Application Guide:
Animal ethics

JCU Animal Ethics

Servicing JCU Researchers

1. Introduction

JCU recognises the significant role animals play in the progression of human knowledge. JCU research projects use animals only when their use is justified and when no other alternatives are available.

All activities involving animals must only be conducted in line with University policy, compliance with relevant legislation and after approval by JCU's Animal Ethics Committee (AEC). Approvals are only issued if the potential benefits of the work are likely to outweigh the effects on the animals concerned.

This guide was developed to assist investigators in their understanding of the regulatory framework that governs the use of animals for scientific purposes and the JCU processes of obtaining ethical review, but investigators should also participate in training and read the Australian Code for the Care and Use of Animals for Scientific Purposes (the Code) and read Chapter 4 of the Animal Welfare Protection Act.

2. What is scientific animal use and when is the ethical review of activities required?

The Code requires that all use of animals for a scientific purpose is subject to ethical review, where the meaning of 'animal' and 'scientific purpose' are as defined in the Code and legislation; and this is regardless of the impact that research has on the animal *(See Code 'Definitions').*

Animal – *"any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods."*

And including *"a live pre-natal or pre-hatched creature as follows if it is in the last half of gestation or development a mammalian or reptilian foetus a living marsupial young."*

Scientific purpose – *"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."*

At JCU animals that are held but not currently being used in a project and those held in displays or in laboratories also require AEC oversight to ensure an acceptable level of care, and a Display/Holding Application needs to be submitted. There are some exemptions to this, as outlined in the AEC's Policy: [The Use of Animals in Short-Term Displays and Demonstrations](#) and include displays such as in open day or demonstrations to school students.

Activities involving animals that may not require ethical review

- The use of animal cadavers under certain circumstances;
- Practical work, work experience and on-the-job training;
- Agricultural extension work;
- Veterinary clinical teaching;
- Acts of veterinary science done as a part of an animal's clinical care;
- Use or re-analysis of tissues or data collected previously for another purpose.

If you feel your activities may be exempt from review, please email the ethics team for confirmation before commencing your work. This won't lead to a delay to your commencement as confirmation can usually be given straight away.

Working Interstate

AEC approval is required for scientific animal use in all parts of Australia, but each state and territory has its own legislation related to the use of animals for scientific purposes. This means that approval from an AEC in one jurisdiction, does not necessarily cover work carried across state borders.

JCU has approval to carry out animal work in six Australian jurisdictions: Queensland, the Northern Territory, Western Australia, South Australia, New South Wales and Tasmania. JCU does not have approval to work in Victoria or the Australian Capital Territory. There are some minor differences in legislation in different states and territories, so researchers should familiarise themselves with the legislation in the jurisdiction(s) in which they will be working. If you are planning on doing research interstate or in a jurisdiction where JCU is not registered, please contact the ethics team for advice.

When working interstate, **you should carry a copy of your AEC approval notice and JCU's license/registration documents for that jurisdiction** (email the ethics team for a copy). The license/registration documents can be provided to you by the ethics office.

Working Under the Approval of Another AEC

Investigators must notify the JCU AEC in writing and provide a copy of the non-JCU AEC's application and approval notice 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. This can be done in an email attaching a copy of the application and the approval from the other AEC(s). *(See Code 2.4.9)*

Except under special circumstances, work conducted at a JCU facility or campus will need to be conducted under a JCU AEC approval. If you plan to use or house animals on a JCU campus or research station under the approval of an external AEC, you need to notify the JCU AEC and provide a copy of the application and approval notice for review by the JCU AEC. Please contact the ethics office for advice.

Where there are collaborations between investigators from more than one institution, an agreement will need to be put in place between the JCU AEC and the AEC of the other institution(s). The ethics team will organise these agreements according to standard agreement templates, investigators won't need to be involved and organising these agreements won't delay the start of the project. *(See Code 2.6.4-7)*

Working Overseas *(See Code 2.6.9-14)*

Depending on the country where your project will be conducted, overseas research may require approval by the JCU AEC. The AEC may accept the approval of overseas activities if:

- If the AEC is satisfied that work and animal care will be meet the principles of the Code, including being reviewed by an ethical review body similar to an AEC;
- Any facilities where the work will be conducted comply with the Code;
- The researchers also acquire any local regulatory requirements for the work;
- The work isn't being conducted overseas to avoid compliance with the Code.

If you plan to conduct research overseas and are unsure whether you need JCU AEC approval or if you have overseas approvals and want the AEC to decide whether they will accept this approval, email the ethics team with details of you proposed work and any approvals you have or will obtain already.

Do my planned activities require ethical review?

If you are unsure whether your planned activity is scientific animal use or requires ethical review, please contact the ethics team at ethics@jcu.edu.au but please don't start the activities before you have received confirmation. Activities involving animals cannot commence until you have received formal notification of ethical approval or

notice of exemption.

3. The James Cook University Animal Ethics Committee *(See Chapter 2.2)*

Animal Ethics Committees (AEC) are committees constituted to conduct the ethical review of animal use. Their functions and membership are prescribed by law, and they oversee all aspects of animal care and use in science in Australia and by Australian-based investigators. AECs ensure that all work is done ethically, humanely and in compliance with legislation and the Code.

AECs have a challenging task, they need to be able to understand complex scientific concepts, technical procedures and activities and be able to apply this understanding to the effects that these activities have on the animals. They need to have a good understanding of the legislation and various regulations that they must also apply when they review submissions. As a group they need to understand animals and their welfare, signs of pain or distress and aspects of their care and husbandry.

Members are volunteers and they devote considerable time and effort fulfilling their roles on the committee, and JCU owes our ability to use animals in our scientific programs to these volunteers.

Table 1. AEC membership categories

Category A— a person with: • Current veterinary registration or qualifications recognised for registration; and • Experience relevant to the institution's activities.	**Category B**— a person with: • Substantial and recent experience in the use of animals for scientific animal use; and • A higher degree in research or equivalent experience.
Category C— a person who: • Demonstrates commitment to, and experience in, furthering the welfare of animals; and • Is not employed by or otherwise associated with the institution; and • Is not currently involved in the care and use of animals for scientific purposes; and • Where possible, have active membership or endorsement by an animal welfare organisation.	**Category D**— a person who: • Is not employed by or otherwise associated with the institution; and • Has never, either in their employment or past their undergraduate education, has never been involved in the use of animals for scientific purposes; and • Does not fit the requirements of any other category.

Category C and D members are independent of the institution to remove any potential conflict of interest from their decisions, and as such they may not have a scientific background. For this reason, it's important that these members are able to understand the contents of applications so these need to be completed using lay language.

If you're interested in becoming a member of the AEC you can submit an expression of interest to ethics@jcu.edu.au .

The Executive Committee

The Executive Committee is a committee that consists of the Chair and one member from either Category C or D that can review certain documents outside of an AEC meeting. They cannot approve new applications, but can approve Amendments if they are minor and not likely to cause harm to the animals, including pain and distress *(see Code Section 2.2.23 and Amendments below).*

4. The Research and Innovation Services Animal Ethics Team

The animal ethics team consists of the Animal Ethics Officer (AEO) and the Manager, Animal Welfare and Research Ethics/Animal Welfare Officer. We aim to facilitate the ethical review process in an efficient and supportive manner.

The team is available to provide advice and assistance to investigators in their dealings with the AEC, including:

- Advice on planning and conducting ethical and compliant animal research

- Advice on the Code and legislation

- Processing of applications and other submissions to the AEC

- Pre-review of submissions to the AEC

- Provision of training in the ethical animal use, the Code and legislation

- Veterinary and animal welfare advice including animal examination (including post-mortem) and disease investigation, anaesthesia and surgical training

Legislation – Scientific animal use

Scientific animal use is regulated through legislation in Australia and each state or territory has their own legislation that covers this work. In Queensland, the legislation is the *Animal Care and Protection Act* (the Act).

The Act outlines how scientific animal use is regulated, including the role and administration of the regulator, the system for registering scientific users of animals, the powers of government inspectors and creates offences related to animal use. Importantly, the Act makes it an offence to use animals for scientific purposes unless:

- You are registered with the regulator or working under the registration of a registered institution;

- You have the approval of an Animal Ethics Committee, that is also registered with the regulator;

- Any requirements of the committee in relation to the use of animals are complied with; and

- Your activities and actions comply with the *Australian Code for the Care and Use of Animals for Scientific Purposes*.

Thus, the Code becomes part of the legislation and regulatory framework. While each state and territory has their own legislation, they all include the Code in legislation in this way, meaning you must comply with the Code no matter where in Australia you work.

When working interstate, you should carry a copy of JCU's license/registration for that state or territory and your JCU AEC approval notice. For a copy of the JCU license/registration for the state where you will be working contact ethics@jcu.edu.au

5. The Australian Code for the Care and Use of Animals for Scientific Purposes

The *Australian Code for the Care and Use of Animals for Scientific Purposes* (the *Code*) is a document that deals more closely with the conduct of activities using animals for scientific purposes. It is a code of conduct that is developed through public consultation, with input from major stakeholders including: the NHMRC, the ARC, the CSIRO, Universities Australia, the RSPCA and other animal welfare organisations as well as the general public.

While the Act outlines the overall regulatory framework, the *Code* outlines a set of principles to be followed when using animals for scientific purposes. It also outlines the responsibilities of all those involved including investigators and animal care staff. It outlines the operation and membership of AECs, prescribes what information the AEC needs to be provided in order to assess proposed animal activities, outlines review pathways for submissions to the AEC and provides more specific advice on certain types of activities such as breeding animals for research, genetically modified animals, wildlife, animals in teaching, surgical procedures, pain and distress, animal monitoring, humane killing and humane endpoints, animal care and animal facilities.

Investigators are expected to read and abide by the *Code*, and have a good understanding of those sections that relate specifically to their work, in particular:

- Governing principles *(Section 1)*
- Responsibilities of AECs *(Section 2.3)*
- Responsibilities of investigators (*Section 2.4)*
- Responsibility of animal carers *(Section 2.5)*
- The sections under the headings *"Responsibilities of Investigators" in Section 2.6*
- Animal wellbeing *(Section 3)*
- The care and use of animals for the achievement of educational outcomes in science *(Section 4) if using animals in teaching*
- Complaints and non-compliance *(Section 5)*

The *Code* also prescribes the external oversight of institutions using animals and their AECs, making it mandatory for an independent external review to take place at least every four years, and most regulators require a copy of the review reports. *"Section 6 "Independent external review of the operation of institutions"* describes the scope of the review, processes and responsibilities of the review panel. It is a requirement of our registration as an organisation that can use animals in science that we undertake these reviews and act on any findings.

6. Principles governing scientific animal use

Apart from ethical review there are several other principles the AEC will apply when reviewing animal activities.

3Rs – Replacement, Reduction, Refinement

The principles of the 3Rs are guiding principles for the ethical use of animals in science. They were outlined in *The Principles of Humane Experimental Technique by M.S. Russell and R.L. Birch in 1959* and have since been almost universally adopted around the world. They aim to ensure that there is constant, ongoing improvement in the treatment of animals in science over time and a push to find ways to replace animal use wherever possible. Investigators and the AEC, are required to apply the principles at every step of animal use, from planning to publication.

Replacement – Methods that avoid or replace the use of animals

The principle of replacement requires that wherever possible, if there is a non-animal alternative, it should be used with the hope that eventually, animals may not be needed at all (although this is unlikely for research involving wildlife or livestock).

Reduction – Methods that minimise the number of animals used in a project

When the use of animals is justified, researchers must ensure that they use the minimum number of animals necessary to achieve their aims.

Refinement – Methods that minimise any adverse impact on the animals and/or enhances their wellbeing.

To address Reduction, investigators need to apply sounds statistical methods when deciding on animal numbers, use non-lethal sampling methods in longitudinal studies, control variation between animals or share tissues and data with other researchers.

Refinement refers to any approach which avoids or minimises the actual or potential pain, distress and other adverse effects experienced at any time during the life of the animals involved, and which enhances their wellbeing. When addressing *Refinement*, investigators should consider the following two questions:

- What can be done to prevent/minimise pain or distress?
- What could be done to improve the animal's lives and create more positive experiences?

For more information on the 3Rs, visit the [NC3Rs website](#).

7. Application procedures

The AEC meets monthly, except January, usually on the first Friday of the month. Submissions to the AEC need to be submitted at least 2 weeks before the scheduled meeting. On rare occasions, and only if there is a good reason, late applications maybe accepted or urgent review may be arranged.

Investigators should always download the latest version of the application forms when beginning to write their application. The forms sometimes change due to changes in regulation or legislation and so applications on old versions may be sent back.

Advice for the preparation of your AEC application

We strongly recommend that investigators learn and understand the principles of the *Code* and ethical use of animals in science before they begin planning their projects. This will improve the quality of your application and the chances it will be approved at the first review.

Animal Ethics Monitors

Animal Ethics Monitors are appointed in each college to act as a source of advice and assistance to researchers and students. Their primary role is to pre-review applications and other submissions, and provide constructive advice to ensure that the submissions are of a quality that would facilitate their approval following ethical review. At the moment, having your AEC application undergo a monitor's review is not mandatory, but it is highly recommended. Please consult Monitor in your discipline for a review.

With support of the AEC and the Research and Innovation Services Research Ethics Team, Animal Ethics Monitors:

- Are a point of contact and advice for researchers in their college on the planning and design of ethical human research
- Provide advice on planning and designing ethical human research projects
- Conduct pre-reviews of submissions for ethical review in order to ensure they are of an acceptable standard
- Provide advice to researchers in responding to feedback and issues identified in ethical review

When submitting your application to monitors for review, keep in mind:

- If you're a student, have your supervisor review your submission before it goes to the monitor
- Try to submit it to the monitor at least a week before the HREC meeting closing date to give them sufficient time to review and provide feedback
- Submit it before you have sought signatures, so that if changes need to be made, these can be made before the final sign-off

Submission of documents to the AEC

All submissions for review by the AEC need to be emailed to the generic email address ethics@jcu.edu.au to ensure they are not mislaid and will be processed in a timely manner. Documents should be signed, and the signature can be a wet signature, electronic or photo signature.

Attachments or other supporting documentation can be submitted, but any documentation must be in lay language, or summarised in lay language in the application itself.

8. Guide to the JCU AEC application form

The JCU AEC has 5 application forms for different types of research that are designed remove or rephrase any redundant or irrelevant questions:

- Application for an Animal Research Project – for research projects;
- Application for an Animal Research Project (Observational field work) – for research that involves observational field work;
- Application for a Teaching Project – for animal teaching practicals and projects;
- Application for an Animal Breeding Program – for animals breeding colonies and breeding animals to supply research or teaching programs;
- Application for Animal Holding/Displays – for animals held by JCU staff or students in displays or on JCU property and not being used for scientific purposes.

Before completing the application form, researchers should:

- Read the *Code;*
- Read all appropriate guidance documents related to your discipline of research and research project;
- Feel free to contact the Animal Welfare Officer to discuss veterinary, compliance or animal welfare aspects of your proposed research;
- Undertake [mandatory animal research ethics training](#) and undertake any additional competency or technical skill training modules as they relate to your planned project;
- Undertake training in the procedures to be used in your projects and complete the appropriate Competency Declaration in LearnJCU to document that you're competent;
- Download the latest version of the forms from the AEC's *Resources, Downloads and Links* webpage.

The ethical review of your research will be guided by the *Code,* and decisions made will be based on this document, related guides, guidelines outlining best practice and the legislation.

For more advice on what information the AEC requires in each question please see the attached Application Guide

Standard Operating Procedures (SOPs)

SOPs are documents that describe from start to finish how a procedure is done. They are tools that should be used in training staff to perform procedures and document when they are competent. Approved SOPs can be referenced in AEC applications, removing the need to describe the procedure and so reduce the administrative burden for investigators.

There are currently over 200 approved SOPs available to use, stored in LearnJCU organisation *Animal Welfare Organisation*. To access the organisation, you can self-enrol by clicking on *Tools* in the left sidebar, then choosing *My Organisations*.

If there is no SOP for the procedure you're needing to describe, you can write one and submit it to the AEC for approval with your application. If the description of the procedure is slightly different to how you would carry it out, you can still reference the SOP, but outline the differences in the AEC application.

When referencing a SOP, you should include the full title as well as the number to make it easier for the AEC to understand what you are proposing to do.

SOPs cannot be used without being approved by the AEC, and to remain approved they must be reviewed every 3 years. If you do reference a SOP in your application, it is expected that you have read it and completed or are being training in the procedure. It's important to know the contents of the SOP before using it as if you do not follow the instructions in the SOP, you will be in breach of your AEC approval.

Administration section

In this section provide details of the investigators working on the project, any conflict of interest or collaborations *(Code 2.1.8(iii), 2.6.4-7).*

All investigators involved in animal work need to be listed on the application and if anyone who isn't listed does work with animals, there will be a breach of the AEC approval.

The AEC can only approve an application if all investigators listed are trained and competent in the roles they will play in the project, or there is a plan to train and supervise the person until they are competent *(Code 1.29).* The AEC determines competency by reviewing the answers in the application and by referencing the training records and declarations of competency in LearnJCU "Animal Welfare Organisation". Therefore, it's important that investigators have completed their competency declarations or else approval could be delayed.

Purpose and procedure categories

Every year JCU reports its total animal use to regulators in each state. These are broken down based on the purpose of the research and the procedures undertaken in the research. The regulator then makes public the states combined animal use, which is important for transparency.

You are asked to choose one category each for the purpose and procedure drop down lists. The procedure category relates to the impact the procedures have on the animals. If, for procedure category, there are several procedures, choose the category that represents the highest impact (the impact generally increases as you go down the list). There should be only one procedure and one purpose category for each application, you do not need to differentiate between what is happening to any animals within that application.

For explanations of each category see the guides at the end of the application.

Duration of project approval

Approvals for research and teaching projects is generally for a maximum of three years, but this is subject to the submission of satisfactory annual progress reports by the due date.

If justification can be provided and funding is available, approvals for up to five years can be given. Justification would include that 5 years of funding is available in the form of a five year grant.

Other legislation and permit requirements related to animal use

As well as legislation related to the scientific use of animals, other legislation, permits and authorities may also apply, and you will be asked to confirm that other approvals have been obtained or been applied for in the application (Table 2.)

Table 2. Permits and approvals often required for scientific use of animals

Type of Work	Approval Required	Organisation to Contact
Parks and wildlife	Scientific Research and Educational Purpose Permit	Queensland Parks and Wildlife
Genetically modified organisms	Notifiable Low Risk Dealing Licensed Dealing	JCU Biosafety Committee
Workplace health and safety	Field work risk assessment	JCU WH&S
Great Barrier Reef Marine Park	GBRMP permit	Great Barrier Reef Marine Park
Prescription and restricted drugs and poisons	Queensland Health Approval	Queensland Health Drugs and Poisons JCU Drug and Poison Management

Please note, some of the legislation governing approvals is state based and so different approvals will be needed in each state or territory in which the project will take place.

Justification

For a project involving animals to be justified, it must:

- Obtain or establish significant information relevant to the understanding of humans or animals; or
- Maintain or improve human/animal health and welfare; or
- Improve animal management or production; or
- Obtain and establish information relevant to understanding, maintaining or improving the environment; or
- Achieve educational objectives.

In this section the questions are designed to allow the AEC to determine whether there is sufficient evidence to support the case that the animal use is justified as outlined in the *Code*. In order for the AEC to be satisfied that a project is justified, there must be evidence that *(Code 1.7)*:

- The project has scientific or educational merit *(Code 1.5(i), Application Question 10);*
- Will result in potential benefits for human, animals or the environment *(Code 1.5(i), Application Question 11);*
- How the 3Rs *Replacement* has been addressed – The use of animals is essential to achieve the stated aims, and there is no alternative to using animals *(Code Sections 1.1(v)(a), 1.5(ii), 1.18-20), Application Question 13);*
- The potential impact the project will have on the animals involved is justified by the potential benefits *(Code 1.3, Application Question 12).*

Tips for this section

- Provide your answers in lay language;
- Provide only a brief overview of the project here;
- If you do need to use scientific concepts or terminology, provide definitions or explanations either in the answer, or in a glossary;
- Read and answer the questions, and only provide the information requested, further details can be provided in the appropriate questions later on (do not provide detailed descriptions of the aims methods, and procedures in this section);
- Don't cut and paste your answers out of a grant application or research proposal;
- Use diagrams to help explain scientific concepts or terminology.

Animal housing, care and husbandry *(Code Chapter 3.2)*

In this section describe how the animals will be housed, fed, watered and cared for as a part of their routine husbandry. Routine husbandry is not part of the project itself, and any changes to the animals routine housing or care related to the research or teaching project needs to be outlined in the methods section.

As with other aspects of the scientific use of animals, routine husbandry must be carried out by someone who is trained and competent. This can be either the investigators or animal care staff or both, but it must be clear who is responsible for the care of the animals at any one time. Animal care staff (including volunteers) conducting routine husbandry do not need to be listed on the AEC application as long as they are not participating in any reaching or teaching using animals.

Methods and experimental design

In this section you need to provide information related to:

- Your choice of species and whether that species has any underlying ethical issues (mainly related to genetically modified mice where the modification may lead to clinical disease) *(see Code Section 2.4.8(v))*;

- Justification for the number of animals you are requesting – there needs to be a reason for the numbers requested) in terms of the research design and statistical basis for numbers of animals per group *(see Code Sections 1.5(iii), 1.21);*

- How the 3Rs – *Reduction* has been addressed, including whether there is an opportunity for tissue sharing *(see Code Sections 1.1(v)(b), 1.21-27)*

- Detailed descriptions of what happens to the animals with enough detail for the AEC to understand what happens to any animal from start to finish. If animals are subjected to tests or procedures more than once, the AEC needs to know how many times they will be subjected to each and the time period in between. SOPs can be used to describe a procedure but the titles and context of the procedure should be outlined in the application;

- How the 3Rs – Refinement has been addressed in terms of the methods described, eg pain relief, housing, environmental enrichment *(see Code Sections 1.28-30)*;

- Outline how the animals will be monitored *(see Code Section 3.1.20* and what criteria will be used to determine the whether the animal is in pain or distress and needs to be removed from the project (humane endpoints) *(see Code Sections 3.1.26-28)*;

- Outlined what will happen to the animals at the end of their use on the project. In general, the animals will either be:

    o   Euthanised – outline the method of humane killing, which must meet the requirements of the Code *(see Sections 3.3.45 and the [JCU AEC's Humane Killing of Animals for Scientific Purposes Policy and Guidelines](#) for acceptable methods by species);*

    o   Re-used – any reduction in the number of animals needs to be balanced against any adverse effects of this re-use taking into account the animal's lifetime experience *(see Sections 1.22, 1.24, 2.3.15);*

    o   Released – if wildlife is to be released it needs to comply with the requirements of the Code and release cannot put the animals at risk *(see Code Sections 3.3.3-39, 3.4.4-5);*

    o   Returned to normal husbandry conditions – if animals are to return to their normal herd or husbandry conditions *(see Code Sections 3.4.4-5).*

Tips for this section

- Read and answer the questions in the appropriate sections;

- Refer to the JCU AEC Guides on [Anaesthesia and Analgesia and Animal Monitoring and Humane Intervention Points/Endpoints](#) and other established guides to ensure your planned activities are best-practice *(see Code Sections 1.16, 2.4.8(viii));*

- Use:

    o   Pictures – to demonstrate equipment used, procedures to be undertaken;

    o   Tables – to describe animal numbers in terms of treatment groups;

    o   Diagrams – to explain metabolic pathways and biological concepts and processes;

    o   SOPs – to describe commonly used procedures

- Make sure you provide a step-by-step description of what will happen to the animals from start to finish and at each step think about how any impact each might have on the animals can be minimised (Refinement applied to each step);

- Don't cut and paste from a grant or research proposal as they aren't in lay language and don't provide the information needed by the AEC to assess your project against the requirements of the Code;

- Don't refer to publications or websites when describing procedures or concepts unless the part being described is also outlined in the application. References and webpages can be provided to support the use of a procedures but the AEC can't be expected to find and go through a publication. Websites can be used but since links can be broken and webpages content can change, they cannot be relied on to provide information;

- If your project is observational or a wildlife survey, you do not need to provide a list of species or their numbers, you can provide these numbers and species when reporting;

- Use/adapt one of the AEC's monitoring sheet templates and submit it with your application.

Signatures and declarations

Everybody working on a project needs to be:

- Named on the application;

- Trained and competent, or be supervised and trained until they are competent *(see Code Sections 1.29, 2.4.4(v)-(vi),*

- Willing to accept responsibilities outlined in the declaration and the Code *(see Code Section 1.31-32, 2.4.8(xviii)-(xxi), Chapter 2.4(investigators) Chapter 2.5(animal carers));*

- Given a copy of the AEC application, and understand and agree to their roles in the project.

It's extremely important that all people working with animals to understand their legal and ethical responsibilities and their responsibilities outlined in the *Code Chapter 2.4(investigators) Chapter 2.5(animal carers),* have read the application and understand their role in the project.

The Principal Investigator (PI) is the person with ultimate responsibility for the conduct of the project and the care of animals, unless the PI is a student, in which case the person with primary responsibility will be the primary Supervisor of the student named on the application.

General tips for applications:

- Use this guide and refer to the sections of the Code outlined in this guide when planning your project and writing your application;

- Proof read the application and ask others to review the application;

- Ask for a monitor to review the application;

- Seek advice from the Animal Welfare Officer

Submission of applications and other documents to the AEC

Completed, signed documents should be submitted to the AEC by the meeting deadline. Meeting dates and submission deadlines are outlined on the JCU AEC's webpages.

9. Application review and AEC decision-making

An AEC application can only be reviewed and approved at a quorate meeting of the AEC. The AEC will review the applications and:

- Approve – the project is approved and can commence.

- Conditionally Approve – the project is approved in principle, but either requires minor modifications or the AEC requires more information, clarification or answers to their questions before the project can be given final approval.

- Defer – the application requires major revisions or changes to the project's methods.

- Not approved – the project falls short of the requirements of the Code, is considered unethical or lacks scientific rigour.

The AEC makes their decision in the following ways:

- Objectively/logically – the application needs to meet the requirements of the legislation, the Code and JCU's policies and procedures;

- Subjectively/emotionally – the application needs to be ethically acceptable to the members, based on their life experience, education, personal values and philosophy.

Work cannot begin on a project and amendments cannot be instituted until the investigator has received an Approval Notification from the AEC (please note that a conditional approval notice is not notice of approval and work cannot commence until the final notice is received).

Enquiries about the review outcome and appealing a decision

If you have any questions about the outcome of the review of an ethics submission or want to appeal a decision, contact the ethics office to discuss the matter. It's best to put your questions or request for appeal in writing.

10. Managing your project

Once your application is approved, you will need to conduct and manage your project according to the approved protocol, any conditions applied on it by the AEC and in line with the *Code*.

Amendments

If you need to change any detail of your protocol you need to submit an [Application for Protocol Amendment](#) outlining details of the changes as well as any change it may have on the impact the project has on the animals.

Amendments need to be approved by the AEC at a meeting unless they are minor and not likely to cause harm to the animals, including pain and distress.

Urgent amendments

If you need to make urgent amendments to a protocol, the amendment may be eligible for Executive Committee review outside of a scheduled meeting if the amendment is minor and there is a good reason for the urgent review. Examples of amendments that the AEC considers as minor include:

- Change to personnel;
- Time extensions of less than one year;
- Changes to administered substances where the new substance is administered in a similar way and has similar actions and side effects eg types of analgesia or anaesthesia;
- Minor experimental design changes with no effect on animal welfare;
- Changes to strain, breed or species where there is no change to welfare or conservation status;
- Where the change addresses one or more of the 3Rs;
- Addition or removal of research locations;
- Addition of new Genetically Modified lines of mice to a project.

For more advice on minor amendments see the [AEC's Operating Procedures](#).

To signal that you need urgent Executive review of an amendment, answer the question at the bottom of the amendment form and provide a reason for the urgency.

Annual and Final Reports

The Code requires that investigators report on their progress and animal use annually and on the completion of their projects. JCU has reporting requirements to every jurisdiction in which it operates, so reports are due at the end of February for activities that took place the previous calendar year.

When reporting the animal numbers used, the following guidelines apply:

- The number of each animal type actually used (not proposed) for the activity during 1 January to 31 December 2019. This also includes control animals, by-catch and non-target animals;

- If the animal was used under different AEC approvals, report each use separately;

- Animals must be counted for each project approved by an AEC, however if the same animals are used repeatedly within an activity (e.g. teaching animal handling once a week), these animals are only counted once for the year;

- When the same animals are used in an approved activity over two or more calendar years, then their use must be reported for each separate year e.g. if 10 cattle were used during Oct 2019 to Feb 2020, 10 cattle must be reported in the 2019 report and the same 10 cattle must be reported again in the 2020 report – reflecting that the same number were used in both calendar years.

Working in Animal Facilities

If your project involves you working in a JCU animal facility or research station you will be required to undertake an induction for that facility.

You will also need to get the signature of the Facility Manager before you submit your application. This is because the facility staff need to ensure that they can accommodate your project in their facility and to make sure any information about the housing and care of the animals is correct. This step can save you time in receiving your final approval, as any incorrect information in the application will need to be corrected after the meeting, delaying approval.

11. Training and Declaration of Competency

Animal Ethics Training

All people using animals need to understand their responsibility under the legislation and the Code. To ensure this, all staff and students who plan to work with animals at JCU must have training in animal ethics. You will need to have provided the ethics office with evidence of training before you can begin to work with animals and all investigators listed on ethics applications will need to have provided the ethics office with evidence of training before the application can be approved.

- Completed the Phase 1: Core Mandated ComPass Training for AEC Members and Animal Users, and a copy of the completion documentation is supplied to the AEC office; or

- Completed animal ethics training at another institution, and evidence of completion of this training is supplied to AEC office; or

- Request an exemption due to recognised prior learning by emailing the AEC office and outlining your experience in scientific animal use under the Australian Code (e.g. senior researchers, previous membership on an AEC or similar experience).

Free training can be completed online through the [ANZCCART ComPass](#) training site. There are several training modules offering training in a number of areas and activities:

1. Core Mandatory Training for AEC Members and Animal Users

   Additional non-mandatory modules can also be completed, as they related to your planned research.

2. Competency Training in Certain Activities:

   - [Aseptic Technique](#)

   - [Minimally Invasive Techniques Without Anaesthesia, Including Wildlife Trapping](#)

   - [Anaesthesia for Minor Procedures](#)

   - [Anaesthesia for Major Procedures](#)

   - [Surgery Principles, Methods and Materials](#)

   - [Performing a Systematic Post-Mortem Examination](#)

   - [Establishing and Managing a Rodent Breeding Colony](#)

   - [Maximising Welfare and Behavioural Assessment in Research Animals](#)

3. Technical Skills Training Guides and Resources

   - [Training Materials for Minimally Invasive Procedures in Research Animals](#)

   - [Training Materials for Performing Aseptic Technique, Surgical Skills, Suturing and Euthanasia Methods](#)

Evidence of training is best done by uploading your documents into the AEC's LearnJCU Organisation:

- Request access to the Organisation 'Animal Welfare' in LearnJCU (which also has a considerable collection of SOPs for use in ethics applications);

- Login to the 'Animal Welfare' Organisation, and click on the 'ComPass Animal Ethics Training' in the left-hand side bar;

- Upload the ComPass Certificate of Completion or evidence of prior knowledge/training into the system.

Competency Training

The Code requires that all people working with animals are trained and competent to carry out their roles in the project, or is being trained and supervised by someone until they are competent *(see Section 1.29)*. This competency needs to be documented in training records and available to the AEC when reviewing your application.

JCU has adopted a procedure-based competency program using SOPs, where the competency measures are outlined in the SOP. These SOPs are available in LearnJCU, and once you are competent, go into the SOP for the procedure and complete the competency declaration for that procedure.

Contact Research and Innovation Services

Research and Innovation Services opens doors across our campuses in Australia and Singapore, making it easier for you to connect with the right people, expertise, facilities, resources, and advice.