ACU Research StewardshipTraining

Update to the National Statement 2025

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November 2025

In recognising Aboriginal and Torres Strait Islander peoples' spiritual and cultural connection to Country and in continuing ACU's commitment to Reconciliation, I would like to commence the meeting by acknowledging the First Peoples and the Traditional Owners and custodians of the Country where ACU campuses are located.

We respectfully acknowledge our Elders past and present and remember that they have passed on their wisdom to us in various ways. Let us hold this in trust as we work and serve our communities.

Overall Changes

- Effective from 1 October 2025
  - All reviews from this date to be in line with 2025 version*
- Major thematic changes:
  - Increased risk of harm rather than vulnerability
  - Emphasis on inclusion – risk mititgation
  - Distinction between research risk vs circumstantial risk
  - Not all research with certain “vulnerable” groups is to be automatically considered higher risk.
  - Community engagement throughout the research process “social and cultural implications.” particularly for participants who may be at increased risk.
  - stronger links to more detailed documentation for Aboriginal and Torres Strait Islander research
- New Section 4

Section 4 - 2025

Section 4 Ethical considerations specific to participants in research

- **Chapter 4.1 Ethical issues in recruitment and involvement of research participants who may experience increased risk**
- Chapter 4.2 **Pregnancy,** the human fetus and human fetal tissue
- Chapter 4.3 Children and young people
- Chapter 4.4 People in dependent or unequal relationships
- **Chapter 4.5 People experiencing physical or mental ill-health or disability**
- Chapter 4.6 Research conducted in other countries
- Chapter 4.7 Research with Aboriginal and Torres Strait Islander people and communities
- **Chapter 4.8 Research conducted during natural disasters, public health emergencies or other crises**
- Chapter 4.9 Research that may discover illegal activity

2023 version

Section 4 Ethical considerations specific to participants

- Chapter 4.1 Women who are pregnant and the human fetus
- Chapter 4.2 Children and young people
- Chapter 4.3 People in dependent or unequal relationships
- Chapter 4.4 People highly dependent on medical care who may be unable to give consent
- Chapter 4.5 People with cognitive impairment, an intellectual disability, or a mental illness
- Chapter 4.6 People who may be involved in illegal activities
- Chapter 4.7 Aboriginal and Torres Strait Islander Peoples
- Chapter 4.8 People in other countries

Assessing Risk

Updates to Risk Assessment made in 2023

- Risk classifications apply to <u>all</u> participant groups.
- Lower risk research:

  "the only foreseeable risk is no greater than discomfort. Research in which the risk for participants or others is greater than discomfort is not low risk research"

Figure 1: Risk profiles of research

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

In assessing the risks of a research project, researchers, institutions and ethics review bodies should only consider the risks that may result from the research, as distinguished from the risks participants would be exposed to if they were not participating in the research.

Section 4 Introduction

- Risk should be considered on a spectrum
- Risk will change over the course of the Research
- Risk can change due to participant's circumstances
- Risk can be hard to determine:

  (a) the nature, design of the research

  (b) sources of risk of harm specific to potential participants as individuals or by virtue of their group membership or other circumstances

  (c) interaction between (a) and (b).

Chapter 4.1 Ethical issues in recruitment and involvement of research participants who may experience increased risk

Sources of Risk for participants:

- Life stages, physical or cognitive states
- Life circumstances:

Context of the research:

- Goals of research
- Social or political implications

Risk Mitigation:

- Proposals should include risk minimisation strategies

Inclusiveness:

- Community consultation
- Aim to include rather than exclude participants

https://www.tudelft.nl/over-tu-delft/strategie/integriteitsbeleid/human-research-ethics/research-design-2-risk-planning-session

What do researchers (and therefore HRECs) need to consider?

- Who are we planning to include as participants?
- Who else might be part of the potential participant pool?
- Could this project increase the risk of harm for participants?
- What is the nature and extent of that risk?
- Are there conflicts of interest that could be a source of increased harm?
- What impact could our findings have on individuals, groups, or communities?
- How can we minimise, mitigate, and manage any increased risks?
- Beyond reducing risk, how can we respect participants' needs and interests and empower them throughout the research process?

MINIMISE RISKS	Can I do this research while collecting less personally identifiable research data?
Which colleagues should I discuss these issues with? Do I have the required expertise in my research team?	Am I sure that my participants fully understand what they will do, what the potential risks are and how their physical, emotional and reputational security will be ensured?
What long-term effects can the research and its outcomes have on the participants and their communities?	Do I have the right insurances, licences and safety certification – the right or expertise – in place?
What difference is there between what is legal and what is ethical?	**MANAGE RISKS**
Putting myself in the participant's shoes: is it possible a lay person may experience participating differently than I am anticipating?	How do I ensure that I legally and responsibly execute the agreement I've made with my participants in the Informed Consent?
Are there any unnecessary risks in the study design?	What is the plan if I or someone else moves to another organisation? What happens if there is a data breach?
Can I do this research with a less vulnerable group of participants?	When and how do I evaluate the decisions I made?

Chapter 4.2 Pregnancy, the human fetus and human fetal tissue

https://neurosciencenews.com/neuroscience-terms/pregnancy/

- Pregnancy and potential to become pregnant during the research
  - Focus on clinical research
  - Not all research risky for pregnancy
  - Only ethical if aimed to directly benefit pregnant woman or fetus.
- Separation of in-utero fetus and the mother.
  - Only ethical if promotes life of fetus and includes signs for monitoring fetal distress
- Where treating health professional involved interests must be disclosed.
- Additional guidance provided regarding consent for use of fetal tissue after separation from mother.

Chapter 4.3: Children and young people

- Significant updates to this chapter, now codifying child assent.
- Researchers must specify:
  - Whether they will obtain assent + consent or young person only
  - how they will assess maturity and capacity to provide assent or consent to participation in the research.
- State or territory legal requirements about age of consent must also be met.
- Research with children or young people must be consistent with the National Principles for Child- Safe Organisations, endorsed by the Australian Council of Governments.

Figure 2: Guide to how participation of children and young people in research is authorised based on levels of maturity, requirements for consent and assent, and other provisions

Category	Type of permission or agreement required			How research participation is achieved
	Child or young person ASSENT	Child or young person CONSENT	Parent/ guardian CONSENT	
Infants who are unable to take part in discussions.	NO	NO	YES	Valid parental/guardian consent
Young children who are able to understand some relevant information and to take part in limited discussions.	YES	NO	YES	Valid parental/guardian consent
Young people of developing maturity who are able to understand the relevant information, although more vulnerable because of a decreased ability to safeguard their own interests.	YES	NO	YES	Valid parental/guardian consent
Young people of developing maturity who are able to understand the relevant information, and for whom parental/ guardian consent is not possible.	YES	NO	NO	HREC approval as per paragraph 4.3.8
Mature young people who are able to understand the relevant information and, due to their maturity, have the ability to safeguard their own interests.	NO	YES	NO	Valid participant consent

Chapter 4.3: Children and young people

https://puskapa.org/en/blog/publication/1137/

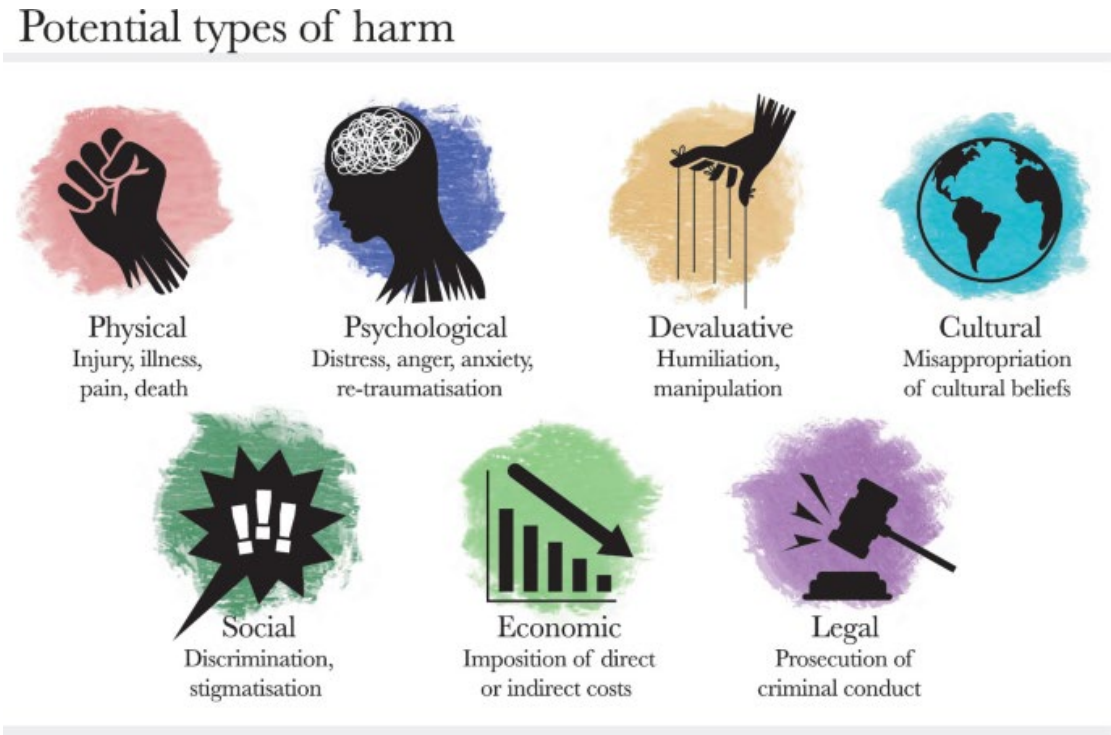
Researchers should advise:

- **How contact may occur** – e.g., in person, phone, email, or online.
- **Possibility of incidental contact** – especially through opt-in methods like surveys or social media.
- **Supervision of direct contact** – who will oversee it (e.g., researcher, teacher, parent).
- **Required credentials** – for researchers and staff, including checks like police clearance or child protection training.
- **Record-keeping** – how contact and any safety concerns will be documented.

https://childethics.com/ethical-guidance/

Chapter 4.4: People in dependent or unequal relationships

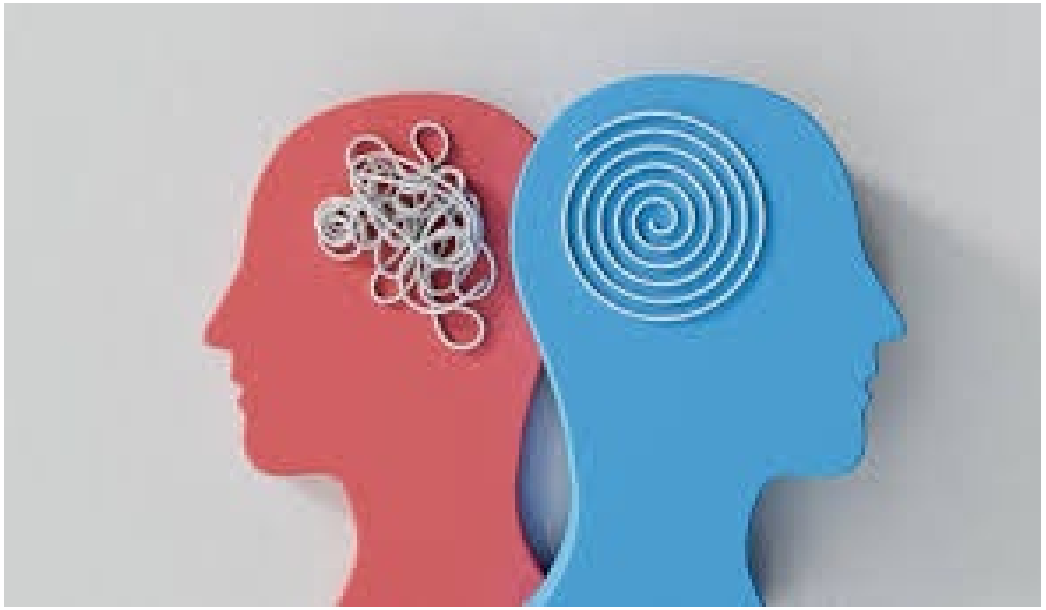
- Researchers and reviewers should assess:
- **Participant autonomy** – whether individuals may feel pressured or unable to decline participation.
- **Power dynamics** – if the invitation comes from someone the participant relies on (e.g., caregiver or service provider).
- **Conflicts of interest** – whether those in authority might benefit from participants' involvement.
- **Risk of harm** – if participation or refusal could negatively impact the individual.
- **Best interests** – whether participation aligns with the participant's wellbeing.



Chapter 4.5: People experiencing physical or mental ill-health or disability

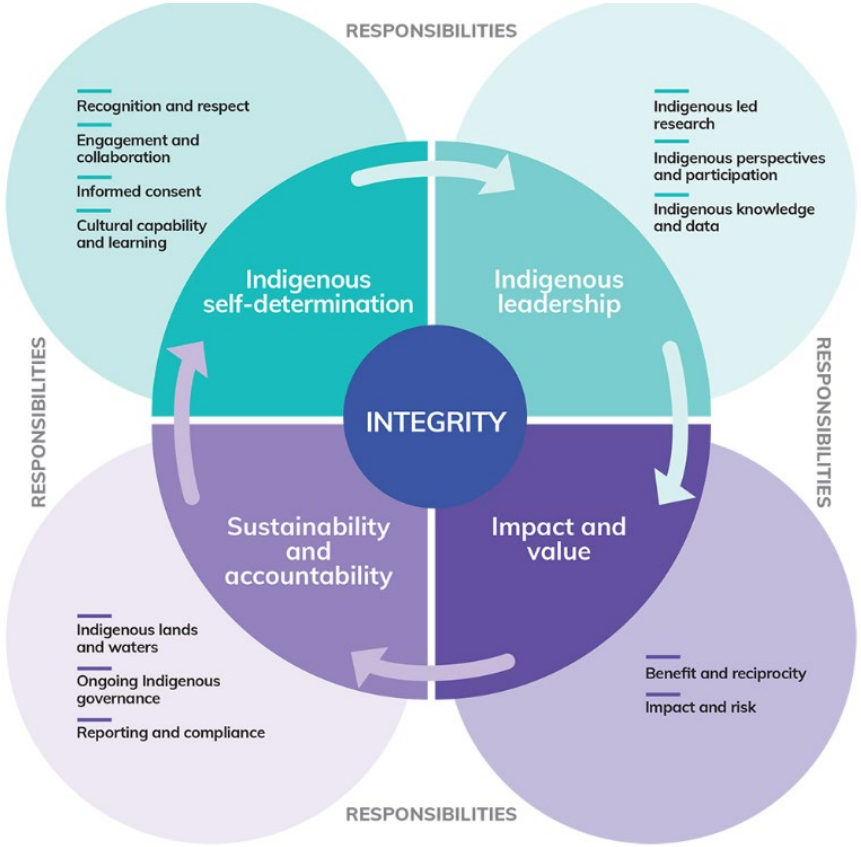
- Combination of previous Chapters 4.4 and 4.5
- The chapter is divided into specific sections regarding:
  - General Considerations around consent,
  - Research with people who are seriously ill or unconscious,
  - Consent for emergency care research and intensive care research,
  - Research with terminally ill participants,
  - Research with people with disability

Chapter 4.5: People experiencing physical or mental ill-health or disability



- Exclusion from research should be justified
- Research design should be enabling for people with disability.
  - Adapting consent processes
  - Ensuring accessible data collection methods, locations, and schedules
- Consultation and engagement
- Participant support strategies
- Ongoing consent

Chapter 4.7: Aboriginal and Torres Strait Islander People and Communities

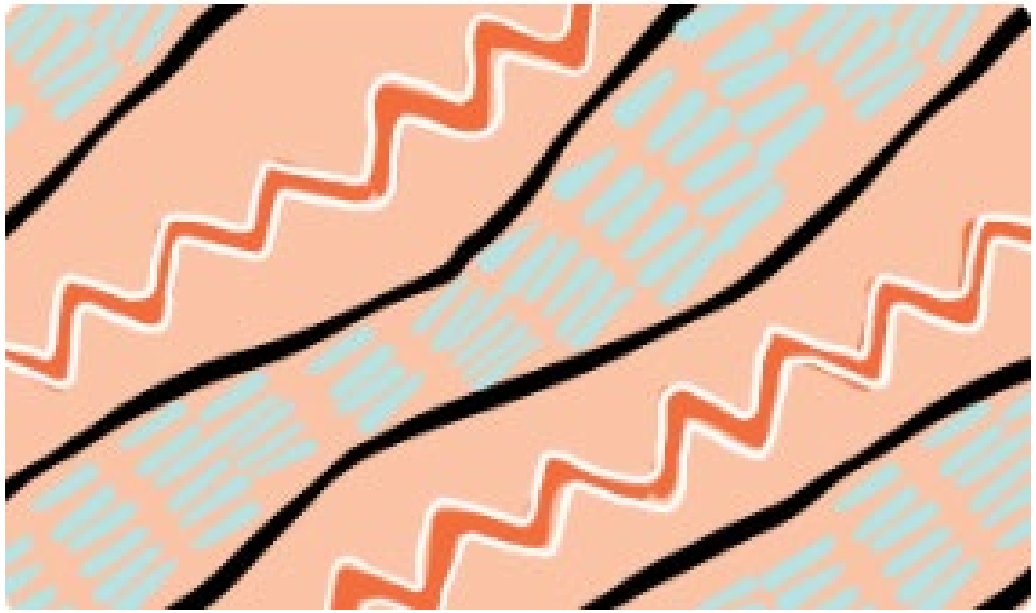


https://aiatsis.gov.au/research/ethical-research/code-ethics

- Researchers **must** consult and apply:
  - NHMRC's *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018)*
  - AIATSIS *Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)*
- Researchers must engage and consult communities in the design and conduct of research
- Risks and benefits must be determined in consultation.
- For research to be assessed as lower risk, the criteria for lower risk research must be met and the guidance ensuring cultural safety must be followed.

Chapter 4.7: Aboriginal and Torres Strait Islander People and Communities

- Guidelines to apply to research where:
  - **Research Focus** – The topic is identified as beneficial or a priority by these communities.
  - **Participant Cohort** – A significant proportion of participants are Aboriginal and Torres Strait Islander people.
  - **Location or Recruitment** – The research is conducted in areas or uses strategies likely to involve these communities.
  - **Data Analysis** – The research includes analysis that specifically identifies these communities.
  - **Research Impact** – The outcomes will specifically affect Aboriginal and Torres Strait Islander people and communities.



https://aiatsis.gov.au/about-aiatsis

Chapter 4.8: Research conducted during natural disasters, public health emergencies or other crises

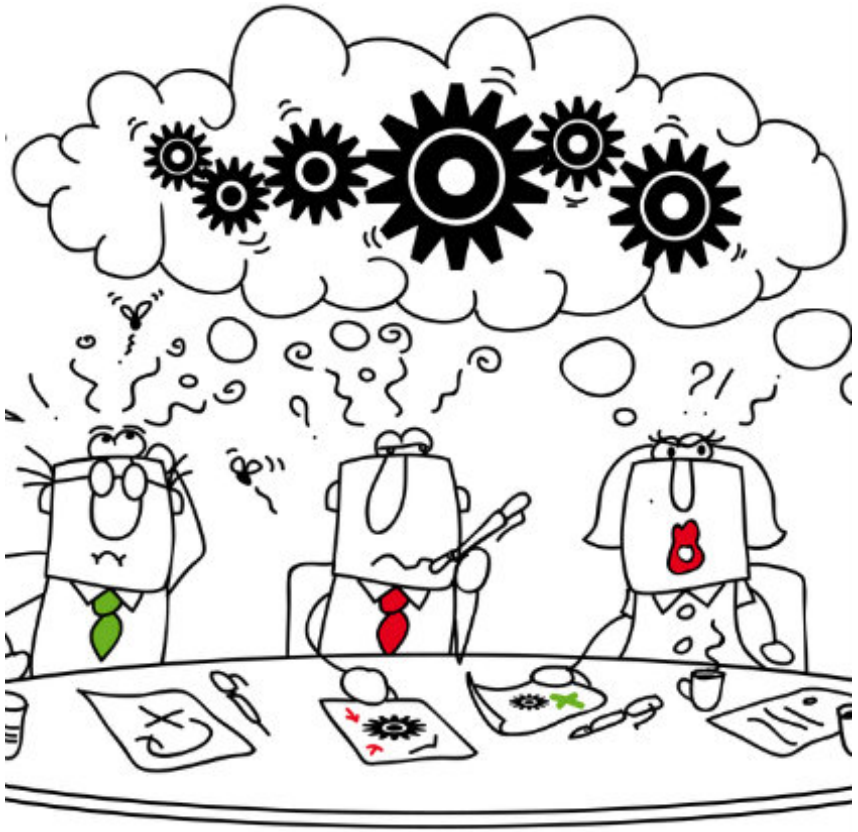
- New Chapter developed in response to COVID-19.
- Researchers should:
  - Assess Feasibility and Impact
  - Justify crisis-specific research
  - Coordinate with crisis responders
  - Design with the Community in mind
  - Respect consent processes

Reviewers should:

- Enable rapid yet ethical review processes.
- Assess research necessity, timing, and coordination.
- Ensure support and safety for participants and researchers.
- Plan for appropriate monitoring.

Where to from here?

- Researchers should review the new Section 4 to gain a better understanding of the updates
- ACU have adopted the 2025 National Statement
- All research applications will be reviewed in alignment with the 2025 National Statement.



Questions?