

Definitions

In these procedures, unless the contrary intention appears:

“ToR” means Terms of Reference,

“RHDC” means Research and Higher Degree Committee,

“National Statement” means the National Statement on Ethical Conduct in Human Research (2025),

“HREC” means Human Research Ethics Committee,

“LRP” means Lower Risk Research Ethics Review Panel.

“OOS” means out of scope

“PRC” means the Proportional Review Checklist

“RET” means Research Ethics Team,

“REMS” means Research Ethics Management System,

These Procedures are made pursuant to the Terms of Reference – Human Research Ethics Committee.

The [National Statement on Ethical Conduct in Human Research 2025](#) (the “National Statement”) requires all research involving humans to be conducted in an ethical manner and sets out the responsibilities of institutions and individual researchers for ethically sound human research. At ECU, all research is required to be tested in the Research Ethics Management System (“REMS”).

The Research and Higher Degree Committee (“RHDC”) holds institutional responsibility for overseeing that research is conducted ethically and has delegated responsibility for operations to ensure this oversight within a robust research governance framework.

Through the Academic Board (AB) and RHDC, ECU has delegated the responsibility to the Human Research Ethics Committee (“HREC”) to undertake the ethical review of human research that is of higher risk to participants, researchers and the community, pursuant to the HREC Procedures.

The National Statement provides institutions with the opportunity to develop processes to facilitate the ethical review of research that is considered to be no more than lower risk to participants. At ECU, the HREC oversees lower risk levels of review, which are delegated to the Lower Risk Research Ethics Review Panel (LRP) in alignment with the National Statement 5.1.10.

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)

Researchers are required to use the Proportional Review Checklist (PRC) within REMS to determine whether any proposed activity requires review, and if it does, the correct pathway for subsequent ethics review. Queries regarding the risk pathway are resolved in consultation with the RET. In extenuating circumstances, where a resolution cannot be reached, an escalation to the HREC Chair will be considered.

Some research may be out of scope (OOS) of ethical review (5.1.17 of the National Statement) and the PRC provides researchers with the opportunity to test if their proposed research falls outside of ethical review via the ‘Scope Test’.

Once researchers have completed the PRC and the proposed work is deemed out of scope due to their responses to the questions in the system, they will be provided with a short application form to complete. Upon submission, REMS will issue an automated confirmation that the proposed research, based on the researchers' responses, has been granted an OOS status and can proceed.

On behalf of the HREC, the RET will conduct audits of OOS applications to ensure projects are in the correct pathway. This audit will be conducted on a monthly basis, whereby a random selection of up to 50% of applications submitted that month are verified. Where time and capacity permit, or where there is a reduced number of applications, a larger percentage will be verified. Should, within the audit process, questions arise if a project is in the correct pathway, the RET will contact the research team to request further information and guide them to the correct pathway as appropriate.

The RET will provide a list of OOS applications to the HREC for noting each month.

Approval History

Procedure approved by:	Research and Higher Degrees Committee (RHDC)
Date Procedure first approved:	(26 August 2025)
Date last modified:	
Revision history:	26 August 2025 Full re-draft of procedures following a review of ethics governance at ECU, pertaining to higher and lower risk review, exempt, out-of-scope and executive review pathways to ensure continued alignment and compliance.
Next revision due:	26 August 2028