



Summary of changes to the *National Statement on Ethical Conduct in Human Research 2025*

The 2025 revision of the National Statement incorporates a fully revised Section 4 and consequential or minor changes to almost all other sections of the National Statement. The revised National Statement includes the following major thematic changes in Section 4:

- framing the need for additional consideration for individual participants or groups of participants in terms of increased risk of harm, rather than in terms of vulnerability
- emphasis on inclusion of individuals and groups frequently excluded or under-represented in research
- drawing a distinction between research with people who are at increased risk due to characteristics or circumstances, and increased risk due to research contexts
- removal of the need for research involving participants potentially at increased risk to automatically require review by an HREC, enabling the use of alternative review processes for lower risk research with the same participants, where appropriate.

The revisions also include recognition of issues related to research with Aboriginal and Torres Strait Islander people and communities in the Preamble and Section 1 of the National Statement and a revised Chapter 4.7.

Table 1. Changes to the National Statement on Ethical Conduct in Human Research 2025

SECTION/CHAPTER	CHANGES	COMMENT
The National Statement: A user guide	Minor changes.	Changes include clarifications to grammar, punctuation and/or formatting.
Preamble	Strengthened language recognising the harms done to Aboriginal and Torres Strait Islander people and communities by poor research practices and the continuing impact of those practices.	

SECTION/CHAPTER	CHANGES	COMMENT
Purpose, scope and limits of this document	New definition of research; added text on what constitutes human research which requires ethics review.	
Section 1: Values and principles of ethical conduct		
Introduction	Inclusion of the six values from the <i>Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders</i> . Minor changes.	Minor changes include clarifications of ambiguous phrasing and grammar, punctuation and/or formatting.
Guidelines	Revised guideline 1.2 to clarify peer review and research merit.	
Guidelines	Minor changes	Changes include corrected references, clarifications of ambiguous phrasing and grammar, punctuation and/or formatting.
Section 2: Themes in research: risk and benefit, consent		
Introduction	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and grammar, punctuation and/or formatting.

SECTION/CHAPTER	CHANGES	COMMENT
Chapter 2.1: Risk and benefit	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting; for example, the way that guidance on the justification of risks is described at 2.1.1 and 2.1.3.
Chapter 2.2: General requirements for consent	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Section 3: Ethical considerations in the design, development, review and conduct of research		
Introduction	Minor changes.	Changes include clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 3.1: The elements of research	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 3.2: Human biospecimens in laboratory based research	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 3.3: Genomic research	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.

SECTION/CHAPTER	CHANGES	COMMENT
Chapter 3.4: Animal-to-human xenotransplantation	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Section 4: Ethical considerations specific to participants		
Introduction	Major changes including descriptions of thematic changes and when to apply the guidance in the section.	
Chapter 4.1: Ethical issues in recruitment and involvement of research participants who may experience increased risk of harm	New chapter.	New chapter introducing major themes and overall guidance.
Chapter 4.2: Pregnancy, the human fetus and human fetal tissue	Focus shifted to 'pregnancy' rather than 'pregnant women' as a defined group.	
Chapter 4.3: Children and young people	Extended guidance on research involving children and young people, including the introduction of the concept of 'assent' to participation in research and the application of advance care planning and directives to the research context.	
Chapter 4.4: People in dependent or unequal relationships	Minor changes.	

SECTION/CHAPTER	CHANGES	COMMENT
Chapter 4.5: People experiencing physical or mental ill-health or disability	Extended guidance on research with people experiencing physical or mental ill-health or disability.	A merger of two previously existing chapters: <i>Chapter 4.4: People highly dependent on medical care who may be unable to give consent</i> and <i>Chapter 4.5: People with cognitive impairment, an intellectual disability, or a mental illness.</i>
Chapter 4.6: Research conducted in other countries	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 4.7: Research with Aboriginal and Torres Strait Islander people and communities	Strengthened guidance responsive to input from key stakeholders.	
Chapter 4.8: Research conducted during natural disasters, public health emergencies or other crises	New chapter.	
Chapter 4.9: Research that may discover illegal activity	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Section 5: Research governance and ethics review		
Introduction	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.

SECTION/CHAPTER	CHANGES	COMMENT
Chapter 5.1: Governance responsibilities of institutions	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 5.2: Responsibilities of HRECs and other ethics review bodies	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 5.3: Responsibilities of researchers	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 5.4: Monitoring	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting changes; for example, language about suspension of research and withdrawal of approval for research at 5.4.14 to 5.4.19.
Chapter 5.5: Minimising duplication of ethics review	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.

SECTION/CHAPTER	CHANGES	COMMENT
Chapter 5.6: Disclosure of interests and management of conflicts of interest	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 5.7: Complaints	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Chapter 5.8: Accountability	Minor changes.	Changes include corrected references, clarifications of ambiguous phrasing and other grammar, punctuation and/or formatting.
Terms used in this document	Reduction and clarification of terms.	