Obtaining Research Ethics Approval

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Research ethics are 'norms of conduct that distinguish between acceptable and unacceptable behaviour' when performing scientific research. [1] Ethical conduct requires more than simply 'doing the right thing'; it requires acting in the right spirit and with respect and concern for fellow human beings, animals, and the environment. [2] In Australia, obtaining ethics approval is mandatory for research involving human or animal participants.

Why is it relevant?

Human research has contributed enormously to scientific breakthroughs. While much of this research carries minimal risk, some forms of human research can involve significant harm if conducted improperly. Historical examples demonstrate how serious ethical failures can lead to the violation of human rights, such as inappropriate and poor research practices that have been conducted in relation to Aboriginal and Torres Strait Islander people in Australia. In recognition of these risks, ethics guidelines have been developed to ensure that interactions between researchers and participants are ethically acceptable to the Australian community, supported by laws that impose general and specific responsibilities on researchers and institutions and establish rights for participants.

Furthermore, ethics review of human research is not uniform; rather, it operates at different levels depending on the degree of risk involved. Ethics review processes also consider potential power imbalances between researchers and participants due to institutional affiliation, socioeconomic factors, or cultural context. Researchers are therefore expected to ensure that participation is voluntary, informed, and free from coercion or undue influence.

As part of the ethics application process, researchers are typically required to justify their study design, including providing a sample size estimate (depending on the research scope) or equivalent rationale to show that the study is methodologically sound and has sufficient statistical power to address the research question. This requirement reflects

the ethical principle that research should avoid exposing participants to unnecessary burden or risk through underpowered or unnecessarily large studies. [3] [4]

Animal research has also been essential to scientific progress, yet it too can involve significant harm if not performed responsibly. Ethical frameworks exist to ensure that the use of animals in research is justified and reflects community expectations regarding animal welfare. Australian laws and institutional guidelines set clear responsibilities for researchers to minimise harm, apply ethical principles such as replacement, reduction, and refinement, and ensure that interactions between humans and animals meet accepted ethical standards. [5]

Practical Steps

1. Determine whether your research requires ethical clearance prior to commencing research.

- According to the *National Statement on Ethical Conduct in Human Research (2025)*, research conducted with or about people, or their data or biospecimens, is considered human research and requires ethical clearance prior to commencing research.
- According to the Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition), research or teaching with live non-human vertebrates and cephalopods requires approval from an Animal Ethics Committee (AEC) prior to commencing any animal work. This includes research or teaching activity that involves the use, handling or observation of animals, or any activity that affects the habitat of animals. In some institutions (e.g., UQ), ethics approval for using biological material derived from animals is also required.

2. Refer to the procedure for ethics review established by your institution.

- Institutions are responsible for establishing procedures for the ethics review of human and animal research. [6] Researchers should therefore follow the ethics review procedures in place at their institution, typically managed by the university's ethics and integrity office. It is likely the type of review required will differ depending on the degree of risk involved in the research. For example, a project which foresees greater than discomfort for participants may require a Full Committee Review, whereas a project in which the only foreseeable risk is discomfort may be deemed suitable for review through a lower risk pathway review. For human research, these procedures will reflect the two broad themes considered in human research ethics: the risk and benefits of research, and participants' consent.[7] For animal research, these procedures will be

underpinned by the obligation to respect animals, which involves balancing whether the potential effects on the wellbeing of animals are justified by the potential benefits to humans, animals and the environment. [8]

Case Study

Case Study 1: Among contemporary examples, the Human Genome Diversity Project (HDGP), which took place between 1991 and 1997, is a well-known case of controversial and unethical research practices, famously labelled by Indigenous leaders in Australia (and many outside Australia) as "the vampire project". The initiative was heavily criticized for portraying Indigenous Peoples as "Isolates of Historical Interest" whose genetic information needed to be harvested before they "vanished". This project faced intense opposition due to its lack of adequate consultation and consent mechanisms, the immortalization of Indigenous cells, and significant concerns regarding biopiracy and the commercial exploitation of genetic material [9].

Case Study 2: A Monash University study that exposed adolescent female rats to non-fatal strangulation and traumatic brain injury to model intimate partner violence has drawn strong ethical criticism. Supporters argue the animal model offers important insights into brain tissue that cannot be analysed in living humans. However, critics question whether the severe suffering and oxygen deprivation inflicted on the animals can be justified when non-animal methods, such as neuroimaging and computational models, are available. [10]

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