

## **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.
- "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 <u>National Statement on Ethical Conduct in Human Research 2025</u> (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 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)

The audit of exempt and out-of-scope applications to ensure they are in the correct pathway is undertaken by the Research Ethics Team (RET) on behalf of the HREC, pursuant to procedures outlined for exempt and out of scope applications.

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.



Where ECU HREC is not the primary review body, and in alignment with Chapter 5.5 of the <u>National Statement</u>, which outlines processes to minimize unnecessary duplication of ethical review, researchers can apply for reciprocal approval. This reciprocal approval will be facilitated via executive review by the HREC Executive, defined pursuant to the HREC Procedures. Ethical approvals other than those issued by an NHMRC accredited HREC may be required to demonstrate equivalency with the <u>National Statement</u>; as in the case of approvals attained outside of Australia.

## **Process**

- When completing the PRC, researchers who have gained ethical approval for their project via an external ethics committee should respond 'YES' to the question regarding prior review.
- Researchers will then be provided with a shorter application form they need to complete.
- Researchers need to attach the original ethics application form as well as their approval confirmation to the REMS application. Approval letter and application have to be issued by the same ethics review committee.
- Once submitted, the RET will process the application and provide it to the HREC Executive for review.
- The HREC Executive is allocated 7 days to complete their review and request additional information if required. The approval will be issued as and if appropriate.
- The HREC Executive will also determine if any additional monitoring responsibilities for the
  approved application are required. Monitoring will be delegated to the primary review body
  unless there are circumstances that warrant dual monitoring by the ECU HREC, such as the
  project being identified as an ECU student project.
- If it is deemed that that reciprocal approval is not appropriate and the necessity of ECU ethical review is determined, researchers will be advised accordingly.

## **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