

Animal Research Review Panel Guideline 31

Ethical decision-making in Animal Ethics Committees

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Introduction

This guideline aims to enhance the capacity of Animal Ethics Committees (AECs) in Australia to undertake effective, ethical decision-making. It has been produced to provide guidance on decision-making processes that put respect and protection of animals at their core.

In 2020, The Animal Research Review Panel (the Panel) carried out an AEC education and training survey. The survey sought information on resources AEC members used and insights into additional material that could be developed to assist AECs.

The results identified a need for information to support AECs assessing applications, and specifically, information on how to address difficulties faced by committee members when navigating difficult discussions at meetings. This included negotiations, the balance of power between different AEC member categories, unconscious bias, challenging the status quo, consensus decision making, accessibility of information for non-scientific members and others, and compassion fatigue. Survey respondents also requested scenarios on complex ethical decision-making.

This guideline is supplementary to guidelines already issued by the Panel, under the umbrella of “Operation of Animal Ethics Committees”, and the National Health and Medical Research Council’s *Australian Code for the Care and use of Animals for Scientific Purposes*, issued by the Federal government.

Ethical decision making and the Australian Code

The introduction to *The Australian Code for the Care and use of Animals for Scientific Purposes* (the Code) states that:

The purpose of the Code is to promote the ethical, humane and responsible care and use of animals for scientific purposes. The Code provides an ethical framework and governing principles to guide decisions and actions of all those involved in the care and use of animals for scientific purpose.

An obligation to respect animals underpins the Code. This obligation brings with it a responsibility to ensure that the care and use of animals for scientific purposes is ethically acceptable, balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits to humans, animals or the environment.

Therefore, a key responsibility of an AEC is to ensure that when making decisions, their underlying philosophy centres on “respect for animals” which must “underpin all decisions and actions involving the care and use of animals for scientific purposes”.

Respect for animals is demonstrated in several ways, including only using animals when justified, applying high standards of scientific integrity, and implementing the 3Rs (replacement, reduction and refinement) (Section 1.1).

Sections 1.5-1.7 of the Code require that to permit research to proceed, researchers need to demonstrate that the project has scientific or educational merit and in addition, that the benefit of the project to humans, animals or the environment outweighs the harm to the animals involved (often described as the harm-benefit assessment).

Animal Ethics Committees and ethical decision making

The primary responsibility of an AEC is to ensure that all activities relating to the care and use of animals are conducted in compliance with the Code (Clause 2.3.1 of the Code). AECs are the principal way of safeguarding the ethical components in the care and use of animals in research (ss 13-16 of the *Animal Research Act 1985* (NSW)). Properly functioning AECs evaluate whether planned research is justified, determining whether it should proceed and if modifications are required to minimise animal harm.

Challenges to the integration of ethical decision-making and the proper functioning of AECs can stem from two sources: first, the structure and operation of AECs; and second, how projects are evaluated.

Structure and operation of AECs

The structural composition and operation of AECs can influence decision-making. Decision-making can also be influenced by the leadership and membership of the AEC, committee dynamics (including member participation) and any inherent bias towards research interests.

While an AEC's membership must meet the defined ratio of members from each category, (Clause 2.2.25 of the Code), the operation of an AEC is often influenced by Category B members due to their substantial and recent experience in the use of animals for research and/or teaching, and further, that these members often hold leadership roles on the committee.

Consequently, the views and contributions of Category C and D members, whose positions on the committee arise due to their demonstrable commitment to, and experience in, furthering the welfare of animals (Category C) and as bringing a completely independent view to the AEC as a member of the general public (Category D), can sometimes be diluted. These members can also be reluctant to raise issues for consideration. This can result in perceived bias in favour of approving projects.

These and other influences are summarised in Table 1, which lists potential procedural and compositional problems of AECs and possible solutions.

Evaluation of project justification by AECs

When evaluating whether the project is justified, AECs need to distinguish three elements, scientific merit, social value and ethical justification.

- Scientific merit – includes evaluating the hypothesis, the experimental design and how the project advances scientific knowledge. A project may have merit in a technical sense (hypothesis, project design) but may not advance scientific knowledge. Thus, technical merit is necessary but insufficient because the project must also advance scientific knowledge noting this may include repetition of previous work to assure scientific validity.
- Social value – the project should make a constructive and beneficial contribution to society. Benefits can be challenging to assess, and can become conflated with institutional strategies and goals, rather than specific scientific and social contributions deriving from the project.
- Ethical justification – the project should demonstrate respect for animals. Adopting respect as an ethical principle recognises that an animal has inherent value and that the interests of the animal need to be considered. The animal's wellbeing ought to be promoted and any argument to override the animal's interests must be carefully appraised with particular justification for activities for which Replacement, Reduction and Refinement (the 3Rs) cannot be fully applied, for the project to proceed (the Code 2.7.4 (v) a).

Harm-benefit analysis

Ethical decision-making can be challenging for a number of reasons. For instance, ethical justification is often subsumed into a harm-benefit assessment that weighs the scientific merit and social value of a proposal against harm to animals. Another factor that complicates decision-making occurs when a project has been subject to independent peer review and received external funding. AEC members may feel that it is not their role to challenge the scientific merit of a project, nor to refuse consent for a funded project to proceed. They may therefore limit their role to recommending how harm to animals can be minimised, without considering the social value and ethical justification. Yet, since these issues are typically not part of the peer review process (with the funding bodies relying upon the administering institutions to undertake this responsibility), the only place they are addressed is by AECs (Schuppli 2011). Complex issues of how pain and distress (physical and psychological) are weighed against scientific merit, social value and ethical justification may therefore not receive the attention they deserve.

Moreover, while harm-benefit assessments appear to be objective, often harms and benefits are not directly comparable. Benefits are projected future benefits and attaining these may not be certain, while some harms to animals will be unanticipated, but will nevertheless occur. Using harm-benefit assessments may also undermine alternative ways of considering ethical issues. For example, non-scientist AEC members may appeal to other approaches to support their decisions, such as, moral intuition, adherence to community standards and social licence, rights-based views or an empathy with animals and values, such as, no unnecessary harm. In addition, harm-benefit analysis may not otherwise take into account where, and how, to determine the upper limits to harm (Grazia and Beauchamp 2019).

Enhancing ethical decision making

The role of the chair

AEC members view the chair as important to their effective participation. The chair can act as a counterbalance to institutional bias which favours scientific interests and potentially creates a daunting, or even hostile atmosphere, for minority members.

In the words of Schuppli and Fraser (2007), the chair should “[keep] the meetings efficient...[maintain] an open and respectful atmosphere where all views are accepted...[play] a neutral role by participating in the discussion without influencing decisions...[ensure] that issues are not missed...[keep] the investigator’s interests in mind and...[help] the committee to reach a consensus”.

Skills in these areas are vital to help alleviate concerns of animal welfare and community members that their contribution carries less weight, because they are outnumbered by scientist members, whose knowledge of technical issues may exceed the expertise of lay members.

The format of the ethics application

The application format can be a useful tool to guide decision-making. Researchers should be provided with templates that require them to clearly set out the scientific merit, social value and ethical justification of their project. The onus is therefore on the researcher to justify the project and identify social and ethical issues separately from the scientific merit of the project.

This approach allows AEC members to identify the separate strands more clearly and target their comments where needed.

Researchers should use plain English that is understandable by non-scientists.

The latter may not read some sections of the application because they do not believe they will understand the technical aspects of the application or if they do read the application, still do not understand some aspects of the project.

Identifying red flags

Red flags are signals that prompt further scrutiny of a project. They can include:

- Discrepancies between the project and the Code or institutional policies and guidelines
- Poorly completed applications
- The potential for high levels of animal suffering
- The type of species involved – for example non-human primates, cats and dogs

Case Studies

A series of case studies has been included to provide scenarios for AECs to consider and explore the issues discussed in this guideline.

Conclusion

This guideline focusses on assisting AECs to enhance ethical decision-making in the evaluation of scientific research. The process extends beyond evaluating the scientific merit of a project and includes consideration of social value and respect for animals. For these reasons, the guideline highlights the importance of the chair, the need for clarity in the ethics application (including the use of plain English) and the significance of red flags. This guideline should be read in conjunction with existing ARRPPolicies and Guidelines.

Acknowledgements

The Animal Research Review Panel acknowledges survey feedback from establishment AECs across NSW regarding their education and training uses and needs which was used to help inform and develop this guideline.

Table 1 – Checklist of potential procedural and compositional problems of research ethics committees, and possible solutions.

Taken and modified from C A Schuppli and D Fraser, "Factors Influencing the Effectiveness of Research Ethics Committees", (2007) 33 *Journal of Medical Ethics*, 294, 298, doi:10.1136/jme.2005.015057.

Problem 1: Committee composition creates a bias towards institutional or research interests versus interests of research subjects and the community

Solutions:

- Increase the number of community members from Categories A, C and D.
- Make committees aware of problems of group deliberation, such as polarisation, concurrence-seeking tendency and suppression of dissent
- Use a committee that it is not affiliated with the institution
- Choose a chair who holds a senior position in the institution
- Use a consensus approach for decision-making but without a requirement for unanimity to allow for dissent by clarifying functions expected of the committee and designing composition accordingly

Problem 2: Committee dynamics prevent full participation of members

Solutions:

- Increase the proportion of minority members to reduce feelings of isolation or intimidation
- Implement administrative processes that allow members to make comments that are collated and distributed prior to the meeting. This can be particularly important for lay members to ask questions where they do not understand technical aspects of the project – ensure that the queries are addressed prior to, or at the meeting
- Chair to ensure that all comments are addressed, giving members a valid voice
- Provide respectful and open committee atmosphere so that members do not feel intimidated and feel their views are valued. Could be achieved by
 - Clarifying policy on the roles of minority members, particularly community members
 - Training members on the roles of all Category members especially C and D so that their distinctive contributions are valued
 - Training members on the mandate of the committee
 - Providing leadership training for the chair to ensure all information and views are considered
 - Training all members on the differences between evaluations for scientific merit, social value and ethical justification and how these operate in practice
- Appoint members to serve as devil's advocate to challenge majority views and prevent "groupthink"

Problem 3: Recruitment methods create a bias towards institutional or research interests versus interests of research subjects and the community

Solutions:

- Recruit community members by
 - Advertising broadly for members
 - Approaching community organisations for nominations
 - Establishing an intake interview process
 - Reducing barriers to joining by providing an honorarium or by recruiting from organisations that recognise volunteer work by their employees

Problem 4: Motivation for joining is to pursue agendas other than the committee mandate

Solutions:

- Consider applications from all people interested in joining, to avoid excluding important views
- Achieve a greater balance in the proportion of different types of members, so that no one perspective dominates
- Ensure, perhaps through interviews, that all prospective members know and accept the mandate of the committee

Problem 5: Excessive workload or inadequate participation for adequate review

Solutions:

- Establish realistic level of time commitment per member and design committee functioning to stay within this limit
- Form another committee to share the workload or divide workload between members
- Develop an expedited review process for proposals of minimal risk or invasiveness
- Ensure prospective members agree to the required time commitment including meetings, preparation and training
- Monitor and limit absenteeism
- Increase committee size to allow members time off
- Ensure that the institution rewards participation of committee members—for example, provide honorarium
- Ethics application form to set out to facilitate adequate review including specifically, the scientific merit, social value and ethical justification of the project

Problem 6: Low turnover limiting new ideas and risk of indoctrination

Solutions:

- Defined terms of office
- Reassess contributions of members on renewal of their term

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CASE STUDY ONE

DOGS AND GOATS

Please note that all place names, the name of the endangered bird and institution name are fictitious.

Background

Eco Island lies off the coast of New South Wales. In the eighteenth century, sailors released goats on the island so if there were shipwrecks, people could capture the goats and have meat to eat. The island is also home to the endangered sea bird, *Diomedidae beautifulus* (Beautiful Albatross). The goats have destroyed much of the vegetation and nesting sites on the island, further endangering the Beautiful Albatross (albatross). Regulators have tried to control the goats by shooting, but the terrain on the island makes this difficult, with some goats avoiding the shooters, meaning that after a decade or so, goat numbers increase. Broad-scale poisoning is also not an option, due to the possibility of ingestion by native animals.

Project

Professor AA from BB University has received funding from the Office of the Environment in NSW to conduct a research project to eradicate the goats. If successful the project methodology can be used on other islands with similar problems.

The project involves two stages. The first is to capture wild dogs and train them to kill and eat goats. In accordance with Schedule 4 of the *Biodiversity Conservation Act 2016* (NSW) the following are listed as a threatening process, so using the dogs and goats in the manner anticipated by the research project would assist in reducing numbers of both these animals, who are listed as a threatening process.

- Competition and habitat degradation by Feral Goats, *Capra hircus* Linnaeus 1758
- Predation and hybridisation by Feral Dogs, *Canis lupus familiaris*

The first stage of the project involves training the dogs by using live goats (who are captured from the wild). It would be possible to use goat carcasses but this makes the project more expensive and resource-intensive, so is not considered feasible.

The second stage involves implanting the dogs with a time-release poison and then releasing them on Eco Island during the non-nesting stage of the albatross. This will give the dogs approximately 8 months to destroy the goats. At the end of the 8 months, rangers would shoot the dogs, but in case they miss any, the poison would kill them.

The project was peer reviewed and the review pointed to three very real environmental benefits of the project: first, the project used two animals (wild dogs and goats) already classified as pests; the project would bring the albatross back from the brink of extinction; and, the project would provide a template for managing goats and other pest animals on islands. The peer review also pointed to the fact that in times of drought the goats have insufficient food and would die a slow death from starvation and thirst.

NOTES:

1. How would members evaluate the harm-benefit analysis and does this represent the limits of ethical decision-making?
2. Is there anything in the scenario that raises a red flag?
3. What is the harm, what is the benefit? – consider not just the animals on the island but also the goats used in training. What about other animals on the island - appears that the dog carcasses will be left on the island. Could other animals ingest the poison pellets?
4. How is the benefit measured – will there be counts of the albatross? What about other animals on the island?
5. What about harm to the dogs?
6. Ethical issues
 - a. Scientific merit
 - b. Social Issues
 - c. Justification
 - d. Don't forget 3.3.43 and 3.3.44 of the Code

CASE STUDY TWO

CAT ERADICATION

Please note that all place and institution names are fictitious.

Background

Cats arrived with the first fleet and in the early days of the colony of New South Wales were valued as a companion animal, as well as for their ability to catch rats and mice. By the end of the nineteenth century, cats had also been classified as “the enemy of the rabbit” and released by the thousands in the hope they would control the spread of rabbits. Barely one hundred years later, predation by free-roaming cats was officially listed as a threatening process to native biodiversity. Free roaming cats are implicated in the decline of native biodiversity and have proved particularly difficult to manage due to their fecundity.

Project

Professor AA from BB University has received funding from the Australian Research Council to trial a new method of cat eradication. If successful, it has the potential to be used across Australia, particularly in outback regions where cat management is particularly problematic, among other things, due to low population density of cats per hectare, which makes current management resource intensive.

The project involves two stages:

Part one are laboratory trials and part two are field trials.

Both parts trial a new poison with two components. The first component renders the cats unconscious and the second kills them. Unlike current methods, which have been critiqued because cats appear to shake and suffer before they die, rendering the cats unconscious means they don't feel anything. The poison is also delivered via a cat trap which does not attract native animals.

For the laboratory trial, cats are sourced from pounds and the dosage of the poison administered until researchers determine the minimum dosage that will render cats unconscious and then kill them. This trial will take twelve months to complete. Once the dosage has been fine-tuned the field studies commence for two years. Statistics will be generated of the number of sightings of cats and native animals during that time, as well as the number of cats killed.

The project was peer reviewed and the review pointed to the very real environmental benefits of the project, noting the damage that free roaming cats cause. The peer review also noted that “animal activists need to understand that it is not possible to manage the environment without invasive animals being culled. This project represents a milestone in that one of these invasive animals, the cat, can be humanely culled.”

NOTES:

1. How would members evaluate the harm-benefit analysis
2. What is the harm, what is the benefit? – cats in the laboratory, cats in field studies. What happens to cat carcasses in field studies? Could other animals ingest the poison by gaining access to the traps?
3. How is the benefit measured? Will the population counts be enough?
4. Ethical issues
 - a. Scientific merit
 - b. Social Issues
 - c. Justification
 - d. Don't forget 3.3.43 and 3.3.44 of the Code

CASE STUDY THREE

FISHING AS A SCHOOL SPORT

Please note that all place and institution names are fictitious.

Ethical Issue: Should we allow school students to participate in fishing as a school sport and have fish humanely killed?

Background

The *Australian code for the care and use of animals for scientific purposes*, Section 4.7 states:

Institutions must ensure that humane killing of animals is not demonstrated to, or carried out by, primary or secondary level students unless it is required:

- (i) To achieve an educational outcome in science as specified in the relevant curriculum or competency requirement, or
- (ii) As part of veterinary clinical management of an animal, under the direction of a veterinarian.

This presents both a legal and ethical issue for many schools in NSW that engage in the activity of fishing as a sport activity. For many, the purpose of this activity is to harvest and kill fish.

Issues

Issues that arise from complying with this section of the Code include:

- Schools must only practise catch and release when fishing or not at all
- Many students may be fishing at times when not at school sport and be poorly educated about good sustainable fishing practices. By fishing in a supervised environment with a teacher, opportunities to learn good animal welfare and sustainable practices will be provided
- Inconsistency as recreational fishing is carried out by millions of Australians not in a school context.

What are the different views and what evidence is available?

In 2022 it is estimated that there are approximately five million recreational fishers in Australia. It is the largest and most widely dispersed recreational activity that uses a natural resource.

The *National code of practice for recreational fishing* has been developed by the Australian government with the objective to empower recreational fishers to make responsible decisions in the pursuit of their passion. It emphasises respect, responsibility and sustainability and applies to all recreational fishing pursuits.

Are there difficult questions need to be explored?

These questions may include:

- Many recreational activities have impacts why should school students not have the same opportunities?
- Is it important to educate students about good animal welfare and sustainable fishing practices?
- Some fishers do not follow good practices – should all be judged by the standards of others?
- How does recreational fishing impact the ecology of any area?

What are the costs and the consequences?

Consequences of demonstrating the humane killing of fish when carrying out fishing as a school sport may include:

- Encouraging/discouraging students to participate in fishing out of school hours
- Teaching students to kill fish humanely, use sustainable fishing practices and learn about the *National code of practice for recreational fishing*
- Destruction of fish and effects on the environment.

CASE STUDY FOUR

NOT IN MY BACKYARD

Please note that all place and institution names are fictitious.

Background:

Re-use of animals is often discussed as a method of reducing the number of animals used for scientific purposes through its ability to facilitate more information from fewer purchased animals. It can also reduce costs associated with animal research. Re-use of animals within institutions or facilities overseen by a common animal ethics committee is common. Less common may be cases where animal re-use occurs between institutions and therefore requires consideration from multiple animal ethics committees who may have different approval outcomes.

Project:

Researchers at the University of North Sunnyvale are performing a level 7 high impact procedure approved by their animal ethics committee. At a recent conference they met with researchers from the Cloudy Mountain Medical Institute who have access to equipment not available in North Sunnyvale that may provide some interesting mechanistic data on outcomes observed by the North Sunnyvale researchers. Together they work on a project proposal in which animals will first undergo the level 7 procedure in North Sunnyvale before being transported to Cloudy Mountain for tissue collection and analysis. The researchers at Cloudy Mountain prepare an ethics application for the sourcing of pre-treated animals from North Sunnyvale to conduct their experiments. However, the animal ethics committee at Cloudy Mountain Medical Institute have previously deemed the level 7 procedure to be too great a risk to animal welfare that the use of animals cannot be justified and therefore unethical.

The committee must now consider if they will approve the use of animals at their institution knowing that the animals have undergone a procedure, they have deemed unethical to be performed at Cloudy Mountain medical Institute.

Notes:

- Section 2.3.1 of the Australian code for the care and use of animals for scientific purposes identifies the primary responsibility of an Animal Ethics Committee is “to ensure, on behalf of the institution for which it acts, that all activities relating to the care and use of animals are conducted in compliance with the Code.”
- An AEC must be satisfied that there is sufficient evidence to support a case that the proposed use of animals is justified
- Section 2.3.15 of the Code states “When considering approval for the reuse of animals, the AEC must take into account:
 - The pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions”
- Section 2.4.1 of the code states that “investigators have personal responsibility for all matters that relate to the wellbeing of animals that they use including their housing, husbandry and care”
- Section 2.4.16 “Investigators must consider the wellbeing of animals used in the project in the terms of the cumulative effects of the animal’s lifetime experience”