Guidelines for Animal Care and Use in Teaching and Research

Registration Number 019

Griffith University Office for Research
Bray Centre N54 Griffith University
Nathan campus 4111
Phone (07) 555 27800
e-mail: animal-ethics@griffith.edu.au
http://www.griffith.edu.au/research/research-services/research-ethics-integrity/animal

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If any of the information contained within these guidelines appears out of date please contact animal-ethics@griffith.edu.au.

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1.0 Introduction

The mission of Griffith University is to engage in outstanding scholarship that makes a major contribution to society and to produce ground breaking research. Some activities conducted at Griffith University necessitate the use of live animals and Griffith University recognises that the use of animals for teaching and research is fundamental to biology, medicine and science. Griffith University is committed to the humane and justifiable use of animals for teaching and research and recognises that laboratory animals are sentient creatures and their use is a privilege accompanied by moral and legal obligations for their humane care. Griffith University is registered to use animals under the Queensland Animal Care and Protection Act 2001 (the Act) and complies with the Australian Code for the Care and Use of Animals for Scientific Purposes (the Code). The Queensland Department of Agriculture and Fisheries monitors animal use and compliance and reviews registrations every four years.

Staff and students who plan to 'use' live 'animals' or 'animal' tissues 'for a scientific purpose' must study the Code and submit proposals to the Animal Ethics Committee (AEC). Staff and students who plan to carry out an activity that falls outside the scope of the Code (activities that involve the use of animal tissues where the animal was not killed for scientific purposes and/or use of animals that aren't animals under the Act and/or use of animals for a non-scientific purpose and/or non-use of animals (observations only)) are encouraged to check whether their project requires animal ethics approval by answering the initial questions presented in the RIMS Questionnaire tab. Further information on this process is available at: https://www2.griffith.edu.au/research/research-services/research-ethics-integrity/animal/animal-ethics-applications.

The Code is reviewed regularly under the stewardship of the National Health and Medical Research Council. Compliance with the Code articulates with the Queensland biotechnology code of ethics and related NHMRC research codes and guidelines (e.g. Australian Code for the responsible conduct of research, 2018).

The following guidelines and policy documents should also be referred to by applicants where applicable to support Section 3 of the Code.

- NHMRC Best practice methodology in the use of animals for scientific purposes (2017)
- Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008)
- A Guide to the Care and Use of Australian Native Mammals in research and teaching
- Principals and Guidelines for the Care and Use of Non-Human Primates for Scientific Purposes
- ANZCCART Euthanasia of Animals Used for Scientific Purposes (2001) (currently under revision)
- The Australian Animal Research Review Panel Polices and Guidelines
- ARRIVE Guidelines (Animals in Research: Reporting *In Vivo* Experiments)

- PREPARE (Planning Research and Experimental Procedures on Animals: Recommendations for Excellence) Guidelines
- ANZCCART Ethical guidelines for students in laboratory classes using animals or animal tissues

The AEC considers applications and may approve projects for up to three years. Approved projects will comply with the Code and AEC-approved policies and procedures adopted by the University. Applicants must comply with these procedures when undertaking research or teaching that involves animals or animal tissues.

2.0 Definitions

Activity[1]: any action or group of actions undertaken that involves the care and use of animals, including acquisition, transport, breeding, housing and husbandry of those animals. An activity may involve one or more procedures. Activities are described in an application to the animal ethics committee. See also 'Project'.

Adverse event[1]: any event that has a negative impact on the wellbeing of an animal. See also 'Unexpected adverse event'

Animal[2]: under the Queensland Animal Care and Protection Act 2001 (ACPA) a legally defined animal is:

- any live vertebrate (this includes amphibians, birds, fish, mammals (other than humans), reptiles;
- live prenatal or prehatched creatures in the last half of gestation or development, including mammalian or reptilian foetuses, prehatched avian, mammalian or reptilian young (eggs)
- live marsupial young;
- a live invertebrate creature of a species, or a stage of the life cycle of a species, from the class Cephalopoda (e.g. octopus, squid, nautilus, cuttlefish);
- livestock, companion animals, laboratory animals, wildlife, pests, feral animals and zoo animals.

The following are not considered legally defined animals under the ACPA:

- humans including human foetus;
- the eggs, spat or spawn of fish;
- a pre-natal, larval or pre-hatched creature, other than those mentioned above;
- another immature form of a creature, other than those mentioned above immature amphibians and fish prior to final metamorphosis (e.g. fish fry and tadpoles).

Animal welfare[1]: an animal's quality of life, which encompasses the diverse ways an animal may perceive and respond to their circumstances, ranging from a positive state of wellbeing to a negative state of distress.

Animal wellbeing[1]: an animal is in a positive mental state and is able to achieve successful biological function, to have positive experiences, to express innate behaviours, and to respond to and cope with potentially adverse conditions. Animal wellbeing may be assessed by physiological and behavioural measures of an animal's physical and psychological health

[1] *Australian Code for the Care and Use of Animals for Scientific Purposes* (8th Edition 2013)
[2] Queensland *Animal Care and Protection Act 2001*

and of the animal's capacity to cope with stressors, and species-specific behaviours in response to social and environmental conditions.

Biological product[1]: any product derived from animals, including blood products, vaccines, antisera, semen, antibodies and cell lines.

Code: Australian Code for the Care and Use of Animal for Scientific Purposes (8th Edition 2013).

Competent[1]: the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and skill to new situations and environments.

Compliance[1]: acting in accordance with the Code.

Conflict of interest[1]: a situation in which a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations, or where an institution's interests or responsibilities have the potential to influence the carrying out of its obligations.

Euthanasia: the humane killing of an animal, in the interests of its own welfare, to alleviate pain and distress. See also humane killing. The key difference between humane killing and euthanasia is the reason that the animal is being killed.

Facility[1]: any place where animals are kept, held or housed, including yards, paddocks, tanks, ponds, buildings, cages, pens and containers.

Genetically Modified Organism: The Gene Technology Act 2000 defines a GMO as:

> (a) an organism that has been modified by gene technology; or
> (b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
> (c) anything declared by the Gene Technology Regulations to be a genetically modified organism, or that belongs to a class or things declared by the Regulations to be genetically modified organisms; but does not include:
>
> - a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
> - an organism declared by the Regulations not to be a genetically modified organism, or that belongs to a class of organism declared by the Regulations not to be genetically modified organisms.

Guideline: any document that aims to streamline a particular process.

Humane killing[1]: the act of inducing death using a method appropriate to the species that results in a rapid loss of consciousness without recovery and minimum pain and/or distress

to the animal. See also euthanasia. The key difference between humane killing and euthanasia is the reason that the animal is being killed.

Investigator[1]: any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys.

Legislation (or Act): Laws made by Parliament which are referred to as Acts.

Livestock[1]: animals used in agriculture and aquaculture.

Monitoring[1]: measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the Code. Monitoring occurs at different levels (including those of investigators, animal carers and animal ethics committees).

On-site animal facility: animal holding facility at a Griffith University campus.

Pain[1]: an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress, and modify species-specific traits of behaviour, including social behaviour.

Project[1]: an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose.

Proposal: a written application to carry out a project for consideration by an AEC.

Responsible Investigator: Griffith University Academic or Staff member, listed as the Responsible Investigator on the protocol with responsibility for all aspects of the project (even if a student conducts the work).

Scientific purposes[1]: all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

Teacher[1]: any person in charge of a teaching activity.

Teaching activity[1]: any action or group of actions undertaken with the aim of achieving a scientific purpose, where the scientific purpose is imparting or demonstrating knowledge or techniques to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements.

Unexpected adverse event[1]: 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 (e.g. during surgery or anaesthesia, or after a procedure or treatment)
- adverse effects following a procedure or treatment that were 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 predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals**.**

Wildlife[1]: free-living animals of native or introduced species, including those that are captive bred and those captured from free-living populations.

3.0 Applicability and goals

Federal, State and Griffith University Regulations, Codes, Policies and Guidelines for Animal Care and Use in Teaching and Research apply to all activities that:

- are carried out by any employee, student or agent of Griffith University involving the use, collection or taking of animals regardless of the location of the use (Griffith University's property or facilities, those of another institution or in the field).
- include the active observation or filming of animals.
- include the use of animal tissues (where the animal was killed for a scientific purpose).

The goal of these Guidelines is to ensure the humane care and use of animals. These Guidelines are intended to provide information to assist researchers, teachers, the Griffith University Animal Ethics Committee, animal care staff, veterinarians and other stakeholders in ensuring the implementation of effective animal care and use based on humane care.

3.1 Activities that are out of scope of the code

Staff and students who plan to carry out an activity that falls outside the scope of the code (activities that involve the use of animal tissues and/or use of animals that aren't animals under the Act and/or use of animals for a non-scientific purpose and/or non-use of animals (observations only)) are encouraged to check whether their project requires animal ethics approval by answering the initial questions presented in the RIMS Questionnaire tab. Further information on this process is available on the animal ethics webpage.

Activities that fall outside of the scope of the Australian code for the care and use of animals for scientific purposes may however fall under a number of the following codes and acts:

- Australian Code for the Responsible Conduct of Research (2018)
- Griffith University Responsible Conduct of Research Policy
- Queensland Animal Care and Protection Act 2001
- Nature Conservation Act 1992
- Biosecurity Act 2014
- Commonwealth Gene Technology legislation

Activities that fall outside the scope of the Code include:

- the use of animal tissues from a dead animal (e.g. cadavers, tissue samples, bones, fluids, excreta) where the animal was not killed for the collection of these tissues,
- the use of animals that are not legally defined animals (e.g. flies or other insects for scientific research),
- where the work with animals is conducted for a non-scientific purposes (e.g. wildlife displays at schools or livestock displays at agricultural shows, animal display at a birthday party, guide dogs being used to raise funds, fish tagging, bird banding and

diagnosis by a veterinarian within routine veterinary practice, or biosecurity inspectors undertaking a disease response), or

- where an activity does not involve the USE of an animal (e.g. observing visually, not including spotlighting, eg. bird watching and whale watching from a public beach using the naked eye or binoculars).

If your animal use is not outside the scope of the Code the submission of an animal ethics application is essential.

How is a 'use' of an animal defined?

The following activities are examples of an animal use and requires approval by the Animal Ethics Committee:

- Conducting an activity for scientific purposes in which a person causes or permits an animal to be acquired, bred, cared for, disposed of or otherwise used;
- Spotlighting or using light sources more powerful than a domestic torch for the purposes of visual observation to collect scientific data (as opposed to hunting);
- Trapping of animals (Elliot, pitfall, cage traps, nets etc);
- Using call playback to stimulate responses by animals;
- Using hair tubes to detect presence of animals;
- Identifying animals by means of marking or placing on or in the animal any form of identifying mark or object, e.g. includes paint or other external marker, microchipping, trimming hair, banding and tagging, toe clipping, ear punching;
- Disrupting habitat abnormally, e.g. turning over logs, entering or remaining in places that people do not normally access such as virgin forest, protected ecosystems, bird rookeries, collecting animals signs (scats, feathers);
- Conducting reptile and amphibian surveys where lizards and frogs are caught by hand, examined and released;
- Excess mice from the Animal Facility that are normally killed by CO_2 asphyxiation are transported to another facility or killed by another method or by a different person so that samples can be taken (how they are killed or by whom is different);
- Animals killed specifically for teaching or demonstration purposes (would not otherwise have been killed at that time);
- Collection of samples from animals killed during a pest animal control program that was modified to ensure certain types of animals would be sampled or that samples were taken at a particular time of year (which animals were killed or when is different).

The following activities are not considered a use of animals, but only if these activities do not involve the abnormal disruption of habitat:

- Observing visually, not including spotlighting, e.g. bird watching and whale watching from a public beach using the naked eye or binoculars;
- Recording observations, note taking;
- Making photographic, sound or digital recordings;
- Collecting faeces (scats) and shed feathers. This activity however may be a breach of the Nature Conservation Act 1992;
- Searching for and recording animal tracks;
- Recording animal tracks through the use of shallow sand pans;
- Causing no abnormal disruption of habitat e.g. walking, remaining or driving in places to which people typically have that type of access, such as public or national parks, tracks, roadsides and farmland.

If your proposed work will do one or more of the following, approval from the Animal Ethics Committee is required:

- causes or permits an animal to be acquired, bred, cared for, experimented on, disposed of or otherwise used;
- marking or placing on or in the animal any form of identifying mark or object, e.g. includes paint or other external marker, microchipping, trimming hair, banding and tagging, toe clipping, ear punching;
- spotlighting or using light sources more powerful than a domestic torch for the purposes of visual observation to collect scientific data (as opposed to hunting);
- changing the treatment of the animal;
- trapping of animals (Elliot, pitfall, cage traps, nets etc) handling the animal;
- using call playback to stimulate responses by animals;
- using hair tubes to detect presence of animals;
- conducting reptile and amphibian surveys where lizards and frogs are caught by hand, examined and released;
- collecting animal tissue directly from the animal;
- requesting another person to obtain animal tissues on your behalf;
- euthanasia;
- changing the timing, manner, or location of euthanasia;
- disrupting habitat abnormally, e.g. turning over logs, entering or remaining in places that people do not normally access such as virgin forest, protected ecosystems, bird rookeries, collecting animals signs (scats, feathers);
- any other way that will affect the animal's life or its death.

4.0 Griffith University Animal Ethics Committee

An animal ethics committee (AEC) is a committee constituted in accordance with the terms of reference and membership requirements specified in the Australian Code for the Care and Use of Animals for Scientific Purposes. Each AEC operates independently according to the Code with volunteer community members, staff of the host organisation and a Constitution. The Griffith University Animal Ethics Committee is made up of at least one member from each of the following categories:

(i) Category A—a veterinary surgeon with experience relevant to the institution's activities.

(ii) Category B—a scientist with substantial recent experience in the use of animals for scientific purposes relevant to the institution and the business of the Committee.

(iii) Category C—a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution.

(iv) Category D—a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education.

The Griffith Biosciences Resources Facility Manager is also a member of the Griffith University AEC and the University may also appoint additional members with skills and background (e.g. in ethics or statistics) of value to the Committee as per Clauses 2.2.5 - 2.2.7 of the Code to assist the Committee to function effectively.

Animal Ethics Committees assess and monitor the use of animals for scientific purposes including research and teaching. They also monitor approved projects to safeguard the welfare of the animals involved.

An AEC assesses proposals by weighing the predicted scientific or educational value of the use against the potential impact on the welfare of the animals. The AEC must be satisfied that the use is essential and justified and conforms to the requirements of the Code. An essential component of this assessment by the AEC involves consideration of the steps taken to comply with the principles of the 3 Rs (replacement, reduction and refinement). Only those activities that conform to all relevant sections of the Code and legislation may be approved.

All new proposals and renewal of existing projects must be assessed at quorate meetings of the AEC. Investigators must not start a scientific or teaching activity involving the use of animals before written approval is gained from the AEC. Griffith University personnel located within other institutions also require approval from Griffith University's AEC as well as the ethics committee of the other institution(s). If a project is to be conducted at another

organisation, or jointly, approval must be gained from both AECs before any animal work may commence. If the research involves the use of animals interstate or overseas there may be a requirement for additional state licensing to be undertaken by Griffith University. Animal ethics approval from Griffith University does not allow research to be conducted in other Australian States unless appropriate State licences are obtained or approval is granted by an interstate ethics committee. The AEC must be notified if any staff or student research or teaching involving animals is proposed in other countries and obtain advice.

The AEC also assesses and regularly reviews written procedures for the management of animal facilities. The AEC must be satisfied that the procedures meet the health and welfare requirements of the species, the scientific or educational requirements of the activities being conducted, and the health and safety of personnel.

The AEC carries out the following monitoring activities:

- inspecting animal housing and laboratories at least annually
- Monitoring field sites through provision of video/DVD/photographic evidence of sites and through delegation of inspection to site managers or other persons
- examining records maintained by investigators, teachers and animal facility managers
- investigating any unexpected, adverse events that may impact on the wellbeing of an animal
- inspecting at an early stage any project likely to cause animals pain or distress
- ensuring activities that are not compliant with the Code cease immediately and remedial action is taken
- authorising a person to respond to emergencies in the absence of the investigator or teacher
- reviewing the annual reports and completion reports submitted to AEC by investigators and teachers

The Griffith University AEC meets during semesters (10 times annually).

5.0 Animal ethics and welfare personnel

Animal ethics and welfare personnel assists Griffith University Animal Ethics Committee and Investigators with all phases of the application for the use of animals for scientific purposes in research and teaching. In this effort, the animal ethics and welfare personnel maintains and promotes a cooperative and open relationship among Investigators, Institutional officials and Government officials. Members of the animal ethics and welfare personnel provide technical support, consultation and training to Griffith University Investigators and assists Responsible Investigators in the drafting of Animal Ethics applications. The Griffith Biosciences Resources Facility Manager oversees Griffith University Animal Facilities to ensure compliance with federal, state and Griffith University standards. Animal ethics and welfare personnel also

provides information sessions in animal care and use and the relevant legislations and administers training for animal users.

5.1 Animal ethics and welfare personnel contacts:

The Animal Ethics Committee Secretary and support staff within the Office for Research can be contacted at: animal-ethics@griffith.edu.au

Griffith Biosciences Resources Facility staff can be contacted at animalfacility@griffith.edu.au.

6.0 Application and review process

6.1 Who requires animal ethics approval?

Any Griffith University staff member or student who wishes to use legally defined **animals** or tissue at Griffith University, at another institution or in the field, for scientific purposes is required to obtain written animal ethics approval prior to any acquirement, breeding or use of animals. No animal may be held, bred or used for any scientific purpose until written approval has been obtained from the AEC.

Griffith University personnel located within other institutions also require approval from Griffith University's AEC as well as the animal ethics committee of the other institution(s). If the research involves the use of animals interstate or overseas there may be a requirement for additional state licensing to be undertaken by Griffith University.

If after reading 3.1 of these guidelines you have determined that your planned activity falls outside the scope of the Code (and your activity will involve the use of animal tissues and/or use of animals that aren't animals under the Act and/or use of animals for a non-scientific purpose and/or non-use of animals (observations only)) you are encouraged to check whether the project does not require animal ethics approval by answering the initial questions presented in the RIMS Questionnaire tab. Further information on this process is available on the animal ethics webpage.

6.2 Planning the activity and future publication

The Code requires the use of animals for scientific purposes to have scientific or educational merit; must aim to benefit humans, animals or the environment; and must be conducted with integrity. When animals are used, the number of animals involved must be minimised, the wellbeing of the animals must be supported, and harm, including pain and distress, must be avoided or minimised. The Code encompasses all aspects of the care and use of animals when the aim is to acquire, develop or demonstrate knowledge or techniques in any area of science. The Code applies throughout the animal's involvement in activities and projects, including acquisition, transport, breeding, housing, husbandry, the use of the animal in a project, and

the provisions for the animal at the completion of their use. The code applies to the care and use of all live non-human vertebrates and cephalopods.

The Code outlines governing principles to guide decisions and actions of all people involved in the care and use of animals for scientific purposes. The principles of Replacement, Reduction and Refinement (known as the 3Rs) aim to reduce the impact of scientific activities on animal wellbeing by:

- **Replacement[3]:** Methods that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented. Before the use of animals is considered, all existing information relevant to the proposed aim(s), including existing databases, must be examined. Replacement techniques that must be considered include the use of epidemiological data; physical and chemical analysis; computer, mathematical and inanimate synthetic models; simulations; in vitro systems; non-sentient organisms; cadavers; and clinical cases. Opportunities to replace the use of animals must be kept under review during the lifetime of a project. Where relevant and applicable, the outcome of this review must be implemented in current projects and taken into account in planning future projects.
- **Reduction[3]:** The number of animals used in a project must be the minimum necessary to achieve the proposed aim(s) and to satisfy good statistical design. The use of too few animals may invalidate the experimental result and result in wastage of animals. The number of animals used may be reduced by the appropriate reuse of individual animals. The benefits of reusing animals must be balanced against any adverse effects on their wellbeing, taking into account the lifetime experience of the individual animal. Reuse of animals requires particular justification and specific AEC approval. Activities involving the use of animals must not be repeated within a project or between projects unless such repetition is essential for the purpose or design of the project (e.g. sound experimental design, statistical analysis, corroboration by the same or another investigator). Reducing the number of animals used should not result in greater harm, including pain and distress, to the animals used. All possible steps must be taken to reduce factors that are not part of the experimental design of the project and are known to contribute to variability of experimental results, including the use of animals of known genetic, biological and behavioural background. Reduction of experimental variables may result in reduced animal use. Where practicable, tissue and other biological material from animals being killed must be shared among investigators or deposited in a tissue bank for subsequent distribution. Breeding of animals must be managed to avoid or minimise the production of excess animals. A new line of animal should not be generated if a similar suitable animal line is available to the investigator. When a new animal line is generated, the colony should be made available as a source for other investigators, as appropriate.

- **Refinement**[3]: Steps must be taken at all times to support and safeguard animal wellbeing. The effectiveness of strategies for supporting and safeguarding animal wellbeing must be kept under review during the lifetime of activities, including projects. Where relevant and applicable, the outcome of this review must be implemented in current activities and taken into account in planning future activities, including projects. People who care for and use animals must ensure that procedures are performed competently, and

  (i) be competent for the procedure they perform, or

  (ii) be under the direct supervision of a person who is competent to perform the procedure.

  The duration of activities must be no longer than required to meet the aim(s) of the project, and must be compatible with supporting and safeguarding animal wellbeing. Animals must not be held for prolonged periods as part of an approved project before their use, without AEC approval.

In addition to the 3Rs, other key principles include only using animals when it is justified, knowing and accepting ones responsibilities, supporting the wellbeing of animals involved, avoiding or minimising harm, including pain and distress to those animals and applying high standards of scientific integrity.

Investigators should also use the information provided in the NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008) when planning their projects. The Guidelines are divided into three parts.

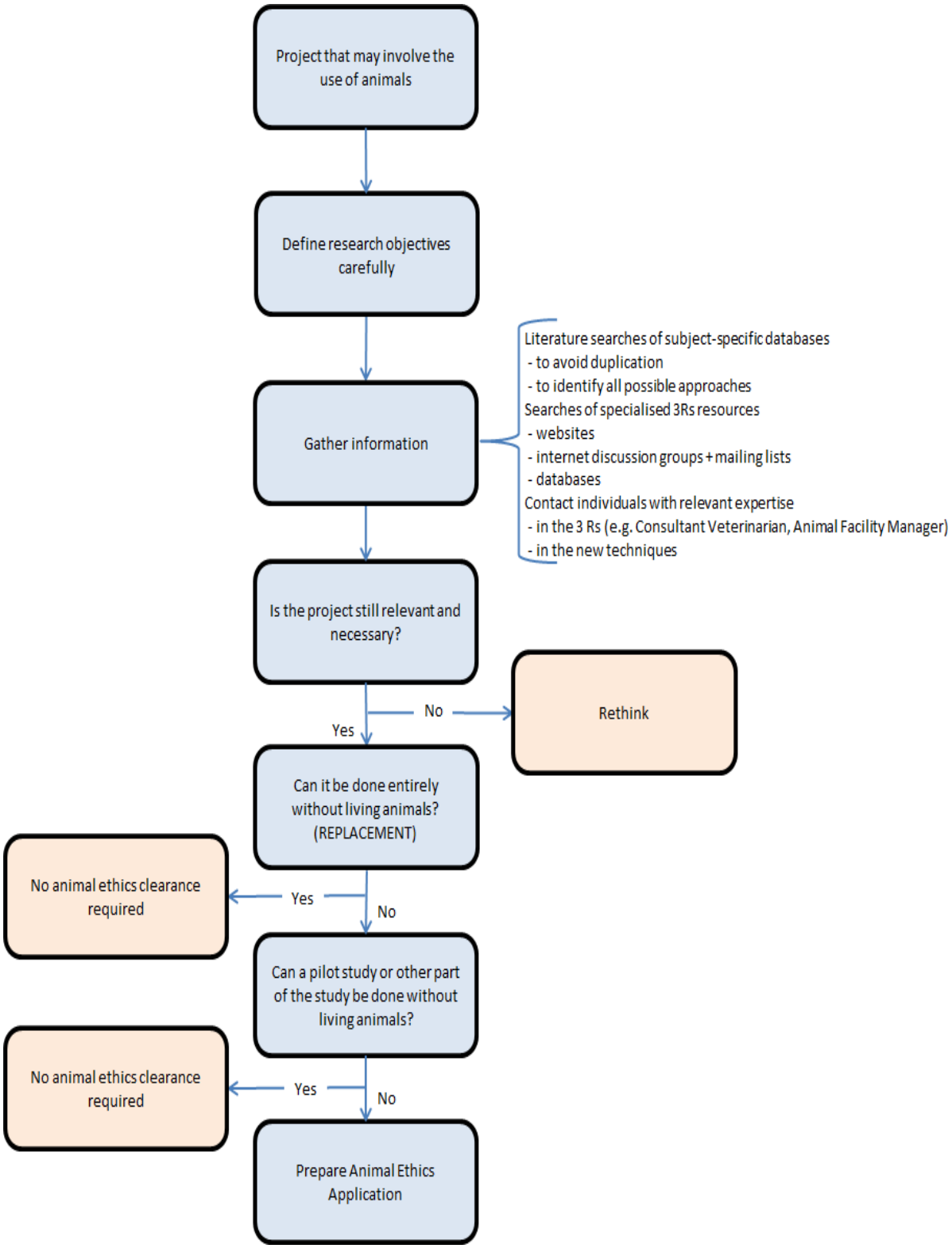
- Part I – Background material to assist understanding and awareness of animal wellbeing and how it relates to scientific activities.
- Part II – Basic strategies for
  - planning research protocols to identify the risk of animal pain and distress
  - conducting research to manage the risk of animal pain and distress
  - reviewing research protocols to minimise animal pain and distress in future research
- Part III provides factsheets on issues to consider for specific research protocols. They have been developed with the aim of providing guidance to investigators, rather than being prescriptive

Animal users are strongly encouraged to seek assistance from an Animal Ethics Advisor and/or the Griffith Biosciences Resources Facility Manager during the planning stages of animal activities.

[3] Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition 2013)

A useful external resource designed to assist researchers in planning of animal experiments is the NC3Rs Experimental Design Assistant. This free resource can be assed at: https://eda.nc3rs.org.uk/.

Flowchart 1: Early planning for a project that may involve the use of animals



Source: Adapted from *Focus on Alternatives* http://focusonalternatives.org.uk/

The ARRIVE Guidelines (Animals in Research: Reporting *In Vivo* Experiments) were introduced in 2010 and many journals now require that authors and reviewers use these guidelines when submitting and reviewing reports of animal-based research. The guidelines provide a detailed checklist of elements that should be included in any reporting of animal research, such as information about animal strain and sex, appropriate statistical calculations and disclosure of adverse events. A copy of the ARRIVE Guidelines Checklist is included in Appendix 1.

6.3 Application

Prior to any acquisition or use of animals, Investigators must receive animal ethics approval from the Animal Ethics Committee. Approval may be granted after the submission of a Field or Lab Based Application, or in cases where another AEC is the Primary AEC, a Prior Review Application in RIMS. Every aspect of animal care and use must be described within the application. Application guidelines and other resources can be accessed on the animal ethics webpage.

Before completing an application, Investigators should be familiar with the following as applicable:

- Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition (the Code)
- Queensland Animal Care and Protection Act 2001
- Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008)
- NHMRC Best practice methodology in the use of animals for scientific purposes 2017.
- ANZCCART Ethical guidelines for students in laboratory classes using animals or animal tissues
- Principals and guidelines for the care and use of non-human primates for Scientific Purposes
- ANZCCART Euthanasia of Animals Used for Scientific Purposes (2001) (currently under revision)

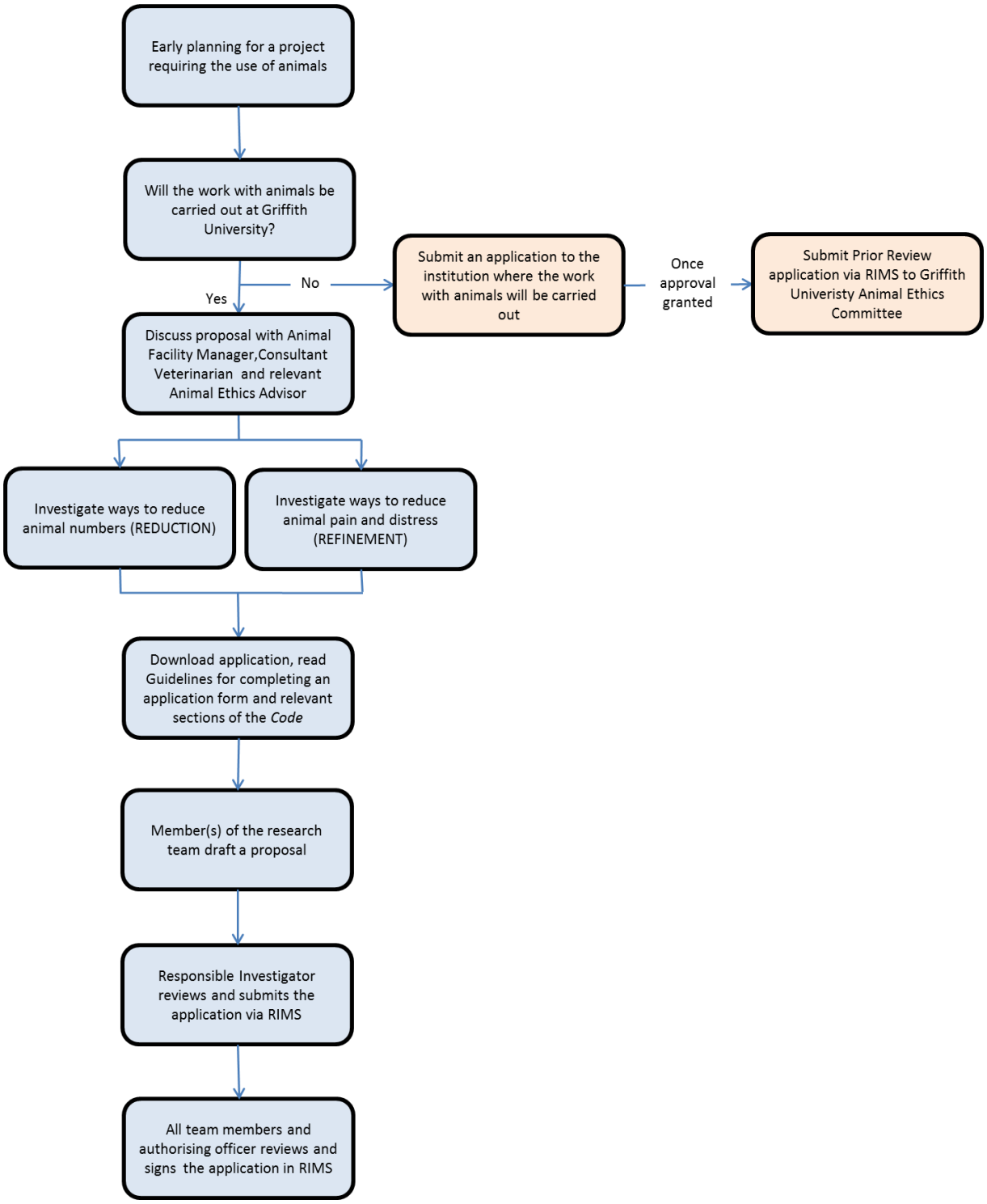
IMPORTANT: Before completing your application, please read the Guidelines for Completing an Application Form, review the questions and consult with an Animal Ethics Advisor.

Submission deadlines are provided online. Applications submitted after the submission deadline will be considered at the following AEC meeting.

Applications should be completed in RIMS and signed off by all investigators and relevant authorising officers before they are considered by the Animal Ethics Committee. Any Investigators on the team who are external to Griffith sign off on the application by using an External Researchers Declaration. Ensure to upload all the necessary documents to the Documents Tab for the Committee's reading. For example, the protocol, Team Member Table,

score sheet, copies of permits, External Researchers Declaration, any essential papers and any approvals from other AECs.

Flowchart 2: Animal Ethics application preparation



6.4 Animal Ethics Committee review process

Field or Lab Based applications

Following receipt of a completed and fully signed application a protocol number is assigned and the application is placed on the agenda for the next AEC meeting. The application is reviewed by the AEC in a quorate meeting and investigators may be interviewed as part of this process. The AEC may make any of the following decisions:

- Approved
- Conditional Approval: work may commence in accordance with the specified conditions
- Provisional Approval (minor revisions requested): revisions to be considered by the Chair of the AEC
- Provisional Approval (minor revisions requested): revisions to be considered by the Executive Committee of the AEC
- Modifications requested and resubmission required to a subsequent meeting
- Rejected

Investigators are notified in writing of the AEC's decision as soon as practical after the meeting.

Note: The acquirement, breeding or use of animals may not commence until an official notification has been issued by the Animal Ethics Committee.

The AEC may also approve applications at a quorate meeting as per 2.1.5 (v) (e) "in advance, for the immediate use of animals, if required, for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people.

More detail of these procedures are described in the AEC Standard Operating Procedures available on the Animal Ethics Committee webpage.

Prior Review applications

As research is often performed collaboratively across institutions, the Griffith University Animal Ethics Committee (AEC) regularly considers applications approved by other AECs. It is a requirement of the Code that investigators notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution (see Clause 2.4.9 and 2.6.8 of the Code).

Following receipt of a completed Prior Review application a protocol number is assigned and the application is forwarded to the AEC Executive for ratification between scheduled meetings. The AEC Executive may:

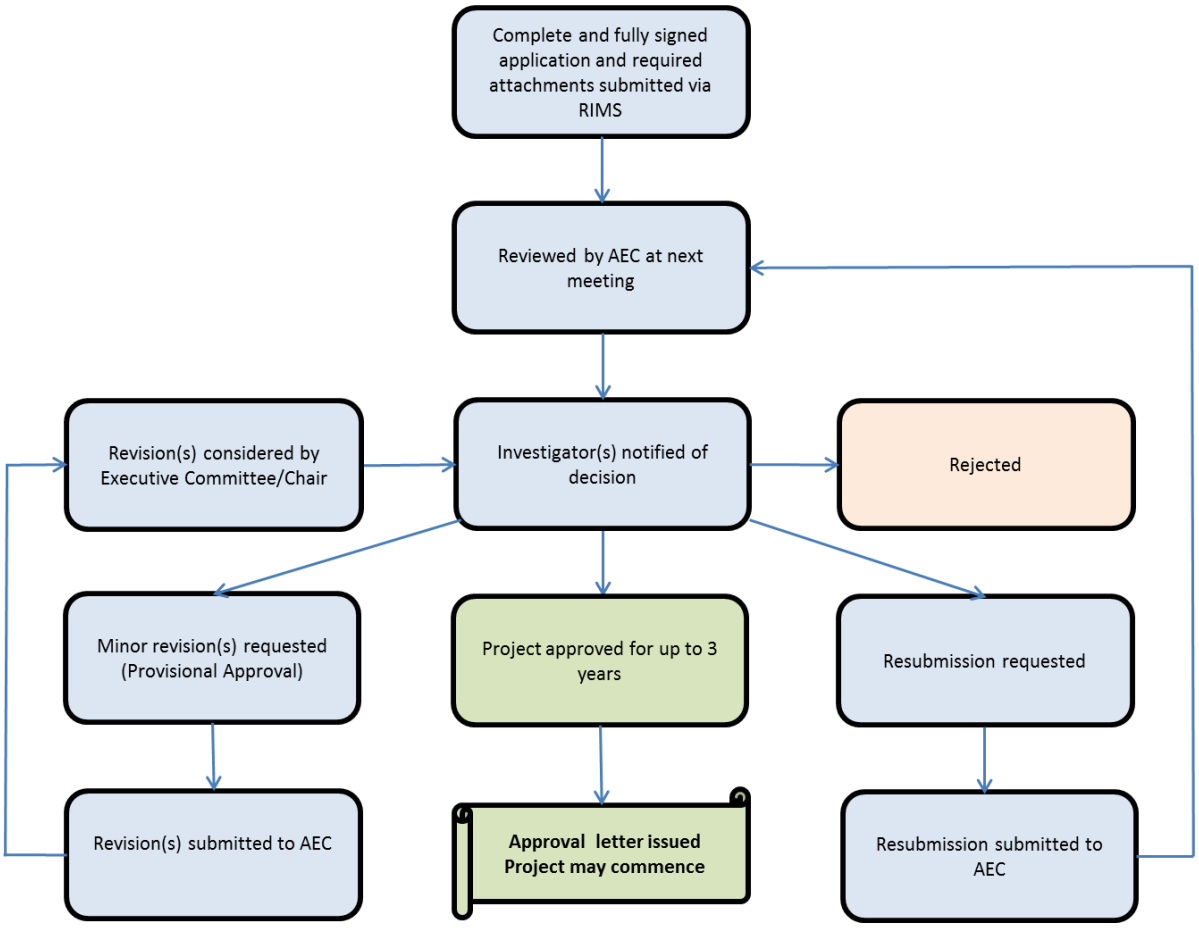
a) ratify the approval of the Primary AEC, or

b) refer the application to the full Animal Ethics Committee at the next scheduled AEC meeting.

The AEC Executive or AEC may ask the applicants to provide further information. If the Executive or full AEC has significant concerns or questions, these will be raised with the researcher and/or the primary AEC.

More detail of these procedures are described in the Ratification of projects approved by other Animal Ethics Committees policy document available at the animal ethics webpage.

Flowchart 3: Animal Ethics Committee Review Process



6.5 Approval

The animal ethics approval letter specifies the duration of the approval. Approvals are normally issued for a period of three years. An extension of approval for a further year beyond the initial expiry date can be considered by the Animal Ethics Committee after the submission of a variation request and progress report. Extensions beyond this must be submitted as a new application. For more information about extending an approval refer to the animal ethics webpage.

The Animal Ethics Approval, Conditional Approval or Provisional Approval Notification Fact sheet, attached to outcome notification emails provides further information regarding the animal ethics approval process.

7.0 Appeals process

Booklet 01 of the Animal Ethics Manual outlines processes for responding to complaints, alleged breaches of ethical standards, or appeals against decisions. This booklet is available on the Research integrity webpage.

Any Chief or Responsible Investigator wishing to appeal an AEC decision can do so in writing to the AEC Secretary (animal-ethics@griffith.edu.au). The AEC Secretary will include the appeal to the next scheduled AEC meeting where the AEC will review the appeal. The AEC Chair will inform the Investigator in writing of the outcome of the AEC review of the appeal. In cases where complaints concerning the AEC process of review (of an application or report) cannot be resolved by communication between the complainant and the AEC, complainants can contact the Manager, Research Ethics and Integrity for review of the process followed by the AEC. The AEC may need to review its process in reaching its decision and re-evaluate its decision in light of the reviewed process, however the ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden as per 5.6 of the Code. If a complaint has not been resolved by the processes outlined above, a complaint can be taken to an external individual or agency for an independent external review. An appropriate external review body will be arranged by Griffith University based upon the specifics of the research methodology, context and complaint.

8.0 Variations to projects

The submission of an application variation request is required to request approval for changes to an approved project such as: a change of location where the research will be performed, time extension, change of technique or species/strain/breed/age of animals specified in current approved protocols or, to add or remove investigators. Variation requests are submitted via RIMS. For the welfare of both animals and personnel, approved protocols should remain up to date in these respects and progress reports should accompany a variation request. Regular updating of changes in personnel also ensures the whole team remains fully

covered by the University's insurance and indemnity arrangements. Variation requests do not require sign off by investigators or an authorising officer.

Variations that involve significant changes to protocols or include any change to the aims and/or hypothesis of a project require the submission of a new application, regardless of the number of animals being used.

In accordance with section 2.2.23 of the Code, Griffith University has established an Animal Ethics Committee Executive. As specified in the AEC Standard Operating Procedures, the AEC Executive may consider requests for minor variations between scheduled AEC meetings. The power is limited to requests for approval of a minor amendment (variation) to an approved protocol which is not likely to cause harm to animals, including pain and distress, such as a one year extension of an existing approval or changes to project personnel.

Interim decisions made by the AEC Executive in response to such requests are presented for ratification or modification by the Committee at the next scheduled AEC meeting.

The table below provides further guidance and examples regarding Minor and Major variations. The AEC Executive may seek further information, and/or refer any variation request to AEC meeting.

Minor variation (AEC Executive)	**Major Variation (AEC Meeting)**
• Change in personnel (where sufficient information detailing the training and competency of the additional team members has been provided) • A ≥ 12 month extension (only one extension permitted for a project, must submit a progress report) • Change in animal gender or strain (where it has been demonstrated that there will be no impact on animal well-being AND there is no change to the aim(s) or hypothesis(es) of the approved project) • Change in drugs used for pain management (if more effective) • Minor change to clinical score sheet/monitoring forms and/or monitoring regime (if more effective) • Minor change to the schedule of blood collection but without an increase in frequency of collections • Minor change to a non-surgical procedure (if less frequent or less invasive)	• Increase in animal numbers where the number of animals requested is ≤ 10% of the original animal numbers approved • Change in animal strain or species • Change in invasiveness of a non-surgical or surgical procedure • Addition or substitution of a non-surgical or surgical procedure • Major change(s) to clinical score sheet/monitoring forms and/or monitoring regime • Change in test compound or drugs used for pain management (other than effectiveness) • Addition of a new intervention • Change to methods of euthanasia • Change to protocol that does not change the aim(s) or hypothesis(es) of the approved project

• Change to method(s) of euthanasia (if less of an impact on animal well-being)	

9.0 Animal monitoring and record keeping

As per Clause 2.4.32 of the Code Investigators must maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers. Under a particular AEC approval, records must include:

(i) the origin/source of the animals and provisions for the animals at the conclusion of their use,
(ii) the number of animals used,
(iii) details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes,
(iv) the condition of the animal, any adverse impact on animal wellbeing and actions taken as a result,
(v) names of people performing the procedures and entering the records,
(vi) names and contact details of people responsible for monitoring and emergency incidents.

The AEC will advise Investigators of any additional information to be recorded. These records must be available for audit by the AEC.

The Code requires that animals are monitored and assessed:

(i) by a competent person who is knowledgeable about the normal behaviour and signs of pain and distress for the species, or a person under the direct supervision of a competent person
(ii) with sufficient frequency to ensure that any harm, including pain and distress, is promptly detected and managed
(iii) in accordance with the AEC approval for the project or activity.

Methods for monitoring and assessment of animal wellbeing should include:

(i) the criteria that will be used to assess wellbeing
(ii) the level and frequency of monitoring to ensure that any changes in an animal's condition are detected early
(iii) the criteria that will be used to determine when action is required
(iv) actions that will be taken so that adverse impacts on animal wellbeing, including predicted effects and unforeseen complications, are addressed rapidly and effectively
(v) the methods for recording observations, treatments and actions

(vi) flexibility to ensure a rapid and effective response to changes during the course of the project or activity.

Records of the monitoring and assessment of animal wellbeing must be:

(i) sufficient to enable the AEC to verify that the wellbeing of animals has been monitored as agreed, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies
(ii) accessible to all people involved in the care of the animal
(iii) available for audit by the institution, the AEC and authorised external reviewers.

9.1 Animals used in Griffith University Animal Facilities

Animals used in Griffith University Animal Facilities must be logged though the animal management database as all animal tracking, breeding, colony management, genotype and phenotype tracking, reporting and compliance are managed by this software. Training in the use of this software is coordinated and provided by animal facilities staff. Investigators using animal facilities should be familiar with this software and keep all records relating to projects up to date.

9.2 Animals used in the field or satellite facilities

Animals used in the field or in satellite facilities should be recorded through the use of a Fieldwork Animal Monitoring Record. This record must include the information provided on the Fieldwork Animal Monitoring Record Template.

Researchers submitting new protocols for the conduct of fieldwork or for research or teaching involving animals at satellite facilities will be required to submit a template of their proposed monitoring records with their initial application so that the AEC can ensure that the data collected complies with relevant legislation and is in a form that is suitable for collecting and verifying the animal use statistics that the AEC is required to submit to regulators and external auditing bodies.

The AEC may require researchers to take photographs and/or videos showing the capture and handling of research animals in the field. The photographs and/or video are to demonstrate the location and wellbeing of animals, and to illustrate the fieldwork equipment and its use.

10.0 Reports

10.1 Annual Reports

A condition of animal ethics approval is that researchers provide a brief, Annual Report for their projects. All reports are due by 25 January each year and are lodged via RIMS. Reports do not need to be signed off by all investigators or an authorising officer.

The AEC reviews all Annual and Progress Reports provided for protocols approved by the AEC as part of their monitoring activities. Upon considering an Annual or Progress Report, the AEC may decide that the approval of the project is continued, suspended, modified or discontinued (Flowchart 4). If the Committee requires more information on the project's progress before a decision on a Report can be made, the AEC may consult with the Investigator(s) or other persons to obtain further information.

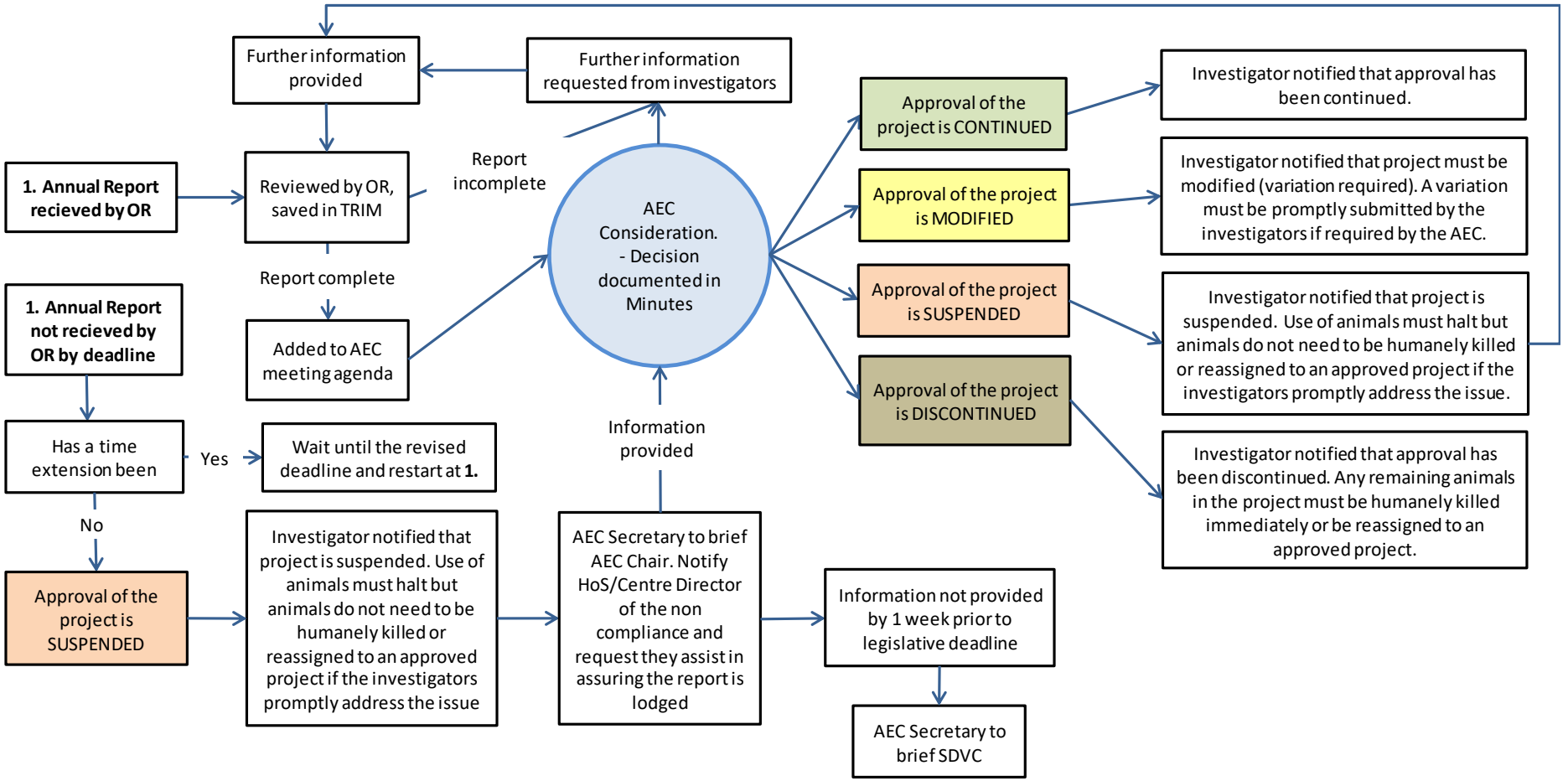
The University uses the information reported to produce the annual Animal Use Statistics Report required by The Queensland Government Department of Agriculture and Fisheries (DAF) as part of requirements under The Animal Care and Protection Act (2001).

Where an Annual Report remains outstanding 1 month after the due date and a time extension has not been granted, the approval of the project will immediately be suspended (use of animals must halt but animals do not need to be humanely killed or reassigned to an approved project if the investigators promptly address the issue). The relevant Head of School, Centre Director or other appropriate person will be notified of the failure of the team to comply with AEC requirements. Should requested reports remain outstanding one week prior to the deadline for submission to the relevant State Regulator, the AEC Secretary will brief the Senior Deputy Vice Chancellor and outline the potentially serious implications of continued non-compliance.

As a result of an unexpected or adverse event being reported for a project, or after the submission of an Annual or Progress Report the AEC may request a further Progress Report, copies of monitoring records and/or other documentation from Investigators regarding a project.

The Code requires that Investigators monitor and assess animals, maintain records of the care and use of animals, and make such records available for audit by the institution, the AEC and authorised external reviewers. Animal monitoring score sheets and other documentation relating to the monitoring of animal management and welfare in research are considered primary materials and are to be stored for at least seven years after the last action is taken on the research project. Please refer to the Griffith University Responsible Conduct of Research Policy for further information regarding the management of research data and primary materials.

Flowchart 4: Annual Report Decision Tree



11.0 Monitoring of approved projects, animals and facilities

The AEC monitors the care and use of animals by inspecting animals, animal housing and the conduct of procedures, as well as by reviewing records and reports.

The Code requires that the AEC monitors all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the AEC (see Clause 2.3.18).

The AEC randomly selects a number of projects each year for audit – this is in addition to the annual self-reporting process. Such audits may either be of specific projects (identified on the basis of the seriousness of the procedures, because of potential concerns raised by other parties) or on the basis of a random selection of active projects. Such random audits will be structured to try to cover a range of research activities from disciplinary areas across the University. An audit will involve a panel of the AEC, meeting with the Investigator or team conducting the protocol. It may involve the observation of procedures, sighting of animal monitoring sheets, or the sighting of other documentation. Alternatively, the audit may involve the AEC requesting that an expert observe a procedure. In cases where animal use is occurring at a remote site, a suitably qualified delegate may be asked to monitor animal care and use and provide a written report which includes still or video images either to the committee at the next meeting or to the Chair before the next AEC meeting.

The Investigator or team conducting the animal research may also be invited to provide feedback on the operation of the University's animal research ethics arrangements and the AEC. The outcome of such audits will be reported to a meeting of the AEC with any recommendations about modifications to, or a suspension of the approval for the protocol, or any policy or procedural issues identified by the audit. The Committee provides an annual report to the institution that will include a summary of the audits conducted in the reporting year.

On-site animal facilities are inspected at least annually by a subset of the AEC and where possible these inspections are combined with scheduled AEC meetings. Where feasible, a Category C or D member will participate in each inspection (see Clause 2.3.20). Off-site animal facilities are also inspected at least annually by a subset of the Animal Ethics Committee or, in cases where the site is remote or accessibility is limited, by a delegate who is suitably qualified to carry out the inspection. In cases where an inspection by a subset of the AEC or a delegate cannot take place, photos of animal facilities will be requested from investigators to allow a remote assessment to be made.

Inspections may be announced or unannounced (see Clause 2.3.21). Due to the availability of animal facility staff, and entry requirements of many animal facilities, the AEC will normally

liaise with the relevant animal facility manager to arrange a facility inspection at least 24 hours before the inspection is scheduled to take place.

With the permission of the relevant animal facilities manager, the Chair and/or Secretary of the AEC, and/or the University's consultant veterinarian, may undertake unannounced inspections of animals and facilities. After an inspection has taken place, a written report will be provided by the inspector either to the Committee at the next meeting or to the Chair before the next AEC meeting. Any issues or problems identified during an inspection must receive appropriate follow-up by the AEC, and if necessary, suspected breaches of the Code will be reported to the University (see Clause 2.3.18).

12.0 Monitoring of the conduct of procedures

The AEC monitors most closely activities that fall into one or more of the categories below:

- procedures performed by Investigators whose competency is unknown
- procedures performed by Investigators who are new to Griffith University
- activities that are likely to cause pain or distress at an early phase during the conduct of the activity, for instance, the study of pain, responses to stressors, models of human and animal diseases, or attempts to change behaviour by physical or chemical means (see Clause 2.3.19)
- procedures performed by Investigators who have reported unexpected or adverse events as a result of the performance of the same or similar procedures.

Monitoring of activities may be carried out by a consultant veterinarian, the relevant animal facilities manager or other suitably qualified and/or experienced delegate and will often be a requirement of the approval granted for a protocol.

Following the monitoring of an activity, a written report will be provided by the monitor either at the next AEC meeting or to the Chair before the next AEC meeting. Any issues or problems identified must receive appropriate follow-up by the AEC, and if necessary, suspected breaches of the Code will be reported to the institution (see Clause 2.3.18).

13.0 Collaborative Research Projects Across Multiple Research Institutions

As research is often performed collaboratively across institutions, the Griffith University Animal Ethics Committee regularly considers applications approved by other AECs. It is a requirement of the Australian Code for the Care and Use of Animals for Scientific Purposes (Code) that investigators notify the AEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the AEC of another institution (see Clause 2.4.9 and 2.6.8 of the Code).

Clause 2.6.4 of the Code requires institutions "ensure that projects involving investigators from more than one institution, or the care and use of animals at more than one institution, are approved and monitored by the responsible AECs. Procedures must be developed and implemented to ensure that:

(i) all parties involved are aware of, and can meet, their respective responsibilities under the requirements of the Code

(ii) a project does not commence before each AEC approves, or the delegate AEC approves (see Clause 2.6.5), activities to be conducted by members of its institution. Each AEC should be responsible for approval and monitoring of animal care and use that occurs at the institution for which it acts

(iii) the responsible AECs are aware of all aspects of the proposed use of animals, and consider the cumulative effects on the wellbeing of the animals involved

(iv) the responsible AECs can inspect the animals so that all phases of the project are monitored, including any animal transport between sites

(v) animals will receive appropriate care in all phases of the project, including any animal transport between sites

(vii) clear communication channels are established between all AECs and all investigators

To meet these requirements, it is highly recommended that a formal collaborative animal research agreement or memorandum of understanding be drafted for each research project involving animal use across multiple institutions.

In general, the AEC of the institution at which the animals are being held will be responsible for monitoring the research at that site. This Institution will provide veterinary advice as appropriate and AEC support. Unless otherwise outlined in a formal agreement, the AEC of the institution at which the animals are being held will take action in the event of a breach of the Act or any other relevant laws and act in the event of breaches regulations, keeping the other Institution fully informed. This may include making a recommendation regarding the withdrawal of the Animal Ethics Approval, and referring the matter to the relevant governing body.

Formal collaborative animal research agreements should outline processes for dealing with concerns and complaints. If any concerns or complaints arise with regards to the conduct of a collaborative research project at a site external to Griffith University, and where there is no formal agreement in place, the process outlined in the Animal Ethics Manual (Processes for responding to complaints, alleged breaches of ethical standards or appeals against decisions) should be followed. Likewise, if a concern or complaint arises relating to work undertaken at Griffith where there is also an external collaborating partner involved in the project, the same process can be initiated. The University has nominated that the standard contact person for

concerns and complaints related to the ethical conduct of animal research is the Animal Ethics Coordinator. The Animal Ethics Coordinator can be contacted by emailing animal-ethics@griffith.edu.au. The Animal Ethics Coordinator will receive and investigate the complaint according to the process outlined in the Animal Ethics Manual, and inform the collaborating AEC.

14.0 Student research

For students, an important source of advice is your supervisor. Supervisors or lecturers are the Chief and Responsible Investigators. Students are named members of the research team, and share responsibility for the ethical conduct of the research, but it is the former who has primary responsibility for the ethical conduct of the research. Supervisors can delegate to students responsibility for submitting reports to the AEC. You must have AEC approval before animal facilities staff can order animals for your laboratory based work.

14.0 Responsibilities of Investigators

Investigators have a number of responsibilities as outlined in Section 2.4 of the Code.

Responsibilities of Investigators include but are not limited to:

- Ensure that records of the animals used for scientific purposes are maintained. These records should allow the tracking of individual animals through the entire project.
- Ensure that animals used for scientific purposes are monitored as outlined in the approved application.
- All deaths or adverse impacts on animal wellbeing must be reported immediately directly to the Griffith Biosciences Resources Facility Manager and to the AEC via an Unexpected Adverse Event report in RIMS.
- The conduct of projects is to be reported each calendar year or at the conclusion of projects using the Report form.
- Use the Variation form to seek AEC approval for changes to project conditions, to extend a project, or to change personnel.
- Provide an annual report for each approved project to the AEC. Failure to do so will result in withdrawal of permission to use animals and suspension of the project. All reports are due by 25 January each year and are submitted via RIMS.

All investigators are responsible for the wellbeing of an animal throughout the period of use of the animal in the approved project, until provisions are made for the animal at the conclusion of their use (see Clause 2.4.1 of the Code). Investigators must ensure that an adequate number of competent people can provide care for the animals (e.g. animal

technicians, investigators). If an investigator acts as an animal carer during this period, their responsibilities include those of an animal carer.

15.0 Responsibilities of Chief Investigators

The University considers the principal supervisor as the Chief Investigator for student research, even if the student holds an academic appointment in their own right. The Chief Investigator must stay abreast of the conduct of projects and offer informed advice on ethical, responsible conduct, and regulatory matters.

16.0 Responsibilities of Responsible Investigators

The Responsible Investigator must be an employee of Griffith University and preferably a person with an academic appointment. Prior to planning or conducting an activity using animals, involved faculty staff and students are expected to be familiar with the relevant regulations and guidelines. Under Queensland law, the Responsible Investigator has ultimate responsibility for the care and use of animals in a project. The Responsible Investigator must:

(i) ensure that all people involved in the project understand and accept their roles and responsibilities

(ii) ensure that procedures and resources are in place so that all people involved in the care and use of animals in the project can meet their responsibilities, including their education, training and supervision, as appropriate

(iii) be competent with respect to the wellbeing of animals used in the project.

This person does not relieve the individual responsibility of each investigator working with animals in the project.

Responsible Investigators must also ensure:

- applications are of an appropriate standard before submission to the AEC
- any matters attached to an approval are resolved promptly
- the project is conducted as approved
- Animal Facilities staff and the AEC are informed when a project changes or new issues arise.

17.0 Monitoring of health and welfare

The Griffith Animal Facilities Procedure – Animal Health Monitoring document outlines the strategies in place to ensure the maintenance of a health status of the animals housed within the Griffith Animal Facilities that safeguards animal wellbeing and meets the requirements of their proposed use.

The Health of animals housed inside Griffith University Animal Facilities is screened every six months by an external laboratory animal monitoring service provider.

18.0 Detection and management of harm, pain and distress

The Griffith Animal Facilities Procedure – Animal Health Monitoring document outlines the monitoring and assessment of animals to ensure that any harm, including pain and distress, is promptly detected and managed.

19.0 Unexpected adverse events

Investigators and animal care staff must immediately notify the Griffith Biosciences Resources Facility Manager and promptly notify (at least within 48 hours) the Animal Ethics Committee of unexpected adverse events which occur that involves the animals under their charge.

The flowchart below (Flowchart 5) shows the steps to follow in the event of an unexpected adverse event inside an animal facility and details what type of reporting to the AEC is required.

A form for the reporting of an unexpected adverse event during the conduct of an approved project can be accessed and lodged via RIMS. In cases where multiple AECs are involved, unexpected adverse events should be reported to each Committee. The AEC will review the report and act in a case by case basis considering the event and the welfare of the animals involved. Under the Code, the AEC can authorise the emergency treatment of euthanasia of any animal.

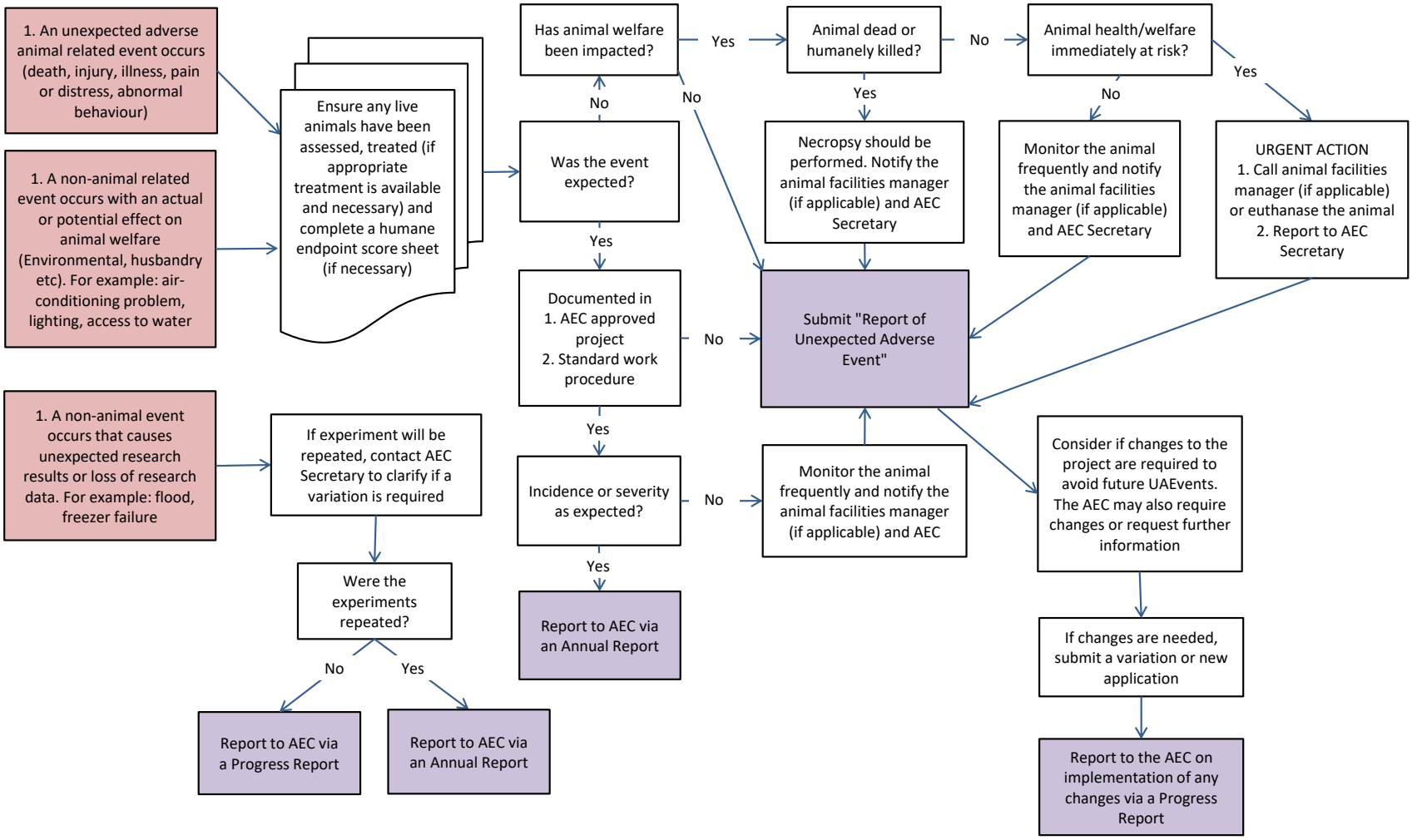
The Code requires investigators to promptly notify the Animal Ethics Committee of any unexpected adverse events (refer to Clauses 2.4.34).

Investigators, Animal Carers and managers of animal facilities should note Clause 3.1.24 of the Code: *"Alleviating unanticipated pain and distress must take precedence over an individual animal reaching the planned endpoint of the project, or the continuation or completion of the project. If necessary, animals must be humanely killed without delay".*

The Code stipulates, *"Animal Carers must: take prompt actions based on the monitoring and assessment of animal wellbeing and in response to unexpected adverse events and emergencies, in accordance with institutional policies and procedures approved by the AEC (see Clauses 2.1.5 [v] [d] and 3.1.23–3.1.25), including liaising with investigators and seeking veterinary advice"* (refer to Clause 2.5.5 [iv]). "*If an emergency welfare intervention is considered necessary for an animal allocated to a project (e.g. treatment or humane killing of an animal), animal carers must take reasonable steps to first contact the responsible investigator. However, the welfare of the animal must be the priority at all times and may necessitate immediate intervention. Animal carers must promptly advise the responsible*

investigator of actions taken and the reasons for emergency interventions. Reporting of the event to the AEC, and responsibility for such reporting, must be in accordance with institutional and AEC policies and procedures (see Clause 2.1.5 [v] [d])" (refer to Clause 2.5.6).

Flowchart 5: Unexpected Adverse Event Decision Tree



In cases where an unexpected adverse event occurs, Investigators have access to an external laboratory animal monitoring service provider for diagnostic investigations. Investigators are advised to arrange the diagnostic investigations through the animal facilities manager.

The Code requires unexpected adverse events relating to animals for which the Griffith Biosciences Resources Facility Manager is responsible, be reported promptly to the AEC in accordance with AEC and institutional policies and procedures. Refer to Clause 2.5.15 [xiv] (b).

In addition, when an animal dies unexpectedly, or is euthanased due to unforeseen complications, a necropsy should be performed by a competent person (Clause 2.1.5 [v] [d] and Clause 3.1.25 of the Code) and the AEC should be notified promptly via the submission of an Unexpected Adverse Event report via RIMS.

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 (e.g. during surgery or anaesthesia, or after a procedure or treatment)
- adverse effects following a procedure or treatment that were 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 predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

The AEC expects a necropsy to be performed if >10% of an experimental group studied is affected by an adverse event and/or more than one animal per treatment in a particular study is affected by an adverse event, unless an alternative arrangement has gained prior approval from the AEC.

As a result of an unexpected adverse event, in order to ensure that animal wellbeing is not compromised and that activities that have the potential to adversely affect animal wellbeing cease immediately, the Chairperson may issue a written notice to the Chief and Responsible Investigator suspending the approval of the activity. Any such suspension must be considered for ratification or modification by the AEC, at the next meeting of the Committee.

19.1 Unexpected adverse events involving material requiring physical containment

The transport of material must comply with the following:

Any guidelines issued by the Regulator for the transport of GMOs (consult with the individual licence to check what conditions apply for the transport of the GMO).

- Gene Technology Act 2000
- Microbiological Risk Groups: AS/NZS 2243.3:2010
- National Health Security Legislation
- Health Act 1937

20.0 Emergency treatment or euthanasia of any animal

Animal facilities staff and consultant veterinarians may carry out the emergency treatment or euthanasia of animals where they reasonably believe this is necessary for the maintenance of animal welfare. In cases of emergency, before an animal is treated or euthanised, all reasonable steps must be taken to consult with the emergency contact person following the procedures outlined in the Animal Facility Procedure – Animal Health Monitoring document. The Chairperson may authorise the emergency treatment or euthanasia of animals, where he or she reasonably believes animal welfare considerations require this, as necessary, for later ratification by the Committee. In cases of emergency, before an animal is treated or euthanised, all reasonable steps must be taken to consult with the emergency contact person. Any treatment or euthanasia must be reported promptly to the emergency contact person and the Committee with reasons for the action taken, and confirmed in writing, as outlined in the Code (See Clause 2.5.6 of the Code).

21.0 Emergencies

In the case of an emergency, such as a fire, flooding, power failure or outage refer to the Griffith University Emergency Management Plan.

In the case of an animal escape, please refer to the appropriate Facility Manual. Hard copies of Facility Manuals are located in each animal facility.

22.0 Animal management

Griffith University Animal Facilities are managed by the Griffith Biosciences Resources Facility Manager. Animal tracking, breeding, colony management, genotype and phenotype tracking, reporting and compliance are managed by an animal management database. Investigators using animal facilities should be familiar with this software and keep all records relating to projects up to date.

The transportation and receival of and animal tissues must comply with the Animal Facilities Standard Operating Procedure for Animal and Animal Tissue Transportation & Receival available from the Griffith Biosciences Resources Facility.

The Griffith Biosciences Resources Facility is responsible for compliance and best practice in accordance with:

- Australian Code for the Care and Use of Animals for Scientific Purposes (the Code)
- Office of the Gene Technology Regulator
- Australian Quarantine Inspection Service
- Queensland Animal Care and Protection Act 2001
- Griffith University policies and procedures
- Occupational health and safety

Animal carers have a number of responsibilities as outlined in 2.5 of the Code.

These include but are not limited to:

(i) apply the principles of the Code in all aspects of the care of animals (see Section 1 of the Code)

(ii) follow relevant policies and procedures established by Griffith University and the AEC (see Clauses 2.1.5 [iv] and [v] of the Code)

(iii) undertake activities in accordance with the conditions and requirements of approval from an AEC

(iv) take measures to ensure that the animals' environment and management are appropriate for the species and the individual animal, and support the animals' wellbeing

(v) ensure that steps are taken to safeguard animal wellbeing by avoiding and minimising harm, including pain and distress, to the animals

(vi) consider the application of Replacement, Reduction and Refinement (the 3Rs) in all aspects of the care of animals for which they are responsible

(vii) ensure that their duties are performed competently

(viii) liaise with investigators and relevant project team members on all matters relevant to the wellbeing of the animals involved

(ix) maintain records of the care of animals

(x) report to the AEC as required.

Where more than one person is responsible for the care of animals, a person must be identified who has ultimate responsibility for the care of those animals. Depending on the situation, this person may be the Griffith Biosciences Resources Facility Manager, or the Investigator with ultimate responsibility for a project. Identification of a person with ultimate responsibility for the care of animals does not relieve the individual responsibility of each person who provides care for animals.

Before an animal is supplied to an approved project for which an Investigator is responsible, responsibility for the wellbeing of the animal rests with Animal Facilities staff.

23.0 Training and competency assessments

All people involved in the care and use of animals in Griffith University Animal Facilities, the field, in satellite facilities or other institutions/organisations must understand their responsibilities and the requirements of the Code. They must also be competent in the procedures they are to perform before they commence work, or must work under the direct supervision of a competent person.

Three tiers of training are being developed by the University with Tier 1 training mandatory for all staff and students listed on an animal ethics application.

Tier 1 – consists of theoretical instruction and assessment (online modules accessible via Learning@Griffith) related to:

- the University's policies and requirements as a registered user of animals
- the Code and other legislation including the specific responsibilities of Investigators and Animal Carers
- 3Rs, including the use of statistical analysis
- the Ethical framework for the use of animals
- the role and responsibilities of the Animal Ethics Committee

This theoretical instruction and assessment is administered through the Office for Research and may be completed online at any time. Please visit the Animal Ethics Training webpage for information on how to enrol.

Further online instruction may be made available and managed by the Griffith Biosciences Resources Facility, for example, an online module related to the use of the animal facilities animal management database.

Tier 2 – will consist of a combination of theoretical instruction, videos and hands on training and will require Investigators and animal carers to demonstrate competence in a range of practical skills, including, but not limited to, handling and restraining animals, minor procedures for identification or sample collection, or delivery of agents by injection or inhalation, analgesia and anaesthesia, euthanasia and disposal. It also covers the biology of animals in use at Griffith, the identification of pain and distress in animals and its alleviation.

Before animals are used, personnel listed on animal ethics applications must be trained in the procedures that they will be performing by a competent person. The type of training and the person providing the training will depend upon the species being used and the types of procedures performed. After the completion of any relevant Tier 2 training, further training may be needed from experts within Schools/Centres and Institutes in specialised procedures.

Tier 3 – will consist of training and competency assessments in specialised techniques and procedures. Advanced training and competency assessment is required for any procedures requiring anaesthesia with recovery, tumour models, infection models, or other procedures specified by the AEC. The person providing the training will depend upon the species being used and the types of procedures performed.

Tier 2 and 3 training sessions administered through the Griffith University Biosciences Resources Facility will likely include:

- biology of animals in use (including dietary needs, housing needs, attention to wellbeing).
- general animal handling and restraint
- administration of substances and blood collection in rodents
- rodent anaesthesia
- surgical techniques in rodents
- identification of pain and distress in the animal in use, including the design and use of monitoring process (score sheets)
- alleviation of pain and distress in the animal in use.
- rodent analgesia
- rodent euthanasia and disposal
- using the animal management database
- transgenic laboratory animals and welfare implications

Once training has been completed, participants can arrange, through animal facilities staff, for their competency to be assessed.

Tier 2 and 3 training and competency assessments that relate to field research will be delivered by a designated trainer.

Personnel listed on an AEC application may apply for an exemption for Tier 2 and 3 training if they meet one of the following criteria:

1) The person has extensive experience in the procedure(s) to be undertaken and believe they can be signed off as competent after observation
2) The person will not be involved with any hands-on work with live animals

To apply for an exemption, email j.currie@griffith.edu.au with a statement justifying the exemption using the subject line 'Animal training exemption request'.

Researchers from other institutions, using animals inside Griffith Animal Facilities are also required to demonstrate competence before undertaking work with animals. The competency assessment involves: 1. The completion of a third party report form (if

applicable), or 2. The observation of the Investigator performing the procedure by a competent person and the completion of a competency assessment record.

23.1 Ongoing assessments to ensure continued competency

The provision of effective training and the assessment of competency are essential for the successful operation of an animal facility and the implementation of the 3Rs.

To promote high standards of animal welfare and good quality *in vivo* research it is essential that the competency of Investigators is continually assessed to ensure that animal users are competent in the procedures they perform – not just at the time of initial certification, but on an ongoing basis.

The University aims to ensure that Investigators continue to be competent in the procedures they perform by maintaining currency of practice and engaging in continuing professional development. The competency of investigators will be reviewed from time to time. Where deficiencies are noted, further training will be required.

Investigators are required to engage in ongoing learning and to maintain the competencies for the procedures they perform. Responsible Investigators are expected to encourage and seek learning opportunities for their team members and encourage participation in ongoing learning activities.

24.0 Acquisition of animals

All animals must be acquired from legal sources and all necessary permits and licences must be obtained by the Responsible Investigator if the animals are sourced from overseas or from their natural habitat. The Responsible Investigator must record and have available for the AEC review, the following:

- number of animals
- species
- source and manner of acquisition
- final disposal of each animal.

Certain animal species require special licences or documentation and are strictly regulated.

Certain animals can be acquired through the completion of an Animal Facility Animal Order Form. This form is available via the staff portal. The completion of a ‘Request to Import Form’ is required to import rodent strains for breeding purposes.

25.0 Research with wildlife in a laboratory environment

The Queensland Department of Environment and Heritage Protection (DEHP) has advised that if an Investigator wishes to take native animals from the wild (wildlife[4]) and place them in a laboratory situation then at the conclusion of the project, the DEHP requires that these animals are either:

1. used in other research programs (please check with DEHP regarding whether further permits are required); or
2. humanely killed at the completion of the project.

If a researcher can demonstrate that the animals are being housed in a biosecurity secure facility (to mitigate the risk of the transmission of any infectious agent) then other options may be considered by the DEHP.

26.0 Facilities/housing

All animals must be maintained in housing systems that meet the applicable regulations, laws and/or policies of Griffith University, NHMRC and the Queensland Department of Agriculture and Fisheries. The Griffith Biosciences Resources Facility Centre Manager must be consulted about all animal housing needs prior to ordering animals. All animals must be maintained in animal facilities and/or laboratories approved by the AEC. All facilities are inspected by the AEC at least once a year. The physical housing and maintenance of animal facilities must be in accordance with Australian standards. Animal housing is also inspected in accordance with the Office of Gene Technology Regulations for PC2, PC3 and Quarantine regulations.

27.0 Occupational Health and Safety – Hazards of working with animals

Griffith University aims for excellence in workplace health and safety, as it does in all its fields of activity and is committed to providing an environment where risks are effectively managed and keeping the health and wellness of our staff, students, contractors and visitors while undertaking work, study or research activities at the forefront.

There are many hazards associated with working with animals:

- physical – bites, scratches, noise, machinery, manual handling
- experimental protocols – chemical, ionising radiation, infectious agents
- Laboratory Animal Allergy
- zoonoses

[4] *Note: Fish listed under the Nature Conservation Act or taken from National Parks are considered wildlife by the DEHP.*

All tasks involved in looking after and working with animals must have a risk assessment conducted and this must be signed off by your supervisor. Risk assessment forms are available from the Animal Facility Risk Assessment folder.

The Risk Assessment will identify the risks and determine the appropriate controls, for example safe laboratory work practices, good animal handling and immunisation where available.

One of the most common problems to the health of staff/students working with animals is Laboratory Animal Allergy (LAA). Research indicates that approximately one third of animal facility workers and researchers working with animals will develop some allergic symptoms and of this group who develop symptoms 10% may then develop occupational asthma.

27.1 Management and prevention of Laboratory Animal Allergy (LAA)

What is Laboratory Animal Allergy (LAA)?

LAA is an allergic reaction to a protein allergen produced by laboratory animals. The condition is common amongst staff/students working with animals either in research or caring for them in an animal facility.

Allergic reactions may also be caused by aerosols, mould/spores or proteins found in the animal feed or bedding. Animal proteins originate from dander, hair, urine, saliva, serum or tissue. Rats and mice are responsible for most allergies.

A person with a known allergy to any animal species must avoid working with that species and notify their supervisor.

Individual risk factors

LAA can take time to develop and there are individual risk factors for some staff/students working with animals. These risk factors are:

- pre-existing allergies eg. Asthma, eczema
- family history of allergy

However, allergies can develop without a previous history and the more the animal is handled, the more likely the handler is to develop an allergy.

Symptoms of Laboratory Animal Allergy fall into two groups:

Skin Symptoms

Irritation (red and itchy)

Hives (contact urticaria)

Wealing (from scratches)

Eczema

Respiratory symptoms

Sneezing, runny/blocked nose

Swollen itchy eyes

Itchy pallet/throat

Chest tightness

Shortness of breath

Wheezing

These symptoms may develop quickly on exposure to the animal (within 10 minutes) or sometimes be delayed for 4-6 hours after exposure.

Symptoms can be variable and severity can range from mild to severe and in worst case scenario life threatening (Anaphylaxis). In extreme cases with respiratory symptoms occupational asthma may develop. Initially symptoms resolve when contact with the animals has ceased. Early reporting and treatment provides a better prognosis.

Allergens

Allergens have been identified in:

- urine, dander, saliva, serum and tissue from – rats, mice, guinea pigs, cats, cattle, horses, fish and insects
- animal feed and bedding

Treatment of allergic symptoms may include: antihistamines, cortisone, tablets, sprays and creams. It is important to note that these treatments control the symptoms but do not eliminate the sensitivity.

It is important therefore to always:

- be aware of the risk factors
- take measures to minimise exposure to animals
- report any allergic symptoms promptly

Health monitoring for Animal Facility workers

Laboratory animal facilities workers are risk assessed. Where necessary, due to the nature of a staff members work, respiratory function testing may need to be conducted.

Laboratory workers who are presenting with symptoms of LAA must report to their supervisor who may then consult with the Health & Safety Advisors and seek medical advice. Refrain from entry to the facility unless medical clearance has been given.

Management and prevention of Laboratory Animal Allergy

- ensure all staff/students required to work in the facility have no pre-disposition to LAA
- consider own risk factors
- report allergic symptoms promptly
- conduct a risk assessment of the tasks involved in working with animals and then:
- develop good work practices that minimise exposure to allergens
- have good animal house facilities
- wear appropriate personal protective equipment – mask, goggles, gown

Work practices

- decrease time spent with animals especially in high density rooms
- decrease airborne allergens when cleaning cages – consider the bedding type used, ventilation and stock density
- risk assessments are completed and safe operating procedures are in place along with the appropriate training and supervision
- wear the appropriate personal protection

Facilities

- increased ventilation and humidity will reduce the airborne allergy load – this must be balanced with animal comfort
- cages can be ventilated with filtered tops

Personal Protective Equipment

- gloves
- lab coats
- closed in footwear
- masks/respirators – will need to be 'FIT' tested to ensure they are appropriate for the task and fit the user
- goggles/glasses
- hand washing – after every contact with the animals using good hand washing techniques
- avoid hand mouth contact

Remember

- LAA is common

- report any allergic symptoms ASAP to your supervisor
- conduct a risk assessment of task prior to commencing work
- discuss any concerns with your supervisor

27.2 Zoonoses

Zoonotic diseases have been defined as a “disease of animals that is transmissible to humans from its primary animal host”. The risk with these diseases varies from relatively minor to life threatening and often the animal shows no sign of the disease. Vaccines are available for some infections and all staff/students who will be working with animals should check their immunisation status prior to commencing work/research.

Information regarding immunisations can be provided by contacting your supervisor, Biosafety Adviser, Local Health and Safety Contact or Griffith Health and Safety.

The transmission of a zoonotic disease in animal laboratory environments is uncommon but potentially serious if it occurs. Good personal hygiene is an important barrier to these diseases along with safe work practices in animal handling and the quality of animal health in the laboratory setting.

The incubation period for zoonotic diseases varies from a few days to months depending on the disease and often symptoms are vague and flu like. Therefore, it is important that if when working with animals you are unwell you see your doctor promptly and alert the doctor to the type of animals you work with. Some zoonotic diseases are notifiable to Workplace Health and Safety Queensland and must be done promptly – report to your supervisor who will notify the Griffith Health and Safety team.

The following animals have been associated with zoonotic diseases:

- Rodents
- Cattle, Sheep, Goats, Pigs
- Dogs, Cats
- Birds
- Bats
- Non human primates
- Rabbits
- Fish
- Kangaroos, Wallabies
- Koalas
- Mosquitoes

Zoonotic diseases include:

Anthrax

- Most human cases are linked with contact with infected cattle or heavily contaminated soil. Exposure can also be through contact with contaminated wool or hides
- Most at risk are people working with carcases
- This acute bacterial disease is often confined to the skin. Cases involving the lungs or gastrointestinal tract are far more serious and often fatal.
- Unique lesion(s) presenting as an itchy painless papule which ulcerates and processes to a black necrotic "eschar"
- Prompt treatment administered by a Doctor is essential

Brucellosis

- from cattle, pigs – also from foetuses, placenta, birth fluids
- transmission is via direct skin contact or inhalation
- treatment – antibiotics
- no vaccine

Cat Scratch Fever

- from a scratch from a cat
- treatment – antibiotics

Chlamydia

- from sheep placental products
- transmission is not fully understood
- pregnant women are at risk - increased risk of abortion
- if pregnant, avoid working with sheep

Cryptococcosis

- Caused by various varieties of yeast, most commonly Cryptococcus neoformans
- Avoid contact with dry bird's faeces, remove faeces after first dampening with water to reduce the risk of inhalation
- If inhaled, infection of the brain and other organs can occur
- Extremely rare in Queensland
- Treatment – antifungal agents. Course of treatment is long and toxicity problems may occur to some drugs.

Gastroenteritis – includes Salmonella, Campylobacter, E coli, Giardia, Cryptosporidia

- can be caught from cattle, sheep, pigs, dogs, rodents, poultry and reptiles but often is food borne transmission
- Likely affects more people in Queensland than any other zoonotic disease
- treatment – range of drugs available, but often settles in a few days without treatment
- good personal hygiene is important

Hendra virus

- The host of this virus are flying foxes (Pteropid bats)
- Hendra virus should be considered in any sick horse when the case of illness is unknown, particularly where signs progress quickly with rapid deterioration.
- Fever, cough, sore throat, headache and tiredness are common initial symptoms in humans
- Symptoms typically develop between 5 and 21 days after contact with an infectious horse
- Hendra virus can be fatal

Hydatid disease

- Caused by the intermediate stage of the dog tapeworm Echinococcus granulosus. It causes cyst formation in internal tissues such as the liver, lungs and brain of grazing animals and people.
- Symptoms in people vary according to the number, size and location of cysts within the body. Hydatid disease can cause serious illness and death.
- Treatment – surgical removal of cysts

Leptospirosis

- from both wild and domestic animals including rodents, pigs, cattle, dogs, possums, bandicoots
- transmission via broken, grazed or cut skin
- mild symptoms (headaches, chills, lethargy) to sever symptoms (fever, abdominal pain, headache, vomiting – can be fatal)
- treatment – antibiotics (there is no vaccine)

Listeriosis

- widespread bacterium in the environment
- people, other mammals, birds, fish, crustaceans and insects can be infected
- antibiotic treatment can be successful. Pregnant women and other susceptible people should avoid contact with potentially infected animals

Lyssavirus

- related to rabies virus
- from bat bites or scratches
- can be vaccinated – rabies vaccine
- first aid very important if bitten or scratched – wash, wash and wash again

Melioidosis

- bacterial disease
- infection may occur through inhalation
- antibiotics are used to treat the disease. Long courses of treatment are required

Psittacosis

- from birds (both wild and domestic)
- transmission via inhalation
- treatment – antibiotics (best if treated early)

Q Fever

- from cattle, sheep, goats
- also from dust contaminated with rickettsia
- inhalation is the most common route of entry
- vaccine preventable
- treatment – antibiotics but condition can recur
- Q fever immunisation program consists of 2 appointments a week apart – at the first appointment a blood test and skin test are performed. At the second appointment the skin test is read, and the results of the blood test evaluated. If required, Q fever vaccination is given.

Ringworm

- usually from cats and dogs, can be from soil transmission
- ring shaped lesion, red edges
- highly infectious
- treatment – anti fungal creams

Ross River Fever

- spread by mosquitoes
- not spread from person to person
- not everyone infected with the virus will develop symptoms
- no specific treatment but rest and medication (not antibiotics) may help
- symptoms may recur but usually not as severe
- no vaccine

- diagnosed by blood test

Tetanus

- caused by a toxin produced by *Clostridium tetani*
- treatment – tetanus antitoxin provided in hospital.
- up to date vaccination is the best protection.

Toxoplasmosis

- humans become infected via infected animal faeces – usually cats who have eaten infected birds or rodents
- can be asymptomatic
- if symptoms – fever, headache, muscle aches, generally unwell
- treatment – if needed, antibiotics
- unborn babies at risk of the disease (via the placenta)

Tuberculosis (TB)

- from humans and non human primates
- most common form involves the lungs
- transmission via inhalation – is highly infectious
- only person with active TB can pass on infection
- treatment – specific antibiotic therapy over months or years
- two yearly surveillance program for those in high risk groups (working with TB or non human primates)
- vaccine (BCG) no longer recommended and only given to high risk groups
- queries – contact Griffith Health and Safety

Prevention

- conduct a risk assessment – with supervisor
- establish good work practices
- check personal immunisation status and talk to your Supervisor, Biosafety Adviser, Local Health and Safety Contact, Technical Officer or Griffith Health and Safety to arrange necessary immunisations.
- seek help if unsure
- always wear personal protective equipment – often people who have suffered a zoonotic disease have not worn protective equipment
- if you experience any symptoms whilst working with animals see a doctor ASAP and let him/her know the type of animals you have been working with
- if you are intending to or become pregnant discuss any concerns with your supervisor or contact the OH&S team (this is confidential)

27.3 Occupational Health and Safety contacts

Griffith Biosciences Resources Facility Centre Manager
Mr Hamish McMath
Phone: (07) 555 28308
Email: h.mcmath@griffith.edu.au

Safety Specialist – Biosafety and biosecurity – Health and Safety
Ms Jamie-Lee Mills
Phone: (07) 373 53663
Email: UBC@griffith.edu.au

28.0 Gene technology clearance

Work conducted involving Genetically Modified Organisms (GMOs) is subject to Gene Technology legislation. The Gene Technology Regulations 2001 scheme is administered by the Office of the Gene Technology Regulator (OGTR). The Regulations set out the different classifications for work involving GMOs and the conditions under which the work must be conducted.

A requirement of the Regulations is that approval to work with GMOs must be sought from either the University Biosafety Committee (UBC) or the UBC and the OGTR, depending on the level of risk.

Dealings involving GMOs at Griffith University fall into one of three categories:

Exempt Dealings – Low Risk (approved by UBC)

Notifiable Low Risk Dealings (NLRDs) – Either PC1 or PC2 – Intermediate Risk (approved by UBC and reported to OGTR)

Licensed Dealings – High Risk (assessed by UBC and approved by OGTR)

The majority of work involving animals falls under the NLRD category. NLRDs are divided into two sub categories, Physical Containment 1 (PC1) and Physical Containment 2 (PC2) and must be conducted in PC1/PC2 certified facilities.

PC1 Dealings include:

- work involving genetically modified laboratory mice and rats

PC2 Dealings include:

- work involving genetically modified mice or rats if the genetic modification confers an advantage on the animal
- genetically modified microorganism introduced into a live animal
- tissue culture cell line expressing a protein which is then injected into a live animal

Note: Introduction of genetically modified somatic cells into animals is classified as an Exempt Dealing.

For further information visit the UBC webpage.

Office of the Gene Technology Regulator: http://www.ogtr.gov.au/

29.0 High risk biologicals

Work involving high risk biologicals requires approval from the UBC. Information regarding high risk biologicals can be found via the UBC webpage.

29.1 Biosafety contacts

Questions relating to the submission of ED, NLRD, DNIR or High Risk Biological Dealing applications

Safety Specialist – Biosafety/Biosecurity (07) 3735 3663 ubc@griffith.edu.au

Questions relating to Biosafety, Quarantine or Security Sensitive Biological Agents

Safety Specialist – Biosafety/Biosecurity (07) 3735 3663 ubc@griffith.edu.au

30.0 Necessary reading

- NHMRC Australian code for the care and use of animals for scientific purposes 8th Edition
- NHMRC Best practice methodology in the use of animals for scientific purposes 2017.
- NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals 2008
- Queensland Animal Care and Protection Act 2001

Where relevant:

- Principals and guidelines for the care and use of non-human primates for Scientific Purposes
- ANZCCART Euthanasia of Animals Used for Scientific Purposes (2001) (currently under revision)
- ANZCCART Ethical guidelines for students in laboratory classes using animals or animal tissues

Appendix 1 ARRIVE Guidelines Checklist

The ARRIVE Guidelines Checklist

Animal Research: Reporting In Vivo Experiments

Carol Kilkenny[1], William J Browne[2], Innes C Cuthill[3], Michael Emerson[4] and Douglas G Altman[5]

[1]The National Centre for the Replacement, Refinement and Reduction of Animals in Research, London, UK, [2]School of Veterinary Science, University of Bristol, Bristol, UK, [3]School of Biological Sciences, University of Bristol, Bristol, UK, [4]National Heart and Lung Institute, Imperial College London, UK, [5]Centre for Statistics in Medicine, University of Oxford, Oxford, UK.

	ITEM	RECOMMENDATION	Section/ Paragraph
Title	1	Provide as accurate and concise a description of the content of the article as possible.	
Abstract	2	Provide an accurate summary of the background, research objectives, including details of the species or strain of animal used, key methods, principal findings and conclusions of the study.	
INTRODUCTION			
Background	3	a. Include sufficient scientific background (including relevant references to previous work) to understand the motivation and context for the study, and explain the experimental approach and rationale. b. Explain how and why the animal species and model being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.	
Objectives	4	Clearly describe the primary and any secondary objectives of the study, or specific hypotheses being tested.	
METHODS			
Ethical statement	5	Indicate the nature of the ethical review permissions, relevant licences (e.g. Animal [Scientific Procedures] Act 1986), and national or institutional guidelines for the care and use of animals, that cover the research.	
Study design	6	For each experiment, give brief details of the study design including: a. The number of experimental and control groups. b. Any steps taken to minimise the effects of subjective bias when allocating animals to treatment (e.g. randomisation procedure) and when assessing results (e.g. if done, describe who was blinded and when). c. The experimental unit (e.g. a single animal, group or cage of animals). A time-line diagram or flow chart can be useful to illustrate how complex study designs were carried out.	
Experimental procedures	7	For each experiment and each experimental group, including controls, provide precise details of all procedures carried out. For example: a. How (e.g. drug formulation and dose, site and route of administration, anaesthesia and analgesia used [including monitoring], surgical procedure, method of euthanasia). Provide details of any specialist equipment used, including supplier(s). b. When (e.g. time of day). c. Where (e.g. home cage, laboratory, water maze). d. Why (e.g. rationale for choice of specific anaesthetic, route of administration, drug dose used).	
Experimental animals	8	a. Provide details of the animals used, including species, strain, sex, developmental stage (e.g. mean or median age plus age range) and weight (e.g. mean or median weight plus weight range). b. Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug or test naive, previous procedures, etc.	

The ARRIVE guidelines. Originally published in *PLoS Biology*, June 2010[1]

Housing and husbandry	9	Provide details of: a. Housing (type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions; tank shape and material etc. for fish). b. Husbandry conditions (e.g. breeding programme, light/dark cycle, temperature, quality of water etc for fish, type of food, access to food and water, environmental enrichment). c. Welfare-related assessments and interventions that were carried out prior to, during, or after the experiment.	
Sample size	10	a. Specify the total number of animals used in each experiment, and the number of animals in each experimental group. b. Explain how the number of animals was arrived at. Provide details of any sample size calculation used. c. Indicate the number of independent replications of each experiment, if relevant.	
Allocating animals to experimental groups	11	a. Give full details of how animals were allocated to experimental groups, including randomisation or matching if done. b. Describe the order in which the animals in the different experimental groups were treated and assessed.	
Experimental outcomes	12	Clearly define the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioural changes).	
Statistical methods	13	a. Provide details of the statistical methods used for each analysis. b. Specify the unit of analysis for each dataset (e.g. single animal, group of animals, single neuron). c. Describe any methods used to assess whether the data met the assumptions of the statistical approach.	
RESULTS			
Baseline data	14	For each experimental group, report relevant characteristics and health status of animals (e.g. weight, microbiological status, and drug or test naïve) prior to treatment or testing. (This information can often be tabulated).	
Numbers analysed	15	a. Report the number of animals in each group included in each analysis. Report absolute numbers (e.g. 10/20, not 50%[2]). b. If any animals or data were not included in the analysis, explain why.	
Outcomes and estimation	16	Report the results for each analysis carried out, with a measure of precision (e.g. standard error or confidence interval).	
Adverse events	17	a. Give details of all important adverse events in each experimental group. b. Describe any modifications to the experimental protocols made to reduce adverse events.	
DISCUSSION			
Interpretation/ scientific implications	18	a. Interpret the results, taking into account the study objectives and hypotheses, current theory and other relevant studies in the literature. b. Comment on the study limitations including any potential sources of bias, any limitations of the animal model, and the imprecision associated with the results[2]. c. Describe any implications of your experimental methods or findings for the replacement, refinement or reduction (the 3Rs) of the use of animals in research.	
Generalisability/ translation	19	Comment on whether, and how, the findings of this study are likely to translate to other species or systems, including any relevance to human biology.	
Funding	20	List all funding sources (including grant number) and the role of the funder(s) in the study.	

References:
1. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG (2010) Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. *PLoS Biol* 8(6): e1000412. doi:10.1371/journal.pbio.1000412
2. Schulz KF, Altman DG, Moher D, the CONSORT Group (2010) CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 340:c332.