AEC on the generation of the new animal line? |       |       |
| Does the animal facility manager provide an annual project report to the AEC? |       |       |
| Does the animal facility manager notify the AEC promptly of any unexpected adverse events? |       |       |
| Does the animal facility manager report to the AEC on the creation and maintenance of genetically modified animals? |       |       |

# Part C: Checklist – Person with ultimate responsibility for the project; conduct, record keeping and reporting

# where this person is not the animal facility manager or a direct report

Note in the following checklist:

* ‘Investigator’ refers to the person with ultimate responsibility for the project
* ‘Investigators’ refers to persons approved by the AEC to conduct activities within the project

## Project authorisation and conduct

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| Do investigators apply principles of the Australian code in animal care and use* planning
* conducting
* reviewing projects?
 |       |       |
| Do investigators follow institute and AEC policies and procedures? |       |       |
| Does the principal investigator apply for and obtain written approval from the AEC for all activities? |       |       |
| 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? |       |       |
| Does the identified person with ultimate responsibility for animal care and use ensure that procedures and resources for meeting responsibilities are in place? |       |       |
| Are the 3Rs applied during the conduct of the project, and do subsequent amendments to the approved project only proceed following approval from the AEC?  |       |       |

## Training and competency

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| Do investigators undertake education and training, and competency assessment, in accordance with institutional and AEC policies and procedures? |       |       |
| 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? |       |       |

## Animal care and well-being

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| Do investigators confirm animals are suitable for their proposed use at the time they are supplied or procured for that use? |       |       |
| Do investigators ensure that procedures involving animals accord with current best practice? |       |       |
| Do investigators consider the well-being of animals used in the project in terms of the cumulative effects of the animal’s lifetime experience? |       |       |
| 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? |       |       |
| Is animal care is provided by an adequate number of competent people? |       |       |
| 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? |       |       |
| Are methods that cause the least harm used? |       |       |
| Are strategies to detect, avoid and minimise any pain and distress in the animals implemented and reviewed? |       |       |
| 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? |       |       |
| 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? |       |       |
| Are there records of monitoring and assessment of animal well-being? |       |       |
| 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? |       |       |
| Do investigators ensure that the scope of monitoring the well-being of the animals at all stages of their care and use in the project is clearly outlined and communicated to all parties? |       |       |

## Animal provisions at project conclusion

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| Do investigators take prompt action regarding provisions for animals at the conclusion of their use, in accordance with procedures and protocols approved by the AEC? |       |       |
| Do investigators use humane procedures for killing an animal that are appropriate to the species and circumstances? |       |       |
| Do investigators ensure that all carcasses and tissues from animals that have died or been humanely killed are disposed in a sanitary and appropriate manner? |       |       |

## Projects involving hazards

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| 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?**•** consider use of substances in gene on/off strains |       |       |
| 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 humans because of naturally acquired or experimentally induced infectious disease? |       |       |

## New animal lines

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| Does the investigator avoid generating a new animal line using genetic modification if a similar, suitable animal model is available to the investigator or a relevant in vitro method can be used? |       |       |
| Does the investigator get AEC approval from the start of the process until the impact of the genotype on well-being is known, and data on mortality, morbidity, and population health of the new line are available.?• Are all procedures used for creating and breeding these animals regarded as part of a project and included in the project application to the AEC? |       |       |
| Do investigators use methods to support and safeguard the well-being of the animals involved? |       |       |
| Does the investigators ensure that animals and their offspring are not sold, or transferred to another facility, unless the recipient of the animals accepts full responsibility for completion of the phenotype assessment? |       |       |

## Privately owned animals

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| For projects involving the use of privately owned animals, 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? |       |       |
| For projects involving the use of privately owned animals, do investigators ensure that people responsible for the daily management of the animals during the project are familiar with and understand the Australian 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? |       |       |

## Xenotransplantation

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| 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** | **Yes/No** | **Comment** |
| Do investigators maintain records of the care and use of animals? |       |       |
| Do investigators maintain records of the number of animals used to create and maintain the new animal line, and the lineage and health status of the animals? |       |       |
| Does the investigator maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers? |       |       |
| Do investigators ensure that records of monitoring and assessment of animals are in accordance with Clauses 3.1.21–3.1.22 of the Australian code? |       |       |
| 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 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? |       |       |
| When activities involve genetically modified animals, do records include the number of animals used for the creation and maintenance of genetically modified animals? |       |       |
| When activities involve genetically modified animals, do records include the lineage and health status of the animals? |       |       |

## Reporting

|  |  |  |
| --- | --- | --- |
| **Responsibility** | **Yes/No** | **Comment** |
| Do investigators report to the AEC as required? |       |       |
| Does the investigator advise the AEC when the clinical status of the animals changes unpredictably? |       |       |
| Does the investigator report regularly to the AEC on the monitoring of a new animal line at a frequency determined by the AEC? |       |       |
| Do investigators provide a final report to the AEC on the generation of the new animal line? |       |       |
| Do investigators provide an annual report for an approved project to the AEC? |       |       |
| Does the investigator notify the AEC promptly of any unexpected adverse events? |       |       |
| Does the investigator provide a final report on outcomes as soon as practicable after completion or discontinuation of a project to the AEC? |       |       |
| Does the investigator report to the AEC on the creation and maintenance of genetically modified animals? |       |       |
| Does the investigator provide other reports as required by the AEC? |       |       |