

<p>P4</p>	<p>Minor surgery with recovery</p> <p>Animal is given appropriate regional or general anaesthesia with as little pain or distress as possible. A minor procedure such as cannulation or skin biopsy is carried out and the animal allowed to recover. Depending on the procedure, pain may be minor or moderate and postoperative analgesia may be appropriate. Field capture using chemical restraint methods is also included here.</p> <p><i>Examples</i></p> <ul style="list-style-type: none"> • <i>Biopsies</i> • <i>Cannulations</i> • <i>Sedation/anaesthesia for relocation, examination or injections/blood sampling</i> • <i>Castration with regional or general anaesthesia and post-operative analgesia</i>
<p>P5</p>	<p>Major surgery with recovery</p> <p>Animal is rendered unconscious with as little pain or distress as possible. A major procedure such as abdominal or orthopaedic surgery is carried out and the animal allowed to recover. Post operative pain is usually considerable and at a level requiring analgesia.</p> <p><i>Examples</i></p> <ul style="list-style-type: none"> • <i>Orthopaedic surgery</i> • <i>Abdominal or thoracic surgery</i> • <i>Transplant surgery</i>
<p>P6</p>	<p>Minor physiological challenge</p> <p>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.</p> <p><i>Examples</i></p> <ul style="list-style-type: none"> • <i>Minor infection</i> • <i>Minor or moderate phenotypic modification</i> • <i>Early oncogenesis</i> • <i>Arthritis studies with pain alleviation</i> • <i>Induction of metabolic disease</i> • <i>Prolonged deficient diets</i> • <i>Polyclonal antibody production</i> • <i>Antiserum production</i>
<p>P7</p>	<p>Major physiological challenge</p> <p>Animal remains conscious for some or all of the procedure. There is interference with the animal's physiological or psychological processes. The challenge causes a moderate or large degree of pain/distress which is not quickly or effectively alleviated.</p> <p><i>Examples</i></p> <ul style="list-style-type: none"> • <i>Major infection</i> • <i>Major phenotypic modification</i>

	<ul style="list-style-type: none"> • <i>Oncogenesis without pain alleviation</i> • <i>Arthritis studies with no pain alleviation</i> • <i>Uncontrolled metabolic disease</i> • <i>Isolation or environmental deprivation for extended periods</i> • <i>Monoclonal antibody raising in mice</i>
<p>P8</p>	<p><i>Death as an endpoint</i></p> <p>This category only applies in those rare cases where the death of the animal is a planned part of the procedures and animals die but are not euthanased. Where predictive signs of death have been determined <i>and</i> euthanasia is carried out before significant suffering occurs, they may be placed in category P6 or P7.</p> <p><i>Examples</i></p> <ul style="list-style-type: none"> • <i>Lethality testing (including LD50, LC50)</i> <p>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.</p>
<p>P9</p>	<p><i>Production of genetically modified animals</i></p> <p>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 <i>and</i> major physiological challenges <i>and</i> 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.</p> <p><i>Examples</i></p> <ul style="list-style-type: none"> • <i>Initial breeding animals for GM production</i> • <i>Animals culled as part of the GM production process</i>

Section 5. Standard Operating Procedures

Standard Operating Procedures (SOPs). Standard operating procedures are used to provide step by step guides to performing relatively complex activities that are likely to be repeated. In the context of the use of animals for scientific purposes they might include activities that require moderate skill levels and that are less complex (e.g. palpating genitalia, taking blood samples) through to complex activities requiring special skills at an advanced level (e.g. arthroscopy, embryo collection).

There is an existing register of SOPs- this is the first place to look to see if the activity(ies) in your project already have relevant SOPs. If SOPs do not exist for the activity(ies) in your project, then you will need to submit one with the application. There is a template available on the Animal Ethics webpage.

There may be some activities that do not warrant an SOP in the context of using animals for scientific purposes:

- Activities that are commonly carried out in the general care of animals whether they are being used for scientific purposes or not e.g. feeding, watering. However, if the project requires significant changes to normal practices then an SOP should be considered. It should also be noted that there may be SOPs at the section level for commonplace activities such as feeding and watering.
- Activities that are unlikely to be repeated e.g. one off experimental diagnostic or surgical techniques. In these cases a description detailed enough to allow replication should be provided in the application, with due regard to confidentiality and intellectual property considerations.

'A standard operating procedure should never be difficult to read or vaguely worded. It should be brief, easy to understand and contain action steps that are simple to follow. A good standard operating procedure should clearly outline the steps and inform the employee of any safety concerns.'

Section 6. Licences for the research project

Licences for the research project.

This is a requirement of the Code (see below) and can facilitate both the success of the application and the execution of the project itself.

2.4.8 During planning, investigators must consider the following factors and be satisfied that:

(xxi) appropriate approvals, and any administrative requirements of the institution and the AEC, are in place. These could include permits and licences, documentation to certify the biological status of animals, biosafety, work health and safety considerations, and arrangements for projects conducted at more than one institution.

N.B. If you intend to use Genetically Modified Organisms (GMOs) then you need to access the [Office of the Gene Technology Regulator \(OGTR\)](#) to ensure you have applied for appropriate permission. You must also notify the Biosafety Committee.

The Committee recognises that in some instances permits/licences may not be granted until the project application has gained approval- in these instances evidence of the application for the permit/licence should suffice.

For example, you might need a licence if you are intending to work with [native wildlife](#).

Section 7. Collaboration

The Code devotes five clauses to collaboration between accredited establishments (CI 2.6.4-2.6.8). The intention is to ensure that projects using animals for scientific purposes involving more than one institution have appropriate scrutiny and oversight. This is effected by requiring formal agreements between the establishments that clearly state which responsibilities are to be carried by the different parties.

The following are examples of collaborative research:

- A research or teaching project carried out at more than one Establishment;
- A research or teaching project involving investigators from more than one Establishment;
- A research or teaching project in which animals are moved from one Establishment to another during the project;
- A research or teaching project where animals are cared for by animal care or research staff of more than one Establishment, either simultaneously or at different times during the project.
- A research or teaching project where the investigators from one Establishment are conducting research or teaching at another Establishment.

To satisfy the requirements of the Code you must:

- Ensure that all relevant Ethics Committees are aware of the project and that they have given approval for it to commence.
- Ensure that a formal collaborative agreement is in place that clearly states who is doing what in the project, including responsibilities for animal care and monitoring, and reporting requirements such as Unexpected Adverse Events.
- Ensure that the agreement details methods and responsibilities for communications between the project team and the Establishments.
- Ensure that the agreement is signed and included with the application(s) to the relevant Ethics Committees.
- Ensure that the project does not commence before all relevant Ethics Committees have given their approval and issued an 'Authority to Use'

In some cases, the Ethics Committees will delegate one to be the approving Ethics Committee. For this to happen the project team will have to notify the Ethics Committees involved so that communication can be established early and decisions made about which committee will hold the delegation.

'Institutions must 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

(vi) clear communication channels are established between all AECs and all investigators.'

Institutions may agree to one AEC (the delegate AEC) approving the entire project, provided that all institutions involved agree to delegate the responsibility for decision making to, and support the necessary actions of, that AEC.

'2.6.6 Arrangements between institutions should be as a formal agreement. Institutions should avoid unnecessary duplication of processes.

2.6.7 Arrangements should include mechanisms for reporting non-compliant activities between institutions and AECs.'

Investigators must 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).

Research Data Management Plan

Research Data Management (RDM) is a recommendation of the *'Australian Code for Responsible Conduct of Research'* and is required by many funding bodies. CSU has established an [RDM policy](#) which requires all active research projects to have an RDM plan, whether the projects are funded externally or not. This section is where you include the RDM relevant to this project. [Good practice in RDM](#) is important to satisfy multiple stakeholders.

Section 8. Project History

It is important that the Committee is able to make informed decisions about the ethical justification for a project. The information elicited by this section allows for contextualisation of the application. This information will not necessarily impede the progress of an application and may facilitate approval.

A **repeated** project may have implications for Reduction of animal use. There would have to be strong justification for an exact repeat of a project. If the numbers and methodology have not changed, what valid reasons are there for repeating the project? One example might be to gain more statistical significance by effectively increasing the sample size?

A **continuation** of an expired project may also have implications for Reduction of animal use. Why does the project need to continue beyond the original anticipated timeframe? Valid reasons might include (not an exhaustive list) ill health of participants, environmental conditions such as drought/bushfire/flood and the unavailability of suitable animals.

A significantly **revised** project may have implications for Replacement, Reduction and Refinement, depending on what revisions have been implemented.

A follow up to a **pilot study** will be influenced by the findings of the pilot study. The Committee should be able to cross reference to the pilot study to ensure that the current application complies

with the pilot study findings and that any results that could facilitate implementation of the 3Rs have been considered.

3.1.4 If the potential impact on the animal, or the validity and efficacy of criteria for intervention to minimise harm, including pain and distress, cannot be predicted on the basis of available evidence, the incorporation of a pilot study into the design of the project must be considered.

Section 9. Animal supplier details

The source of the animals being used must be recorded for compliance with the legislation and for reporting requirement to the NSW government. There are also reporting requirements to governments of other jurisdictions.

With privately owned animals the project team must ensure that the ‘*Animal use consent form*’ and ‘*Animal use information form*’ are completed.

Section 10. Fate of animals

The ‘*Re-use*’ of animals may not be known if your project is using animals from the CSU teaching herd/flock. In these instances, choose the ‘*Return to normal husbandry conditions or natural habitat*’ option.

N.B. The option of ‘*euthanasia*’ in this context is referring exclusively to the intended fate of the animal(s) as a **consequence and integral part** of the project. That is, euthanasia is an intended, deliberate outcome of the project, rather than a contingency in the case of welfare concerns that arise during the project.

It is **NOT** referring to euthanasia carried out as a consequence of unforeseen events e.g. injuries, medical emergencies. Euthanasia due to unforeseen events is addressed in section 11.4 ‘*Animal management*’ as an intervention measure if welfare issues are identified.

3.4.1 Provisions for animals at the conclusion of their use must be made promptly and in accordance with the animal ethics committee (AEC) approval. Provisions may include:

- (i) rehousing (rehomeing) (see Clauses 3.4.2–3.4.3)*
 - (ii) return to normal husbandry conditions or natural habitat (see Clauses 3.4.4–3.4.5)*
 - (iii) humane killing (see Clauses 3.3.45–3.3.46)*
 - (iv) reuse (see Clauses 1.22, 1.24 and 2.3.15)*
 - (v) tissue sharing (see Clauses 1.26, 2.4.24 and 2.5.10).*
-

What method of euthanasia will be used? The method used has to comply with published guidelines or, if there are no guidelines, industry accepted standards. The American Veterinary Medical Association’s (AVMA) Guidelines for the Euthanasia of Animals is a suggested reference.

Areas where euthanasia is conducted in institutional settings should be isolated from other activities, where possible, to minimize stress on animals and to provide staff with a professional and dedicated work area. Attempts should be made to minimize smells, sights, and sounds that may be stressors for animals being euthanized. (AVMA guidelines 2020 p55)

Where will euthanasia be performed? **Refinement** must be considered when euthanising- apart from appropriate techniques, consideration must also be given to killing in an area that is physically separate from other animals. If possible, euthanasia should be performed out of sight, hearing and olfactory range of other animals- this may not be practicable in all cases due to the acute sensory abilities of some species e.g. ultrasonic hearing in some rodents, strong sense of smell in dogs.

3.3.45 The method and procedures used for killing an animal must be humane and: (vi) ensure that animals are killed in a quiet, clean environment away from other animals

There may be considerations for euthanasia that are not obvious, and these should be weighed when determining the method and place. Examples include the persistence of fear pheromones when killing multiple individuals of the same or related species, and balancing handling and restraint against the stress they can cause in otherwise unhandled (e.g. wild) or minimally handled (e.g. extensively farmed) animals.

Who will perform the euthanasia? It is important to nominate the team member(s) responsible for this function- they must be competent and have current experience with the species.

What training and experience do they have in the euthanasia methods used? To ensure that euthanasia is carried out with minimal pain and distress to the animal it is necessary that the operator is practised and skilled with the species involved and under the expected circumstances.

Animal remains disposal details. The destination of carcasses and other biological waste may become important if tracking is required. In many cases the destination will be the normal waste disposal method e.g. VDL waste facilities.

Section 11. Animal monitoring, housing and management

Monitoring. There are multiple references in the Code about the need for investigators and animal carers to monitor animals. The Chief Investigator is ultimately responsible for monitoring during the life of the project

Monitoring: 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).

2.4.4 Investigators must:

(vii) maintain records of the care and use of animals

2.4.8 During planning, investigators must consider the following factors and be satisfied that:

(xiv) procedures are in place for monitoring and managing animal health during the project

(xvii) the wellbeing of the animals is regularly monitored and assessed by competent people

2.4.18 Investigators must take steps at all times to safeguard the wellbeing of animals by avoiding or minimising known or potential causes of harm, including pain and distress, to the animals. Steps include:

*(vi) ensuring that animals are **monitored** and **assessed** at all stages of the project for signs of pain and distress, including deviations from normal behaviour (see Clauses 3.1.20–3.1.21). Such monitoring and assessment must be conducted at a frequency sufficient to detect such signs at an early stage, as determined by the procedure, and ensure that the planned endpoints are detected*

(vii) maintaining records of monitoring and assessment of animal wellbeing (see Clauses 2.4.30– 2.4.33 and 3.1.22)

2.4.20 Investigators must:

(ii) ensure that the scope of monitoring the wellbeing of the animals at all stages of their care and use in the project is clearly outlined and communicated to all parties. Depending on the type of project, this may include monitoring by animal carers.

How will animals be identified? Identification may be fundamental to the experimental design e.g. if randomisation or blinding are used. At the very least it is important in most species for recording ill health/injury/death. The method of identification will vary depending on species and context. The identification might be permanent e.g. brands, microchips, or temporary e.g. rodent tail marking, cage cards.

If it is not appropriate or possible to identify individual animals in your project e.g. large numbers of fish all subject to identical treatment, then this should be answered as ‘Not applicable due to...’. Even in these circumstances good practise suggests that the group should be identified so that data can be allocated to the treatment/procedure applied.

Which member/s of the research team will be responsible for monitoring the animals on a daily basis? If it is not practical to monitor the animals on a daily basis e.g. extensively managed animals, then it should be stated here and the proposed monitoring frequency stated.

Which member/s of the research team will be responsible for monitoring the animals at night, on weekends and holidays? There is an expectation that animals in research projects will be monitored ‘with sufficient frequency to ensure that any harm, including pain and distress, is promptly detected

2.4.32 Investigators must ensure that records 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) any additional information requested by the AEC

(vi) names of people performing the procedures and entering the records

(vii) names and contact details of people responsible for monitoring and emergency incidents

and managed'. This includes ensuring adequate monitoring of animals during periods outside nominal working hours.

What method/s will be used to monitor the animals? The answer to this question could be a summary of the answers to the following three questions, or refer directly to those responses. The answer could include the physical methods used to monitor e.g. visual, physical examination, CCTV etc but should include how often they will be monitored (frequency), what criteria are being used for interventions and the nature of those interventions if they become necessary.

The aim of this question and the three following it is to ensure that the ACEC knows **what is being monitored, how that monitoring is occurring, what will trigger interventions and what will happen if interventions are necessary.**

3.1.21 *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.

3.1.22 *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.

Some points about monitoring:

- Monitoring records may be of several types. For example:
 - *General records of animal health during the project*- these records may be completed by either the investigators and/or animal care staff, depending on the way the project is being run
 - *Records of procedures undertaken during the project/experimental records* e.g. surgical interventions, treatments applied. Where these details are recorded is at the investigator's discretion. It may be convenient to use the animal health records for this purpose, or the nature of the project might dictate a separate set of records e.g. specific procedures might be better recorded in standalone documents for ease of reference/analysis.
 - *There are some records that, by their nature, will be standalone.* An obvious example is anaesthetic monitoring records.
 - All types of records may be combined but this is unlikely given the difference in focus of the data collected in each one. Experimental records may be subject to higher confidentiality and intellectual property considerations, for example, than general records.
- It is very unlikely that *'one size will fit all'* in terms of monitoring records. Several examples are provided in the *'Forms'* page of the Animal Ethics website but in many instances these will need to be contextualised for the specific project.
- The requirements for monitoring will vary dependent on several factors. Some factors that might be important include:

- *Species*- For example, it may not be practicable to perform physically close daily monitoring with extensively farmed species (e.g. sheep) or the species may only lend itself to behavioural observations as an early indicator of ill health (e.g. many fish spp.)
- *Life stage*- For example, close physical monitoring of near term pregnant animals may be counterproductive, depending on the degree of domestication, species behaviour and how habituated they are to human interference.
- *The nature of the project*- For example, handling may be limited by the procedures performed (e.g. animals that have been treated with radioactive material/cytotoxic chemicals) and this may limit the ability to record e.g. vital signs.
- *How the animals are managed*- For example, sheep on an extensively managed farm may be monitored less frequently and without direct physical contact, compared to those that are penned, or in metabolism crates. In this example the level of detail may also vary. **However, if ill health/injury is noted then the expectation under the Code is that immediate action is taken** to remedy the situation.
- Some records will be simpler than others e.g. surgical projects may have more complex record keeping requirements than feed trials.

Important points about monitoring records:

- The ‘records’ can be either paper or electronic
- The daily health monitoring records **must** be accessible to all members of the team with responsibility for animal care in the project.
- If sensitive/confidential/IP information is a factor, then a strategy to keep this information separate should be considered. However, there must be sufficient information recorded to allow staff charged with daily care to make informed decisions about the need for intervention, or at least to inform the relevant person in the research team.
- The monitoring records **must** be accessible for inspections/audit
- The monitoring records **must** include the following features at a minimum:
 - Date
 - Animal identification- this might be individual animals or based on a group identification such as pen/tank/cage etc. Individual animals should always be identified if possible.
 - Observation columns- observations are usually a mix of quantitative and qualitative. The columns should follow a frequency pattern dependent on the nature of the project e.g. hourly, daily, weekly
 - **A description of intervention points**- see also ‘animal management’ below
 - Actions taken when intervention points are reached

Housing

Where will the animals be housed? This information allows the Committee to confirm that procedures are being performed in facilities that have been inspected and approved (within CSU) and that the facilities are appropriate for the procedures being proposed.

There are responsibilities imposed by the Code on the Institution, investigators, the Committee and animal carers regarding oversight and suitability of the facilities used for care and scientific use of animals. The Committee inspects the CSU facilities on an annual basis. The facilities are listed on CSU’s licence as an accredited establishment as ‘*Designated land for accreditation as an animal*

research establishment'. CSU is also a licensed animal supplier and the facilities used to hold animals are detailed in this licence.

If the facilities are not on the existing CSU licence, then they will have to be inspected by the ACEC before the project can commence. If the facilities are too remote to physically inspect then evidence allowing the suitability of the facility will need to be accessed- this evidence might include still photos, video and/or written evidence from a delegate of the Committee.

The ACEC needs to know that the facilities are listed on the accreditation licence, have been recently inspected and endorsed as fit for purpose (suitable for the species, procedures, length of project etc.).

If the housing has not been inspected recently or at all, then it will need to be inspected if logistically possible. If the housing is too geographically distant, further information might be required in the form of photographic/video evidence or more detailed description of the housing.

Describe the type of housing that will be provided? The housing may be subject to existing applicable standards/guidelines e.g. *Australian industry welfare standards and guidelines for goats May 2019, Australian Animal Welfare Standards and Guidelines for Cattle Edition One 2016, Guidelines for the housing of mice in scientific institutions 2012*. On the basis of the information provided the ACEC may compare the housing against the guidelines to confirm that CSU is pursuing best practice.

What is the maximum and minimum number of animals per cage/pen/paddock? This information may be compared to existing standards and guidelines to confirm that CSU is pursuing best practice. There may be situations where the guidelines cannot be satisfied due to experimental design- the reasons for this could be explained in Section 2.3 of the '*Project description*'- '*Refinement*'.

Will animals be single housed? Wherever possible social species should be kept in socially stable groups. This is not always possible due to experimental design- the reasons for this could be explained in Section 2.3 of the '*Project description*'- '*Refinement*'.

Feeding and water provision? Automated systems have an inherently higher risk of failure- for example a power failure or blockage in a rodent facility using fully automatic watering systems could leave thousands of animals without water for several days.

Frequency and method of feeding and watering should ensure that contingencies are addressed- apart from automated systems breaking down other issues might include: accommodating shy feeders, ensuring that resources are available to all heights of animals in the cohort, ensuring subject familiarity with the system/food used (e.g. some animals may require training to use nipple water dispensers, some may have been weaned too recently, some food stuffs may not be accepted at first), identifying resource guarders/bullies and managing them.

Describe the environmental enrichment that will be provided? Ensuring **positive welfare** is just as important as avoiding negative welfare.

Environmental enrichment can be a significant factor in improving the welfare of animals being used for scientific purposes and it has been argued that it may improve experimental outcomes. Wherever possible, and within the constraints of the experimental protocol, environmental enrichment should be provided. Literature searches will usually provide significant amounts of information regarding enrichment for many species. The AWO can assist with suggestions if required.

There may be some protocols that by their nature cannot include some or all forms of environmental enrichment e.g. the need to keep social animals in isolation, requirements after surgery that limit interaction with the environment/conspecifics. **This should be explained in this section.**

List any other husbandry procedures that may be required during the study (e.g. foot trimming).

In most projects this will be answered with *'Not Applicable'* due the project length.

If the project is of sufficient length that normal husbandry procedure will occur within the scope of the project then they should be noted here.

Animal management.

Explain what will be done if an animal health / welfare issue is identified? List the criteria for intervention, treatment or withdrawal of the animals from the study. The criteria listed will vary depending on the nature of the project, the species and, in some cases, the temperament of individual animals.

It is important that the criteria clearly set out **when** treatment/intervention/withdrawal will be implemented and that the monitoring of the animals allows for **early** intervention using the criteria.

In the majority of cases the criteria will also be integrated in the monitoring format as they will provide the basis of either treating the subjects and/or terminating their involvement in the project.

If the project includes an **anticipated mortality rate** (e.g. extensive sheep management, lambing ewes, feedlot cattle, and some wildlife studies) then what criteria will be used to determine whether the ill health/death is related to the project *'treatment'* rather than the expected causes of morbidity/mortality and therefore becomes an *'unexpected adverse event'*? Information might include descriptions of clinical signs or increased severity that incriminate treatment involvement. This information is important to allow the Committee to understand when the need for further diagnostic tests/necropsy might be warranted and when the investigator can be satisfied that mortalities/morbidities fall within the anticipated rates/severity.

The descriptions of what will be done to respond to health and welfare issues do not necessarily need to be extremely detailed. It may be enough to state that *'appropriate veterinary treatment will be applied/sought'* or *'the individual animal will be retired from the project'* or similar. Detailed information about drug doses, routes of administration and so on are not required- they will be recorded on either Unexpected Adverse Events reports and/or appropriate monitoring forms.

It may be necessary to euthanise animals on welfare grounds, as opposed to euthanasia as an integral part of the project (Section 10.2). If euthanasia is performed on welfare grounds, how will this be done, and by whom? 'Intervention' can include euthanasia. The method of euthanasia and the person performing it should be identified in this section.

Who is responsible for the management of emergencies? There must be at least one named person with responsibility for emergencies.

Which practice/veterinarian will provide veterinary services? State their contact details. This may be one nominated practice but in some cases may involve several practices.

If there are a number of sites being considered for the project then it may not be possible to provide details at the time of application. If this is the case, then wording to the effect of *'the local veterinary*

practice-details to be provided' should suffice. Once the locations have been finalised the Committee must be advised as well as the details of the nominated veterinary practice.

Section 12. Technical competence.

The table provides the opportunity to nominate exactly **who** is competent to do **what** in the project. It also assists the Committee to recognise the lines of responsibility within the project by clearly identifying those team members who are already competent and those who will receive training and supervision within the team.

The Code supports team members who still require training in activities by allowing them to operate under the **direct supervision** of other team members who are already competent.

Current experience and/or training required. If the team member already has suitable **experience** then state this. If they do not, then make a short statement about how they will achieve this training/experience.

The emphasis in this section is on **experience** with the procedures/species. **Qualifications** are important and should be included, but they may not by themselves allow the Committee to make a determination about the competence of the team member.

EXAMPLE: a veterinarian with specialist qualifications in canine internal medicine is very highly **qualified** but may have next to no post graduate/recent **experience** (or be competent) with rodents- the argument that principles can be extended across species is valid in some endeavours e.g. aseptic technique, but does not necessarily hold up in other areas e.g. handling, restraint, assessment of pain.

EXAMPLE: a specialist physician (human) by definition is highly qualified and may have considerable expertise in venepuncture in humans, even those who are challenging (e.g. obese, infants, geriatrics). However, this does not indicate **competence** in non-human species and the further the species deviates from primate anatomy the less likely it is that their skills and knowledge could be transferred. Groups such as lagomorphs, rodents, reptiles and birds present challenges that are not present in human subjects.

The code uses the following definition:

Competent: 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

This definition is not inclusive of the Australian Qualifications Framework (AQF) levels, which overtly reference the scope of how, and manner in which, the competence is expected to be applied. There are different expectations of someone who is competent at Certificate II level as opposed to Certificate IV level, for example.

The remaining information requests in this form are straightforward. However, if you have any questions about them, please contact the Governance Officer or the Animal Welfare Officer.