Griffith UNIVERSITY
Queensland, Australia

FACT SHEET FOR COMPLETING AN ANIMAL ETHICS APPLICATION

July 2021

GENERAL POINTS

- Applications should be written in plain English, suitable for an interested, educated person from the general community. Applications written in the language of the specialist (i.e. like a grant application) are rarely comprehensible for all committee members. Failure to provide a clearly understood lay description could result in the application requiring resubmission.
- Applications should be submitted for projects rather than for each experiment or separate procedure.
- State legislation requires that all projects be reviewed by the AEC on an annual basis. Researchers are required to provide an annual report for their projects describing the progress made during the previous calendar year.
- Where projects are to be conducted at more than one institution, or if investigators listed on a project come from more than one institution, the AECs of each institution need to assess and approve the application before work can commence. The first AEC to consider the application should be the Committee where the animal work will take place. This should also be considered the 'primary AEC' and should be responsible for all reporting on the project to regulators and NHMRC. Where the Griffith University AEC is not the primary AEC but Griffith personnel are involved, a 'Prior Review' application needs to be submitted along with a copy of the full application submitted to the other institution's AEC and the approval issued.
- Before the submission of an application, it is STRONGLY recommended that it is perused by an Animal Ethics Advisor or colleague who is involved in animal research, especially if the applicant has little experience with submitting applications.

Tips for completing specific questions to maximise the chance of first time approval

Coversheet – Project Title

Where possible use "plain English". However, a more technically-phrased title that matches the title of a grant application is also acceptable.

Ensure that the title is not identical to other projects, unless the application is replacing a previous approval with the same title.

Coversheet – Chief Investigator Details

The Chief Investigator must be an employee of Griffith University and preferably a person with an academic appointment. The Chief Investigator can not be a HDR student.

Coversheet – Selection of a Responsible Investigator

One of the Internal Investigators must be identified as the Responsible Investigator. This can be selected at the role drop down box at the Chief Investigator section of the Coversheet or at the Internal Investigators section.

The Responsible Investigator (RI) must be an employee of Griffith University and preferably a person with an academic appointment.

The Responsible Investigator is the person with ultimate responsibility for the care and use of animals in the project (see 2.4.5 of the Code)

Ordinarily, the RI is closely involved with a project, and there is no doubt about that person's responsibility. Where students are using animals in a teaching and/or research program, the RI has responsibility to ensure that students carry out procedures and conduct themselves in an ethical manner.

Acceptance of this responsibility is implicit when the application is signed and submitted.

Coversheet – Start and End dates (Project Duration)

Please submit your application more than a month (preferably two months) before your planned starting date. Ensure the start date does not pre-date the next AEC meeting date.

Projects are normally approved for a maximum period of three years provided no significant modifications are made to the approved protocol. An extension can be granted for one further year. Further approvals require the submission of a new application.

Submission deadlines are available on our website.

Questionnaire – 10 (Lab) 11 (Field) – Project Aim

This section is crucial in assessing the scientific merit and the necessity of animal use.

The level of details should fall between broad generalities and an exposition of the intricacies of the project's empirical and theoretical background.

Many applicants have trouble expressing the aims and purposes of their project in lay terms. Some researchers give a brief abstract that would be suitable for a journal but is mystifying to the committee. Other researchers go to the other extreme and give an extensive background found in a grant application, which also mystifies the committee.

Please detail the aim of the study, the reason you want to complete it (e.g. the benefit it may provide to humans or animals), what result you expect to achieve and why. The aims and significance of most projects can be explained in approximately half a page of plain English. When addressing this issue, think about the style of English you would use if you were explaining your project to an intelligent person with a basic science education.

If the use of jargon and scientific language cannot be avoided, it is essential that the acronyms and glossary question is completed to allow all members of the AEC to have sufficient information to complete an assessment of the proposal.

Questionnaire – 12 (Lab) 14a (Field) – Ethical Justification of Animal Use

This question allows the Committee to assess the balance of harms to benefits in this study to support the case of ethical acceptability of the proposed use of animals. It is important to address and acknowledge the harms that the animals will endure (negative experiences), which might range from mild inconvenience (ie. handling) to more uncomfortable or invasive procedures. These must be considered alongside the potential benefits of the study. A common mistake in answering this question is to ignore the harms and mention only the benefits, which makes it hard for the Committee to assess the harm/benefit ratio.

Questionnaire – 13 (Lab) 14 (Field) – 21 – 3Rs justification

In this question, a clear description of the steps taken to consider and apply the 3Rs (Replacement, Refinement, Reduction must be provided (clauses 1.18-1.30 of the Code). Therefore, your application must convince the AEC that:

1. Animal use is essential to achieve the stated goal (i.e. no other means are available);
2. The minimum number of animals required to achieve valid data has been proposed for use, with the least possible impact on the well-being of animals involved.
4. All possible alternatives to using have been investigated and used wherever possible. The AEC must be informed of alternatives that exist and why these cannot be used.
5. All Refinements which may improve animal welfare have been considered.

Questionnaire – 16 (Lab) Best Practice Methodology

Investigators need to provide statistical justification for why they require the use of the number of animals requested. This includes information about the proposed statistical analysis, blinding and randomisation, outcome measures, independent variables and experimental design. Investigators are encouraged to upload supporting documents such as sample size calculations and pictorial diagrams.

An example of an acceptable statement:

"We will use 4 groups of twenty animals each. Group one will have x and drug A. Group two will have x and drug B. Group three will have x and both drugs. Group four will be controls (no x and no drugs). Data will be compared using a Student's "T" test. Using data from previous experiments or from a pilot study, a sample size calculation (provided) shows that that twenty will be an adequate group size to show significant results."

Examples of unacceptable statements:

"Rats of this strain cost $11.00 each. We have $110 dollars available, therefore we propose to use ten rats."

"We have time to perform about three studies per week. Therefore in a year we will be able to use about 3 x 52 = 156 animals."

"I've been doing this for years and have published similar work in peer reviewed journals. I know it will take about 200 animals."

“Our previous (successful) ethics application had a sample size of 20 subjects; this we plan to use 20 in this comparable experiment.”

"I need about 200 animals."

“We choose to use only 5 animals to minimise loss of life”

“This experiment will require a total of 10 subjects in order to achieve significant results.”

Questionnaire – 20 (Lab) – Protocol and Sequence of Events

The Committee often has difficulty discerning the sequence of events that occurs to the animals, particularly when there are different groups of animals receiving different treatments. Uploading a complete protocol document is requested here to outline the experiment/s as a whole including all relevant information.

Accordingly, please list the procedures in sequence. Flow charts and other diagrams are very helpful to the committee. If there are several groups of animals that receive different

combinations of treatments, please list them in tabular form and include the number of animals in each group.

The AECs must assess the impact on animals of all procedures and the project as a whole.

The application should therefore focus on what is happening to the animals and what is being done to ensure their wellbeing.

The impact of procedures needs to be clearly detailed. The investigator should provide step-by-step examination of all treatments (substances, dose rate, routes, volumes, needle size, anaesthetics, analgesics, surgical procedures etc) and the expected effects on the animals.

The Checklist contains an extensive list of items that should be considered while completing your application.

Questionnaire – 21 (Lab) Daily Animal Monitoring

The level of monitoring required will vary according to the type of research and animals used. Some of this information may have already been provided in answer to the question on impact but it should be reiterated for the assistance of the committee. Details should include methods used and frequency of monitoring. Please note that for animals in the Biosciences Facility, it is an expectation that monitoring will occur daily and this must be captured in the monitoring scoresheet. A monitoring sheet appropriate for the study and animal model should be provided, including relevant clinical signs that may be observed. It is essential that all necessary columns of this table are completed fully.

A template animal monitoring scoresheet is available but this MUST be modified for your animal model and particular study. The unmodified template WILL NOT be accepted as a monitoring scoresheet.

It is recommended that prior to submission; you discuss your animal monitoring template with the Animal Facilities Manager, if any animals will be housed in Griffith University Animal Facilities.

Questionnaire – 24 (Lab) – 47 (Field) – Pain and Distress

The possibility of pain/stress must be assessed and information on how this will be dealt with provided. This must include an acknowledgement that all animals experience stresses from transportation and especially, in the case of wildlife, the stress of capture. Where pain may be experienced, the use of analgesics must be considered.

Questionnaire – 43 (Lab) – 58 (Field) – Supervision of Experiments and Care of Animals (Team Member Table)

Applications where the relevant experience in procedures to be undertaken and the species being used has not been included will not be approved by the committee. Only include names of Animal Facilities staff if they will have some involvement with your study outside their normal duties.

It is STRONGLY recommended that prior to submission; you discuss your application with the Animal Facilities Manager, if any animals will be housed in Griffith University Animal Facilities.

The template Team Member Table is available at: https://www.griffith.edu.au/research/research-services/research-ethics-integrity/animal/animal-ethics-applications

Questionnaire – 35 – 43 (Field) – Impact

It is very important that you provide all the relevant information and answer the questions as fully as possible. The Checklist will help you in this.

The Checklist contains an extensive list of items that should be considered while completing your application.

Questionnaire – 26 (Lab) 46 (Field) – Re-use of Animals

Re-use will be authorised when it reduces the number of animals bred for research and when the previous research was relatively innocuous, e.g. reward training, behavioural observation, and drawing of blood samples.

Questionnaire – 50 – 53 (Lab) 62 – 69 (Field) – Other Approvals

Any required approvals/permits should be sought before an application is submitted, with copies provided to the AEC.

Animal Usage Tab – Invasiveness

The categorisation of procedures aims to give some indication of the 'invasiveness' or 'impact' of the work on the animals involved. Select the highest appropriate numeral code from those listed on the Animal Usage Tab to describe the types of procedures carried out on the animals in the project. Where projects involve animals being subject to different procedure categories, please save each group separately on the Animal Usage Tab.

The table below provides further details regarding how different types of animal use should be categorised:

#	Description	Examples
1	**Observation Involving Minor Interference** Animals are not interacted with or, where there is interaction, it would not be expected to compromise the animal's welfare any more than normal handling, feeding, etc. There is no pain or suffering involved.	• Observational study only • Breeding animals for supply, where only normal husbandry procedures are used • Breeding or reproductive study with no detriment to the animal • Feeding trial, such as Digestible Energy determination of feed in a balanced diet • Behavioural study with minor environmental manipulation • Teaching of normal, non-invasive husbandry such as handling and grooming
2	**Animal Unconscious Without Recovery** Animal is rendered unconscious under controlled circumstances (i.e. not in a field situation) with as little pain or distress as possible. Capture methods are not required. Any pain is minor and brief and does not require analgesia. Procedures are carried out on the unconscious animal which is then killed without regaining consciousness.	• No experiments of living animals eg animals killed painlessly for dissection, biochemical analysis, tissue studies, etc • Collecting blood or plasma from anaesthetised dogs prior to euthanasia • Teaching surgical techniques on live, anaesthetised patients which are not allowed to recover following the procedure
3	**Minor Conscious Intervention without Anaesthesia** Animal is subjected to minor procedures that would normally not require anaesthesia or analgesia. Any pain is minor and analgesia usually unnecessary, although some distress may occur as a result of trapping or handling.	• Injections (not vaccination trials), blood sampling in conscious animal • Minor dietary or environmental deprivation or manipulation, such as feeding nutrient-deficient diets for short periods • Trapping and release as used in species impact studies etc • Trapping and humane euthanasia for collection of specimens • Stomach tubing, branding, dehorning young animals, shearing
4	**Minor Operative Procedures With Recovery** The animal may be rendered unconscious with	• Biopsies • Cannulations (minor) • Sedation/anaesthesia for relocation,

	as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and post-operative analgesia may be appropriate. Field capture using chemical restraint methods is also included here.	examination or injections/blood sampling
5	**Surgery With Recovery** Animal may be rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Post-operative pain is usually considerable and at a level requiring analgesia.	• Orthopaedic surgery • Abdominal or thoracic surgery • Transplant surgery • Cannulations (major) • Mulesing, castration without anaesthesia • Other major surgeries
6	**Minor Physiological Challenge** Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge may cause only a small degree of pain/distress or any pain/distress is quickly and effectively alleviated.	• Minor infection, minor or moderate phenotypic modification, early oncogenesis • Arthritis studies with pain alleviation • Prolonged deficient diets, induction of metabolic disease • Polyclonal antibody production • Antiserum production • Vaccination trails
7	**Major Physiological Challenge** Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological	• Major infection, major phenotypic modification, oncogenesis without pain alleviation • Arthritis studies with no pain alleviation • Uncontrolled metabolic disease • Isolation or environmental deprivation for extended periods • Total body irradiation and reconstitution • Monoclonal antibody raising in mice

	processes. The challenge causes a moderate or large degree of pain/distress which is not quickly or effectively alleviated.	
8	**Death As An Endpoint** This category only applies in those rare cases where the death of the animal is a planned part of the procedures. • Where predictive signs of death have been determined and euthanasia is carried out before significant suffering occurs, they may be placed in category 6 or 7. • It does not include: death by natural causes; animals which are euthanased as part of the project; animals which are euthanased if something goes wrong; animals euthanased for dissection or for use as museum specimens; or accidental deaths.	• Lethality testing (including LD50, LC50) • Toxicity testing with death as a planned end-point without euthanasia • Dose rate studies for feral animal control; or • Disease studies in which it is planned that animals will die Death as an end point does not include: • Death by natural causes (incidental to the scientific use) • Animals which are euthanased on completion of the project • Animals which are euthanased as a result of an unexpected adverse event • Animals euthanased for dissection or for use as museum voucher specimens • Accidental deaths
9	**Production of Genetically Modified Animals** This category is intended to allow for the variety of procedures which occur during the production of genetically modified animals. As animals in this category may be subjected to both minor and major physiological challenges and surgical procedures, this category reflects the varied nature of the procedures carried out. It effectively includes ALL animals used in GM production other than the final progeny which are used in a different category of procedure.	• Initial breeding of animals used for GM production including vasectomised males, donor and recipient females • Breeding and maintenance of GM colonies • Animals culled as part of the GM production process

Animal Usage Tab – Animals Requested

The number of animals should be adequate to achieve reliable results, either in terms of sufficient statistical power or in terms of replication across experiments.

The AEC recognises that some projects require hundreds and even thousands of animals. Where a large number of animals are required, the applicant should take special care to describe how the number of animals relates to the number of experimental and control conditions in the questionnaire or attached Protocol. If the study is observational or you are not sure of how many animals may be encountered, please provide a best estimate, and explain how numbers have been calculated.

Check to ensure that the total number of animals requested is the same as the number indicated in the questionnaire or attached Protocol.

Animal Usage Tab – Locations

If animals will be housed or used inside a Griffith Animal Facility (Biosciences Facilities) please specify the location on the Locations Tab.

Documents Tab

Where relevant, ensure to attach an animal monitoring sheet to the Documents Tab and, if applicable, a welfare assessment score and judgment sheet tailored appropriately for use during the project if animals are to be held for any period. An example of a lab animal monitoring template can be accessed via: https://www.griffith.edu.au/research/research-services/research-ethics-integrity/human/applications-and-forms. Information regarding how the wellbeing of animals will be monitored and assessed throughout the project, the frequency of monitoring and assessment, the actions to be taken if problems are identified, and the criteria for intervention points and humane endpoints must be included.

Annual/Final /Progress or Adverse Event Report

Annual, Final and Progress Reports can be submitted via RIMS. Annual Reports are due by 25 January each year.

A Report of Adverse or Unexpected Event Form can also be submitted via RIMS. In the case of an adverse or unexpected event the Animal Facilities Manager and AEC Secretary should be notified promptly (by email or phone) and a completed report submitted via RIMS.

Ethical Guidelines for Students Using Animal or Animal Tissues for Educational Purposes and Conscientious Objection

This document should be printed and used in classes where students use animals or animal tissues for educational purposes.

Students, including HDR students, should be made aware of the Conscientious Objections to the Use of Animals or Animal Products in Teaching and Assessment Policy.

The most common problems with applications that delay approval

Common problems with applications that may result in delays to the approval process include:

- The application is not written in plain English and clarification is required. Failing to describe the aims and benefits in simple language prevents the lay members of the AEC being able to assess the remainder of the application - ***Ensure all specialist language has been replaced or explained***
- The use of animals is not adequately justified or the statistical justification is poorly addressed. (see 1.1 of the Code for the criteria used by the AEC in determining if a project is justified and in weighing up the benefits of the project against the potential effects on the animals) - ***Ensure you appropriately address each of the 3Rs. You may require a biometrician to provide justifications for the numbers proposed.***
- The severity of the procedures is not adequately justified.
- The use of non-animal alternatives is not adequately addressed.
- There is inadequate or insufficient information, especially with respect to procedures, dose rates and monitoring - ***Provide full details of procedures. When referring to SOPs, provide a copy of the SOP.***
- There is a discrepancy between the numbers of animals requested and the description of the experiment(s) in the text of the application

Further information

The first contact point for further information about these matters is the relevant Animal Ethics Advisor. If your Animal Ethics Advisor cannot assist you, please contact the Animal Ethics Coordinator in the Office for Research by emailing animal-ethics@griffith.edu.au or calling 56618.

You can find a list and contact details of AEAs, as well as the details of the contact details of the ethics team in the Office for Research by visiting the Griffith University Research Ethics and Integrity website: https://www.griffith.edu.au/research/research-services/research-ethics-integrity/research-ethics-and-integrity-team

RIMS - Please refer to the Quick Reference Guide available at https://www.griffith.edu.au/__data/assets/pdf_file/0026/209744/Create-a-Animal-Ethics-Application-Quick-reference-guide-v1.15.pdf for instructions on how to complete a new application. For RIMS technical support please call Enterprise information Management Support on 55 544.