ANIMAL RESEARCH REVIEW PANEL

Animal Ethics Committee reporting and amendment application templates

Animal Research Review Panel Guideline 26

March 2018

**Introduction**

The *Australian code for the care and use of animals for scientific purposes* 8th Edition 2013(the Australian Code) requires the following reports to be submitted to Animal Ethics Committees (AECs):

1. Annual project progress report

2. Final project report

3. Unexpected adverse incident report

4. Report on the creation and maintenance of genetically modified animals.

Additionally, before any amendments to approved projects are allowed, investigators must seek written approval from the AEC via an application for the amendment.

Many institutions have developed excellent reporting and application templates that comply with the requirements of the Australian Code. The NSW Department of Primary Industries and the Animal Research Review Panel gratefully acknowledge the assistance provided by a number of Institutions in the development of the following templates.

These templates are a basic guide for information that may assist AECs in reviewing and monitoring the care and use of animals on a regular and ongoing basis. It is anticipated that individual institutions and AECs, if they choose to use the templates, will modify them to suit their requirements.

Templates

[**1. ANNUAL PROJECT REPORT FOR ANIMAL RESEARCH 2**](#_Toc504455470)

[**2. FINAL PROJECT REPORT FOR ANIMAL RESEARCH 10**](#_Toc504455471)

[**3. UNEXPECTED ADVERSE EVENT REPORT 18**](#_Toc504455472)

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# 1. ANNUAL PROJECT REPORT FOR ANIMAL RESEARCH

The *Australian Code for the care and use of animals for scientific purposes* (the Australian Code) requires that:

* Institutions, in consultation with the Animal Ethics Committee (AEC), must develop documentation for reporting on an approved project or activity that has been completed or discontinued (Clause 2.2.32 (iii)).
* Investigators must provide the AEC, in accordance with AEC and institutional policies and procedures an annual report for an approved project, regardless of the duration of approval for the project (Clause 2.4.34 (i))
* The AEC must allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code (Clause 2.3.2 (iii))

Please complete all sections of the annual report form. The information provided allows the AEC to determine whether the animals used in this project have been justified and if the research has been conducted as approved. Projects are approved for a **maximum of X years**. Animal Research Authorities are issued for a **maximum of 12 months**. Ongoing project approval is subject to the AEC’s consideration and approval of this annual report.

After expiry of the current Animal Research Authority, animal work must cease until you have received a renewed authority. For ongoing projects this means applications must be made in time for review by the AEC and renewal before the expiry date.

**1. ADMINISTRATION**

**1.1** Project details

|  |  |
| --- | --- |
| Project Approval Number: |  |
| Title of Project: |  |
| Time Period Covered in this report |  |
| Date of expiry of current Animal Research Authority: |  |

**1.2** Principal Investigator details:

|  |  |
| --- | --- |
| Name (Title, Name, Surname) |  |
| Phone (work/mobile) |  |
| Email |  |

**1.3** Please indicate if this report is the:

1st Annual Progress Report

2nd Annual Progress Report for this project

**2. ANIMAL USAGE DETAILS**

**2.1** Provide details of animals used during this reporting period:

*If reporting fauna surveys, please attach a list of all species and numbers surveyed.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Animal Species/Strain** | **Purpose Category (See Appendix)** | **Procedure Category**  **(See Appendix)** | **Total Number approved for the Project** | **Number used for the first time during the last 12 months** | **Cumulative number used to date** |
| Example: Mouse- Balb/c | 1. Stock breeding | 1.Observation involving minor interference | 150 | 50 | 120 |
|  | Choose an item. | Choose an item. |  |  |  |
|  | Choose an item. | Choose an item. |  |  |  |

*(Add or delete rows as necessary)*

**2.2**.Did the number of animals used vary from the number approved?

Yes  No

If **yes**, please provide details

**2.3** Provide details of any unexpected adverse incidents for this period in the table below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Animal ID** | **Incident Date** | **Date Reported to AEC** | **Number animals affected** | **Brief description of cause and modifications made to reduce mortality.**  **If not reported to AEC, why not?** |
|  |  |  |  |  |

*(Add or delete rows as necessary)*

It is the policy of the Animal Ethics Committee (AEC) that unexpected adverse events, including unexpected deaths, are reported to the AEC within…..hours/days.

**3.** **PROJECT PROGRESS SUMMARY**

**3.1** Give a summary of work done (in lay terms) and progress achieved during this reporting period.

**3.2** List the aim(s) of the approved project and describe how these have been achieved (or are being achieved). If the aims have **not been achieved**, please explain.

**3.3** Has the wellbeing of the animals been consistent with that anticipated in the project application?

Yes  No

If **no**, please provide details

**3.4** Describe any problems that may have interfered with progress of the project.

**3.5** Are any changes to the approved project likely to be needed?

Yes  No

If **yes**, please provide details including whether an amendment application will be submitted.

**3.6** Are there any other outcomes to date (e.g. publications, methods to reduce any negative impact on animal welfare or methods to reduce or replace the use of animals)? Please describe.

**3.7** Further comments by Principal Investigator

**4. PRINCIPAL INVESTIGATOR SIGNATURE**

|  |  |
| --- | --- |
| Principal Investigator (printed) |  |
| Principal Investigator (signature) |  |
| Date |  |

*By signing this form, you confirm that the research has been conducted in compliance with the Animal Research Act and the Australian Code for the care and use of animals for scientific purposes, and the conditions of AEC approval.*

**Acknowledgements**

The contributions of the Executive Officers of the Animal Ethics Committees of the Office of Environment and Heritage, the Garvan Institute of Medical Research, CSIRO North Ryde and CWLA, Macquarie University and the University of Sydney as well as Dr Irma Villaflor from the Children’s Medical Research Institute to the development of this template is gratefully acknowledged.

**Appendix (See** [**Form L: Animal Use Statistics – Section D**](http://www.animalethics.org.au/forms)**)**

**PURPOSE**

Enter the **most appropriate** numerical code **(A1- A10)** from those listed below to describe the **primary** purpose of the project (one purpose only for each project should be entered).

|  |  |
| --- | --- |
| **Purpose Code:** | **Description:** |
| **A1** | ***Stock breeding*** Breeding projects to produce new teaching or research stock. Include the animals used to produce progeny and any breeders or progeny culled in the process, NOT the final progeny themselves (as these will be counted under the project in which they go on to be used). |
| **A2** | ***Stock maintenance*** Holding projects for animals maintained for use in other projects. These animals may be maintained under an Animal Research Autority because they require special management. If they are not held under an Authority, (eg normal stock animals kept mainly for commercial production, but occasionally used in research) then they are only counted in the project where they are used for teaching/research.  *Examples*   * *Fistulated ruminants which are maintained under a holding project, for use in other short term feeding trial projects* * *Non-breeding colony of diabetic rats held for research in other projects* |
| **A3** | ***Education*** Projects carried out for the achievement of educational objectives. The purpose of the project is not to acquire new knowledge, rather to pass on established knowledge to others. This would include interactive or demonstration classes in methods of animal husbandry, management, examination and treatment.  *Examples*   * *Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis* * *Sheep used in shearing demonstration classes for students; Dogs used to teach animal care to TAFE students* |
| **A4** | ***Research: human or animal biology*** Research projects which aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology. |
| **A5** | ***Research: human or animal health and welfare***  Research projects which aim to produce improvements in the health and welfare of animals, including humans. |
| **A6** | ***Research: animal management or production*** Research projects which aim to produce improvements in domestic or captive animal management or production. |
| **A7** | ***Research: environmental study***  Research projects which aim to increase the understanding of animals’ environment or their role in it. These will include studies to determine population levels and diversity and may involve techniques such as observation, radio tracking or capture and release. *Examples*   * *Pre-logging or pre-development fauna surveys* |
| **A8** | ***Production of biological products***  Using animals to produce products other than milk, meat, eggs, leather, fur, etc.  *Examples*   * *Use of a sheep flock to donate blood to produce microbiological media* * *Production of commercial anti-serum* * *Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals* * *Quality Assurance testing of drugs* **butdo not include animals which come under Purpose A10, below.** |
| **A9** | ***Diagnostic procedures***  Using animals directly as part of a diagnostic process.  *Examples*   * *Inoculation of day old chicks with ND Virus to determine virulence* * *Water supply testing using fish* |
| **A10** | ***Regulatory product testing***  Projects for the testing of products required by regulatory authorities, such as the APVMA. **If the product testing is not a regulatory requirement, eg it is part of a quality assurance system only, those animals should be included in the appropriate category selected from above.** (This would be normally be Purpose A8 (Production of biological products) in the case of QA testing.)  *Examples*   * *Pre-registration efficacy or toxicity testing of drugs and vaccines* |

**PROCEDURE**

Enter the **highest appropriate** numerical code **(P1- P9)** from those listed below to describe the type of procedures carried out on the animals in the project. The descriptions given are a guide only. **Note:** for each project include additional lines for each procedure category where different animals within the same project are subjected to different procedure categories.

Where 'Death as an endpoint' or 'Production of genetically modified animals ' applies, animals must be placed in these categories (P8 or P9) rather than any others which might also appear appropriate

|  |  |
| --- | --- |
| **Procedure Code:** | **Description:** |
| **P1** | ***Observation Involving Minor Interference***  Animals are not interacted with or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved.  *Examples*   * *Observational study only* * *Breeding animals for supply, where only normal husbandry procedures are used* * *Breeding or reproductive study with no detriment to the animal* * *Feeding trial, such as Digestible Energy determination of feed in a balanced diet* * *Behavioural study with minor environmental manipulation* * *Teaching of normal, non-invasive husbandry such as handling and grooming* |
| **P2** | ***Animal Unconscious Without Recovery***  Animal is rendered unconscious under controlled circumstances with little or no pain or distress. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal which is then killed without regaining consciousness.  *Examples*   * *Laboratory animals killed painlessly for dissection, biochemical analysis, etc* * *Teaching surgical techniques on live, anaesthetised patients which are not allowed to recover following the procedure* |
| **P3** | ***Minor Conscious Intervention***  Animal is subjected to minor procedures which would normally not require anaesthesia or analgesia. Any pain is minor and analgesia is usually unnecessary, although some distress may occur as a result of trapping or handling.  *Examples*   * *Injections, blood sampling in conscious animal* * *Minor dietary or environmental deprivation or manipulation, such as feeding nutrient-deficient diets for short periods* * *Trapping and release as used in species impact studies* * *Trapping and humane euthanasia for collection of specimens* * *Stomach tubing, shearing* |
| **P4** | ***Minor Surgery With Recovery***  Animal is given appropriate regional or general anaesthesia with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and postoperative analgesia may be appropriate. Field capture using chemical restraint methods is also included here.  *Examples*   * *Biopsies* * *Cannulations* * *Sedation/anaesthesia for relocation, examination or injections/blood sampling* * *Castration with regional or general anaesthesia and post-operative analgesia* |
| **P5** | ***Major Surgery With Recovery***  Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Post operative pain is usually considerable and at a level requiring analgesia.  *Examples*   * *Orthopaedic surgery* * *Abdominal or thoracic surgery* * *Transplant surgery* |
| **P6** | ***Minor Physiological Challenge***  Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress or any pain/distress is quickly and effectively alleviated.  *Examples*   * *Minor infection* * *Minor or moderate phenotypic modification* * *Early oncogenesis* * *Arthritis studies with pain alleviation* * *Induction of metabolic disease* * *Prolonged deficient diets* * *Polyclonal antibody production* * *Antiserum production* |
| **P7** | ***Major Physiological Challenge***  Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress which is not quickly or effectively alleviated.  *Examples*   * *Major infection* * *Major phenotypic modification* * *Oncogenesis without pain alleviation* * *Arthritis studies with no pain alleviation* * *Uncontrolled metabolic disease* * *Isolation or environmental deprivation for extended periods* * *Monoclonal antibody raising in mice* |
| **P8** | ***Death As An Endpoint***  This category only applies in those rare cases where the death of the animal is a planned part of the procedures and animals die but are not euthanased. Where predictive signs of death have been determined *and* euthanasia is carried out before significant suffering occurs, they may be placed in category P6 or P7.  *Examples*   * *Lethality testing (including LD50, LC50)*   **It does not include:** death by natural causes; animals which are euthanased as part of the project; animals which are euthanased if something goes wrong; animals euthanased for dissection or for use as museum specimens; or accidental deaths. |
| **P9** | ***Production of genetically modified animals***  This category is intended to allow for the variety of procedures which occur during the **production** of genetically modified animals. As animals in this category may be subjected to both minor *and* major physiological challenges *and* surgical procedures, this category reflects the varied nature of the procedures carried out. It effectively includes ALL animals used in GM production other than the final progeny which are used in a different category of procedure.  *Examples*   * *Initial breeding animals for GM production* * *Animals culled as part of the GM production process* |

# 2. FINAL PROJECT REPORT FOR ANIMAL RESEARCH

The *Australian Code for the care and use of animals for scientific purposes* (the Australian Code) requires that:

* Institutions, in consultation with the Animal Ethics Committee (AEC), must develop documentation for reporting on an approved project or activity that has been completed or discontinued (Clause 2.2.32 (iii))
* Investigators must provide the AEC, in accordance with AEC and institutional policies and procedures, a final report as soon as practicable after completion or discontinuation of the project (Clause 2.4.34 (iii))

Please complete all sections of the Final Report form below. The information provided allows the AEC to determine whether the animals used in this project have been justified and if the research has been conducted as approved.

**1. ADMINISTRATION**

**1.1** Project details

|  |  |
| --- | --- |
| Project Approval Number: |  |
| Title of Project: |  |
| Time period covered in this report (last 12 months) |  |
| Date of expiry of current Animal Research Authority: |  |
| Date of project completion |  |

**1.2** Principal Investigator details

|  |  |
| --- | --- |
| Name (Title, Name, Surname) |  |
| Phone (work/mobile) |  |
| Email |  |

**2. ANIMAL USAGE DETAILS**

**2.1** Provide details of animals used during this reporting period.

*If reporting fauna surveys, please attach a list of all species and numbers surveyed.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Animal Species/Strain** | **Purpose Category (See Appendix)** | **Procedure Category**  **(See Appendix)** | **Total Number approved for the Project** | **Number used for the first time during the last 12 months** | **Cumulative number used to date** |
| Example: Mouse- Balb/c | 1. Stock breeding | 1.Observation involving minor interference | 150 | 50 | 120 |
|  | Choose an item. | Choose an item. |  |  |  |
|  | Choose an item. | Choose an item. |  |  |  |

*(Add or delete rows as necessary)*

**2.2**.Did the number of animals used vary from the number approved?

Yes  No

If **yes**, please provide details and justify:

**2.3** Provide details of any unexpected adverse incidents for this period in the table below**:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Animal ID** | **Incident Date** | **Date Reported to AEC** | **Number animals affected** | **Brief description of cause and modifications made to reduce mortality.**  **If not reported to AEC, why not?** |
|  |  |  |  |  |

*(Add or delete rows as necessary)*

It is the policy of the Animal Ethics Committee (AEC) that unexpected adverse events, including unexpected deaths, are reported to the AEC within…..hours/days.

**3. PROJECT ACHIEVEMENTS SUMMARY**

**3.1** Give a summary of work done (in lay terms) over the full project.

**3.2** List the aim(s) of the approved project and describe how these have been achieved (or are being achieved). If the aims have **not been achieved**, please explain.

**3.3** Has the wellbeing of the animals been consistent with that anticipated in the project application?

Yes  No

If **no**, please provide details:

**3.4** Describe any problems that may have interfered with progress of the project.

**3.5** If rehoming was approved by the AEC as part of this project, please provide details of the animals rehomed.

**3.6** Are there any other outcomes to date (e.g. publications, methods to reduce any negative impact on animal welfare or methods to reduce or replace the use of animals)? Please describe.

**3.7** I intend to submit a new application for this work to continue:

Yes  No

**3.8** Further comments by Principal Investigator

**4. PRINCIPAL INVESTIGATOR SIGNATURE**

|  |  |
| --- | --- |
| Principal Investigator (printed) |  |
| Principal Investigator (signature) |  |
| Date |  |

*By signing this form, you confirm that the research has been conducted in compliance with the Animal Research Act 1985 and the Australian Code for the care and use of animals for scientific purposes, and the conditions of AEC approval.*

**Acknowledgements**

The contribution of the Executive Officers of the Animal Ethics Committees of the Office of Environment and Heritage, the Garvan Institute of Medical Research, CSIRO North Ryde and CWLA, Macquarie University and the University of Sydney as well as Dr Irma Villaflor from the Children’s Medical Research Institute to the development of this template is gratefully acknowledged.

**Appendix (See** [**Form L: Animal Use Statistics – Section D**](http://www.animalethics.org.au/forms)**)**

**PURPOSE**

Enter the **most appropriate** numerical code **(A1- A10)** from those listed below to describe the **primary** purpose of the project (one purpose only for each project should be entered).

|  |  |
| --- | --- |
| **Purpose Code:** | **Description:** |
| **A1** | ***Stock breeding*** Breeding projects to produce new teaching or research stock. Include the animals used to produce progeny and any breeders or progeny culled in the process, NOT the final progeny themselves (as these will be counted under the project in which they go on to be used). |
| **A2** | ***Stock maintenance*** Holding projects for animals maintained for use in other projects. These animals may be maintained under an Animal Research Autority because they require special management. If they are not held under an Authority, (eg normal stock animals kept mainly for commercial production, but occasionally used in research) then they are only counted in the project where they are used for teaching/research.  *Examples*   * *Fistulated ruminants which are maintained under a holding project, for use in other short term feeding trial projects* * *Non-breeding colony of diabetic rats held for research in other projects* |
| **A3** | ***Education*** Projects carried out for the achievement of educational objectives. The purpose of the project is not to acquire new knowledge, rather to pass on established knowledge to others. This would include interactive or demonstration classes in methods of animal husbandry, management, examination and treatment.  *Examples*   * *Animals used by veterinary schools to teach examination procedures such as pregnancy diagnosis* * *Sheep used in shearing demonstration classes for students; Dogs used to teach animal care to TAFE students* |
| **A4** | ***Research: human or animal biology*** Research projects which aim to increase the basic understanding of the structure, function and behaviour of animals, including humans, and processes involved in physiology, biochemistry and pathology. |
| **A5** | ***Research: human or animal health and welfare***  Research projects which aim to produce improvements in the health and welfare of animals, including humans. |
| **A6** | ***Research: animal management or production*** Research projects which aim to produce improvements in domestic or captive animal management or production. |
| **A7** | ***Research: environmental study***  Research projects which aim to increase the understanding of animals’ environment or their role in it. These will include studies to determine population levels and diversity and may involve techniques such as observation, radio tracking or capture and release. *Examples*   * *Pre-logging or pre-development fauna surveys* |
| **A8** | ***Production of biological products***  Using animals to produce products other than milk, meat, eggs, leather, fur, etc.  *Examples*   * *Use of a sheep flock to donate blood to produce microbiological media* * *Production of commercial anti-serum* * *Production of products, such as hormones or drugs, in milk or eggs from genetically modified animals* * *Quality Assurance testing of drugs* **butdo not include animals which come under Purpose A10, below.** |
| **A9** | ***Diagnostic procedures***  Using animals directly as part of a diagnostic process.  *Examples*   * *Inoculation of day old chicks with ND Virus to determine virulence* * *Water supply testing using fish* |
| **A10** | ***Regulatory product testing***  Projects for the testing of products required by regulatory authorities, such as the APVMA. **If the product testing is not a regulatory requirement, eg it is part of a quality assurance system only, those animals should be included in the appropriate category selected from above.** (This would be normally be Purpose A8 (Production of biological products) in the case of QA testing.)  *Examples*   * *Pre-registration efficacy or toxicity testing of drugs and vaccines* |

**PROCEDURE**

Enter the **highest appropriate** numerical code **(P1- P9)** from those listed below to describe the type of procedures carried out on the animals in the project. The descriptions given are a guide only. **Note:** for each project include additional lines for each procedure category where different animals within the same project are subjected to different procedure categories.

Where 'Death as an endpoint' or 'Production of genetically modified animals ' applies, animals must be placed in these categories (P8 or P9) rather than any others which might also appear appropriate

|  |  |
| --- | --- |
| **Procedure Code:** | **Description:** |
| **P1** | ***Observation Involving Minor Interference***  Animals are not interacted with or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved.  *Examples*   * *Observational study only* * *Breeding animals for supply, where only normal husbandry procedures are used* * *Breeding or reproductive study with no detriment to the animal* * *Feeding trial, such as Digestible Energy determination of feed in a balanced diet* * *Behavioural study with minor environmental manipulation* * *Teaching of normal, non-invasive husbandry such as handling and grooming* |
| **P2** | ***Animal Unconscious Without Recovery***  Animal is rendered unconscious under controlled circumstances with little or no pain or distress. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal which is then killed without regaining consciousness.  *Examples*   * *Laboratory animals killed painlessly for dissection, biochemical analysis, etc* * *Teaching surgical techniques on live, anaesthetised patients which are not allowed to recover following the procedure* |
| **P3** | ***Minor Conscious Intervention***  Animal is subjected to minor procedures which would normally not require anaesthesia or analgesia. Any pain is minor and analgesia is usually unnecessary, although some distress may occur as a result of trapping or handling.  *Examples*   * *Injections, blood sampling in conscious animal* * *Minor dietary or environmental deprivation or manipulation, such as feeding nutrient-deficient diets for short periods* * *Trapping and release as used in species impact studies* * *Trapping and humane euthanasia for collection of specimens* * *Stomach tubing, shearing* |
| **P4** | ***Minor Surgery With Recovery***  Animal is given appropriate regional or general anaesthesia with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and postoperative analgesia may be appropriate. Field capture using chemical restraint methods is also included here.  *Examples*   * *Biopsies* * *Cannulations* * *Sedation/anaesthesia for relocation, examination or injections/blood sampling* * *Castration with regional or general anaesthesia and post-operative analgesia* |
| **P5** | ***Major Surgery With Recovery***  Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Post operative pain is usually considerable and at a level requiring analgesia.  *Examples*   * *Orthopaedic surgery* * *Abdominal or thoracic surgery* * *Transplant surgery* |
| **P6** | ***Minor Physiological Challenge***  Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress or any pain/distress is quickly and effectively alleviated.  *Examples*   * *Minor infection* * *Minor or moderate phenotypic modification* * *Early oncogenesis* * *Arthritis studies with pain alleviation* * *Induction of metabolic disease* * *Prolonged deficient diets* * *Polyclonal antibody production* * *Antiserum production* |
| **P7** | ***Major Physiological Challenge***  Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress which is not quickly or effectively alleviated.  *Examples*   * *Major infection* * *Major phenotypic modification* * *Oncogenesis without pain alleviation* * *Arthritis studies with no pain alleviation* * *Uncontrolled metabolic disease* * *Isolation or environmental deprivation for extended periods* * *Monoclonal antibody raising in mice* |
| **P8** | ***Death As An Endpoint***  This category only applies in those rare cases where the death of the animal is a planned part of the procedures and animals die but are not euthanased. Where predictive signs of death have been determined *and* euthanasia is carried out before significant suffering occurs, they may be placed in category P6 or P7.  *Examples*   * *Lethality testing (including LD50, LC50)*   **It does not include:** death by natural causes; animals which are euthanased as part of the project; animals which are euthanased if something goes wrong; animals euthanased for dissection or for use as museum specimens; or accidental deaths. |
| **P9** | ***Production of genetically modified animals***  This category is intended to allow for the variety of procedures which occur during the **production** of genetically modified animals. As animals in this category may be subjected to both minor *and* major physiological challenges *and* surgical procedures, this category reflects the varied nature of the procedures carried out. It effectively includes ALL animals used in GM production other than the final progeny which are used in a different category of procedure.  *Examples*   * *Initial breeding animals for GM production* * *Animals culled as part of the GM production process* |

# 3. UNEXPECTED ADVERSE EVENT REPORT

Numbers bracketed in italics below refer to relevant sections of the *Australian Code for the Care and Use of Animals for Scientific Purposes (8th edition 2013)* (The Australian Code).

The Australian Codedefines an Adverse Event as: any event that has negative impact in the wellbeing of an animal.

Itdefines an Unexpected Adverse Event as: an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.

An unexpected adverse event may result from different causes, including but not limited to:

* death of an animal, or group of animals, that was not expected
* adverse effects following a procedure or treatment that was not expected
* adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study
* a greater level of pain or distress than was predicated in the planning of the project or activity
* power failures, inclement weather, emergency situation or other factors external to the project or activity that have a negative impact on the welfare of the animals

Prompt action must be taken in response to unexpected adverse events and emergencies, including alleviation of pain and distress, in accordance with institutional and AEC policies and procedures. Alleviation of pain and distress of a severity that was not anticipated in an approved project must take precedence over an individual animal reaching the planned endpoint of the project or activity, or the continuation or completion of the project or activity. If necessary, animals must be killed humanely without delay *(3.1.24)*

When an animal dies unexpectedly, or is humanely killed due to unforeseen complications, a necropsy should be performed by a competent person *(3.1.25).*

The Australian Code also states in part that:

Investigators must provide to the AEC…prompt notification of any unexpected adverse events *(2.4.34).*

It is the policy of the Animal Ethics Committee (AEC) that unexpected adverse events, including unexpected deaths, are reported to the AEC within…..hours/days.

**1. Project Details**

|  |  |
| --- | --- |
| Project Approval Number: |  |
| Title of Project: |  |
| Date of expiry of current Animal Research Authority: |  |
| Name of Principal Investigator |  |

**2. Animal Details**

|  |  |
| --- | --- |
| Species (and strain if appropriate) |  |
| Number of animals involved |  |
| Number of animals in the treatment group the animal belonged to |  |
| Identification number (s) |  |
| Date of adverse event |  |
| Location of animal(s) at time of adverse event |  |

**3. Event details**

**3.1** Describe the event: what happened? Include details of the symptoms and/or signs exhibited by the animal, e.g. weight loss, diarrhoea, vomiting, respiratory difficulty, collapse, abdominal swelling or other signs of injury or distress, or found dead.

|  |
| --- |
|  |

**3.2** At what stage of the project did the event occur? What treatments/procedures had been performed on the particular animal(s) prior to the event? Include a timeline of events if relevant.

|  |
| --- |
|  |

**3.3** What action was taken when the event happened or was discovered? (e.g. animal euthanased, vet called, pain relief was administered and animal monitoring changed).

|  |
| --- |
|  |

**3.4** What investigations have taken place? (e.g. necropsy, histopathology, haematology, faecal tests, microbial culture). If an animal died and a necropsy was not done, explain why.

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**3.5** Supporting Documentation (photos/references/path reports e.t.c):

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**3.6** Findings and recommendations of the attending or consultant veterinarian:

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| --- |
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**3.7** Why/how do you think this event occurred? What immediate and long-term actions are being taken to prevent a recurrence? (e.g. modification to procedures or experimental design, housing, monitoring or researcher/student training or supervision).

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**3.8**  What immediate and long-term actions are being taken to prevent a recurrence? (e.g. modification to procedures or experimental design, housing, monitoring or researcher/student training or supervision).

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**3.9** Is there any other information or comment you wish to provide in relation to this event?

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**4. PRINCIPAL INVESTIGATOR SIGNATURE**

|  |  |
| --- | --- |
| Principal Investigator (printed) |  |
| Principal Investigator (signature) |  |
| Date |  |

*By signing this form, you confirm that the research has been conducted in compliance with the Animal Research Act 1985 and the Australian Code for the care and use of animals for scientific purposes, and the conditions of AEC approval.*

**Acknowledgements**

The contribution of the Executive Officers of the Animal Ethics Committees of the Office of Environment and Heritage, the Garvan Institute of Medical Research, CSIRO North Ryde and CWLA, Macquarie University and the University of Sydney as well as Dr Irma Villaflor from the Children’s Medical Research Institute to the development of this template is gratefully acknowledged.

# 

# 4. REQUEST TO AMEND AN APPROVED PROJECT

The *Australian Code for the care and use of animals for scientific purposes* (the Australian Code) requires that:

Before commencing a project, or an amendment to an approved project, investigators must:

(i) submit an application to the AEC

(ii) obtain written approval from the AEC. (Clause 2.4.10)

Changes must not be made and animals must not be ordered until you have received written confirmation from the AEC that this amendment request has been approved.

**1. ADMINISTRATION**

|  |  |
| --- | --- |
| Project Approval Number: |  |
| Date of expiry of current Animal Research Authority: |  |
| Title of Project: |  |
| Principal Investigator |  |

Is the amendment for:

Removal or change in personnel Yes  No

If the answer is **yes,** for **removing personnel** please proceed to section **2.1**, for **adding new personnel** please proceed to section **2.2**

If the answer is **no,** please proceed to section **3.**

**2. CHANGE OF PERSONNEL**

**2.1 Removing personnel from project:**

|  |  |
| --- | --- |
| Name |  |
| Date of Departure: |  |
| Signature of Principal Investigator: |  |

**2.2 Adding new personnel to a project:**

|  |  |  |
| --- | --- | --- |
| Name |  | |
| Relevant qualifications, experience and training relating to animal research and the species and techniques used in this project |  | |
| Position on this project  (e.g. Associate Investigator) |  | |
| Has the proposed person had any AEC approval withdrawn or been suspended from working with animals for any period?  If yes, please provide details including Animal Research Authority number | Yes  No | |
| Give details of specific duties or tasks the person will be involved with or responsible for |  | |
| Telephone |  | |
| Email |  | |
| Declaration for new person:  I confirm that I have read the project application nominated above and agree to comply with the procedures described and any conditions imposed by the Animal Ethics Committee. I have read the Australian Code for the Care and Use of Animals for Scientific Purposes (NHMRC 8th Ed. 2013) and the NSW Animal Research Act 1985 and NSW Animal Research Regulation 2010 and agree to work within the requirements of these documents. | | *Name:* |
| *Signature:* |
| *Date:* |
| Declaration of Principal investigator:  I certify that the use of animals in this project will conform to the Australian Code for the Care and Use of Animals for Scientific Purposes (NHMRC 8th Ed. 2013) and the NSW legislation. I accept responsibility for the conduct of all procedures detailed in the approved application, and for the supervision of all personnel delegated to perform any such procedures. | | *Name:* |
| *Signature:* |
| *Date:* |

*(Please copy and paste additional boxes if more than one new person is to be added)*

If there is no further amendment requests please proceed to section **4**.

**3. CHANGES TO THE PROJECT**

**3.1** Describe the aims of the project in lay terms. You may insert the aim(s) as written in the original application.

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|  |

**3.2** What part(s) of the approved project do you wish to amend?

*e.g. location of research, number and/or species of animal(s), experimental design, techniques or procedure, administration of substance, animal husbandry or housing, duration of project*

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**3.3** Please describe the proposed amendment **in lay terms**. How will the proposed action(s) differ from that already approved in the original project?

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**3.4** What is the anticipated positive and negative impact of the amendment on the animal(s), including all possible/potential risks to animal welfare? Describe how any potential negative impacts will be minimised**.**

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**3.5** Justify why the proposed amendment is necessary to meet the aims of the project.

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**4. PRINCIPAL INVESTIGATOR SIGNATURE**

|  |  |
| --- | --- |
| Principal Investigator (printed) |  |
| Principal Investigator (signature) |  |
| Date |  |

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Disclaimer: The information contained in this publication is based on knowledge and understanding at the time of writing (March 2018). However, because of advances in knowledge, users are reminded of the need to ensure that information upon which they rely is up to date and to check currency of the information with the appropriate officer of the Department of Primary Industries or the user’s independent adviser.

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