

Definitions

In these processes and procedures, unless the contrary intention appears:

“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

“RET” means Research Ethics Team,

“REA” means Research Ethics Advisor,

“REMS” means Research Ethics Management System.

“RRTC” means Research and Research Training Committee

These Processes and Procedures are made pursuant to the Procedures of the Human Research Ethics Committee (“HREC”), which has been delegated the responsibility for overseeing that research is conducted ethically, including the oversight for lower risk levels of review.

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 of 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)

Exempt and out-of-scope applications will be audited by the Research Ethics Team (“RET”), on behalf of the HREC, to ensure they are in the correct pathway, pursuant to the 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 pursuant to the procedures outlined in this document. In extenuating circumstances, where a resolution cannot be reached, an appropriate escalation will be considered.

1. Terms of office

- Within each school the Executive Dean (ED) in consultation with the ADR and ADD will appoint LRP members, who
 - Must be a level E, D or C academic with an established record of research excellence and who is currently highly research active¹.
 - exceptional Level B academics may also be considered on the condition that they will be actively mentored² by an identified level D/E member of the panel.
 - Must have had direct experience in conducting human-related research that has required ethics approval.
 - Must have a good working knowledge and understanding of the *National Statement*.
 - Must not be found to have seriously breached professional conduct standards over the previous 3 years.
- LRP membership should be of sufficient size to manage application load, and this is managed by the RRTC in accordance with section 4 below. This can include temporary expansion of membership to manage short periods of higher demand.
- Each School will inform the RET of all appointments for noting at the next meeting of the HREC and RRTC.
- Prior to commencing their role on the LRP, all LRP members are required to attend an induction facilitated by the RET and Research Ethics Advisor (REA) and sign a confidentiality statement. This includes any LRP member appointed as part of a temporary membership expansion; LRP Chairs require additional induction.
- Ethics applications will only be assigned to LRP members who have completed the induction provided by the RET and signed the confidentiality agreement. The RET will record training status, and regular updates on induction and ongoing ethics training will be provided to the LRP Chair for tabling at the school-based RRTC.
 - Schools will decide the actions that should be taken if this training remains uncompleted, including advice to HREC to consider the termination of LRP membership, pursuant to section 3 of these procedures.
- Appointments of LRP members can be made for 1, 2 or 3 years at the discretion of the school, to a maximum of 9 years. The initial term of appointment of the LRP Chair is for 3 years, with the option of one renewal term of the same length. Under exceptional circumstances, and subject to formal approval from the HREC Chair, a LRP Chair may be appointed for a third 3-year term.
 - At least 50% of the LRP members must be level C/D or E, with representation across each of these academic levels.
 - Under exceptional circumstances, level B membership may rise above 50%, such as during a short period of high demand that has necessitated the temporary expansion of LRP membership.
 - It is the remit of the individual school to ascertain and allocate an appropriate workload for LRP members and the LRP Chair. It is expected that this work will contribute to and be allocated under the academic's university service contribution as assigned by the ADD.
 - Must retain current research ethics training requirements as specified in section 3 "Responsibilities" below.
 - Schools should decide on the best composition of their panels with respect to the nature of their program of research in relation to its disciplinary needs, methodology expertise or a mixture of both.

¹ **research-active**, is defined as a) having been involved in the design and conduct of research projects and/or have been a named chief investigator on an externally funded competitive research project in the past 2 years, and b) have a track record of publishing high-quality research publications relevant to their career stage.

² **mentoring** is as per the usual good academic mentoring practices adopted in the school

- Every effort must be given to ensuring Athena Swan and Gender Equity Diversity and Inclusion (GEDI) principles for committee membership.
- University academic or service centres, or other ECU-affiliated entities that are unable to establish an LRP, may negotiate with a relevant school for support of the review of their research ethics applications.

2. Appointment of the Chair

- Within each school, the Executive Dean (ED) in consultation with the ADR and ADD, will nominate a LRP Chair.
 - Must meet all requirements for LRP membership
 - Must be a level E or D (preferably), academic with an established record of research excellence and who is currently highly research active. Under exceptional circumstances, a Level C appointment may be considered by the DVCR.
 - Must have suitable experience, such as ideally membership of an ethics review body in the last 5 years or an appropriate level of ethics training. In exceptional circumstances, other relevant experience will be considered.
- These nominations should be discussed with and approved by the HREC Chair and will be noted at the next meeting of the HREC.
- Once the HREC Chair has approved the appointment, the REA/RET will induct the new appointee.
- Depending on the school's expected number of lower risk reviews, the ED/ADD may assign a specific university workload service fraction for this work.
- Ideally, this person will not be the ADR, as they will report to the school through the RRTC, which is chaired by the ADR.
- A school, based on the number of lower risk applications reviewed each year, may consider the appointment of an LRP Deputy Chair in accordance with this process.
 - In the absence of an LRP Deputy Chair, a school may also nominate an acting chair to be inducted to cover a specified period when the LRP Chair is not available

3. Responsibilities

- The LRP Chair will conduct a final review of lower-risk applications submitted by their School and reviewed and approved by LRP members. They will provide a final sign-off on approval if satisfied with the LRP members' review.
- It is within the remit of the LRP Chair to return the application to the researchers to provide further information as deemed required to facilitate the final approval of the application.
- The LRP Chairs will meet annually with the HREC Chair in a format to be determined by the HREC Chair. The HREC Chair will facilitate the attendance of LRP Chairs for at least one meeting of the HREC annually.
- LRP Chairs will be members of their respective school RRTC and provide updates to the RRTC as required.
- Ethical review of applications will be conducted online, unless otherwise determined by the HREC Chair.
- Each LRP member, including the LRP Chair, is responsible for
 - Adhering to ECU's guidelines and policies.
 - Maintaining the confidentiality of information received in the exercise of their duties and ensuring it is maintained at all times.
 - Providing feedback on the ethical acceptability of research ethics applications in a timely manner. If they assess the level of risk to participants described in the application as higher risk, they will escalate the review of the application to the higher risk review pathway via the RET.
 - Re-reviewing of application resubmissions and amendments as required.

- Promptly notifying the RET if they cannot conduct reviews due to conflicts of interest or other impediments.
- Promptly informing RRTC, through the LRP Chair, and RET of their inability to continue to serve as a member of the LRP.
- Each LRP member should attend continuing education or training programs in research ethics at least once every 3 years.
- All research ethics applications that involve Aboriginal and Torres Strait Islander people or communities are reviewed in parallel, from a perspective of cultural appropriacy as per university practice, by Kurongkurl Katitjin. Further, as per current ECU practice, this review is undertaken through the HREC in accordance with the HREC Procedures.
- The appointment of any LRP member may be terminated by the HREC on the recommendation of the RRTC through the LRP Chair, in consultation with ED/ADD or ADR, if they reach the conclusion that:
 - It is necessary for the proper and effective functioning of the LRP; or
 - The person has failed to carry out their responsibilities as a LRP member; or
 - The person is deemed to be no longer a fit and proper person to serve on the LRP.

Any such decision will be provided to the member in writing by the HREC Chair, as soon as is practicable.

4. Accountability

To the HREC:

- Accountability of all ethical components and matters of the LRP is to the HREC, through the LRP Chair. This includes, but is not limited to, all aspects relating to the content of applications received, decision-making processes, outcomes, COI and dispute resolution. These principles and processes are fully outlined in the HREC procedures.

Accountability to the school RRTC

- The LRPs are a key research support structure within schools and are therefore comprised of research-active academic members of each school. Hence, there is a need for schools to have formal oversight of their membership and performance only. The LRP must be included as a standing item for the school-based RRTCs, as they provide important conduits of information about research matters to the ED and the school executive. Matters to be considered and reported on to the RRTC should maintain the confidentiality and integrity of the ethics review process, are supported by the RET (see section 5) and are restricted to the following:
 - Tracking the number of submitted and approved lower-risk applications (for planning purposes at the start of each year, and then for review as the year progresses). This information may be retrieved via the REMS School Ethics Dashboard or alternative ECU systems.
 - Ensure sufficient panel membership to manage application load while maintaining a working knowledge of the National Statement and REMS.
 - Determining and recommending to the ED and school executive the need for additional LRP members, including temporary expansion of membership to manage short periods of high demand.
 - Ensuring that all panel members meet the composition requirements stated above, to the extent of information available to RRTC members (i.e. integrity matters will need to be ascertained by ED).
 - Based on update reports from LRP Chair, ensure that all members are formally recorded as being adequately trained/updated for this role
 - Based on discussions with the LRP Chair, the RRTC can request additional Professional Development opportunities for the LRP, including but not limited to on-campus LRP workshops or meetings.

- On the basis of advice from the LRP Chair, monitor, and where needed, initiate corrective action around the performance of all panel members in terms of their acceptance (or not) and timely completion of reviews
- The school RRTC does not contribute to, and has no oversight of, or influence on, the ethics review process itself or details of submitted applications, including, but not limited to, the investigators and project details, the names of reviewers assigned to the application, or the ethics review decision. This is to ensure the confidentiality and integrity of the ethics review process in line with the *National Statement*.
- The RRTC will receive an annual school-level report, prepared by the RET. This will be in alignment with the annual RHDC reporting requirements and schedule and should be used by schools to guide and inform the composition mix of their LRP.

5. Duties and Functions of the RET

The RET, in facilitating and supporting the ethical conduct of research, will:

- Review and audit applications to ensure correct pathway determination of all submissions and modify accordingly and in consultation with the HREC Chair if required.
- Review ethics annual and final reports, changes to research team members and requests for extensions.
- Provide a record of training status and regular updates on induction and ongoing ethics training to the LRP Chair for tabling at the school-based RRTC.
- Provide advice and executive support to the LRP Chair or Deputy Chair as requested.
- Provide advice and executive support to the LRP as required.
- Report adverse events and complaints pertaining to the ethical conduct of research projects to the appropriate entity.
- Provide/facilitate training and education for the ECU research community, including but not limited to ECU's HREC and LRP, to promote ethics literacy.
- Implement systems adopted by ECU to promote efficient ethical review.
- Provide an annual report to the school RRTC on lower-risk applications reviewed by the school's LRP, in line with the annual RHDC reporting requirements and schedule.

6. Complaints and Enquiries Processes

6a. Complaints or enquiries about the status and outcomes of the lower-risk review process.

- Complaints or enquiries regarding lower-risk review processes or outcomes should, in the first instance, be directed to the RET. The RET will facilitate a resolution and escalate the matter appropriately as and if required. This escalation could be either to the appropriate LRP Chair, HREC Chair or to the Manager, Research Governance.

6b. Complaints about ethically approved research

- Complaints about ethically approved research are managed in accordance with 6c of these procedures (below), the ECU Conducting Research with Integrity Policy, the Research Misconduct Guidelines, the Academic Misconduct Rules (Student) and any other relevant ECU governance document.

6c. Suspension and discontinuation of research

- When a complaint is received or an issue (e.g. an adverse event or an external enquiry or advice about ongoing research) is uncovered, a meeting will be convened between the REA, Research Integrity and Governance Adviser and Manager, Research Governance to determine if the issue relates to an ethical concern; if so, the process below will apply. If not, the issue will be managed under the Research Misconduct Guidelines, the Academic Misconduct Rules (Student), or by another institutional process.

- Where a complaint (or adverse event notification) is received or an issue is uncovered, and there may be reason to believe that the continuance of a research project will compromise participants' welfare, or if the conditions of ethics approval are not being adhered to, the below process will be employed to determine whether ethics approval and/or authorisation for the project should be suspended or withdrawn.
 - The REA or a member of the RET, if the REA is unavailable, will gather relevant information pertaining to the ethical issues.
 - The REA/RET will consult with the relevant LRP Chair (or Deputy Chair) to agree on any suspension recommendations.
 - If suspension is required, the REA/RET, on behalf of the LRP Chair (or Deputy Chair), will issue an immediate suspension of ethics approval and/or research activities in writing to the research team.
 - Once ethics approval is suspended, where possible, the research team should provide notification of the project's suspension to the participants.
 - The LRP Chair (or Deputy Chair), REA, and/or RET members will discuss and gather further information or interview parties if deemed relevant.
 - The REA/RET, in consultation with the LRP Chair (or Deputy Chair), will summarise in writing the nature of the issues identified and any actions or recommendations, which will be provided to the research team, including a recommendation on whether any data collected (outside of approval) can be used (for publishing or towards completion of a degree).
 - Where a research integrity concern is identified, the REA/RET will refer the matter to the Research Integrity Team on behalf of the LRP Chair (or Deputy Chair).
 - Complaint outcomes will be confidentially communicated to the ED and line manager, as per ECU process.
- In cases where projects have been suspended, the research team must not resume any research activities until the LRP Chair (or Deputy Chair), in consultation with the REA/RET, has determined and confirmed in writing that:
 - The research is modified to provide sufficient protection for participants or address the concerns that led to the suspension, or
 - The researcher establishes to the satisfaction of the LRP Chair that continuation of the research will not compromise participants' welfare.
 - Outcomes of complaints processes, including but not limited to suspensions and discontinuations, will be documented and noted at the next appropriate HREC meeting.

It is important to note that all decisions pertaining to any issues must consider the context and stage of the project and be determined in alignment with the National Statement on Ethical Conduct in Human Research 2025.

6d. Complaints and Conflicts of Interest raised against LRP members

- Any complaint against an LRP member, including the LRP Chair, that brings into question their fitness and propriety to serve on an LRP, needs to be raised formally and will be assessed in accordance with the Policy: Staff Code of Conduct.
 - In cases where a complaint is upheld, the HREC Chair will be informed, and a decision to terminate the individual's panel membership, pursuant to section 3 of these procedures, will be made by the HREC. The LRP Chair, in the case of an LRP member, and the ED, the ADR, and the ADD will be informed of any terminations.
 - All complaints, along with their resolutions (decision and action taken), will be documented and noted at the next appropriate HREC meeting.
- Any raised conflicts of interest, real or perceived, against an LRP member need to be raised formally and will be assessed in line with ECU's Conflicts of Interest Policy.

- In cases where a real or perceived conflict of interest is assessed to exist, the involved panel member must refrain from participating in deliberations or influencing decisions related to the matter.
- All conflicts of interest, along with their resolutions (decision and action taken), will be documented and noted in the next meeting of the HREC and RRTC.

7. 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