



Edith Cowan University Ethics Operating Procedures

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RESEARCH ETHICS AT ECU

The [National Statement on Ethical Conduct in Human Research](#) 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, Academic Board hold institutional responsibility for overseeing the way in which research is conducted and have delegated this overall responsibility within a robust research governance framework. This document summarises the Terms of Reference for each of the review committees shown in Figure 1 below, which function within ECU’s research ethics governance framework.

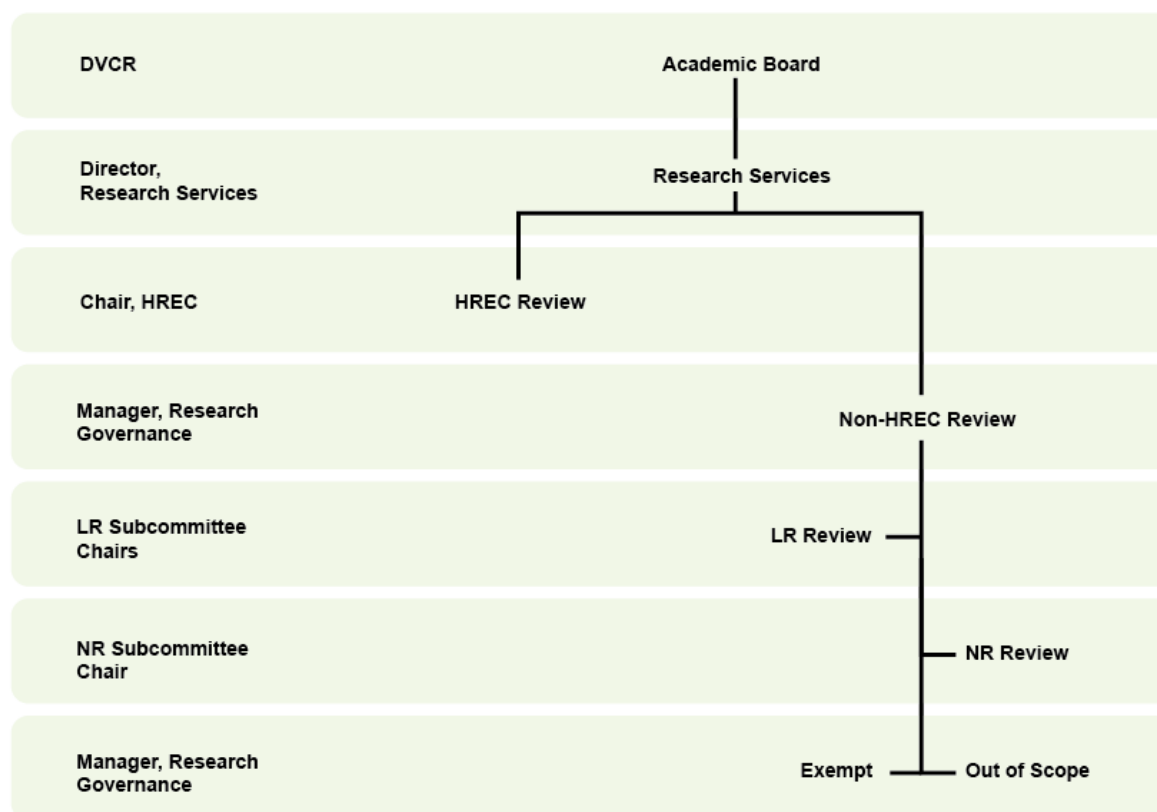


Figure 1: ECU Research Ethics Governance Framework

The ECU Academic Board (AB) has delegated the authority to the Human Research Ethics Committee (HREC) to undertake the ethical review of human research that is of greater than low risk to participants. Chapter 5, sections 5.1.1, 5.1.2, and 5.1.3 of the National Statement enable the development of institutional processes to facilitate the ethical review of research that is considered to be no more than low risk to participants. At ECU, the Manager of Research Governance oversees these additional institutional levels of review.

The remainder of this document provides the Terms of Reference for each Committee and Subcommittee under this model.

RESEARCH ETHICS MANAGEMENT SYSTEM

The Research Ethics Management System manages the application, review and monitoring of all human research ethics applications at ECU. Researchers are required to enter REMS to determine whether the proposed activity requires review, and if it does, the correct pathway for the review.

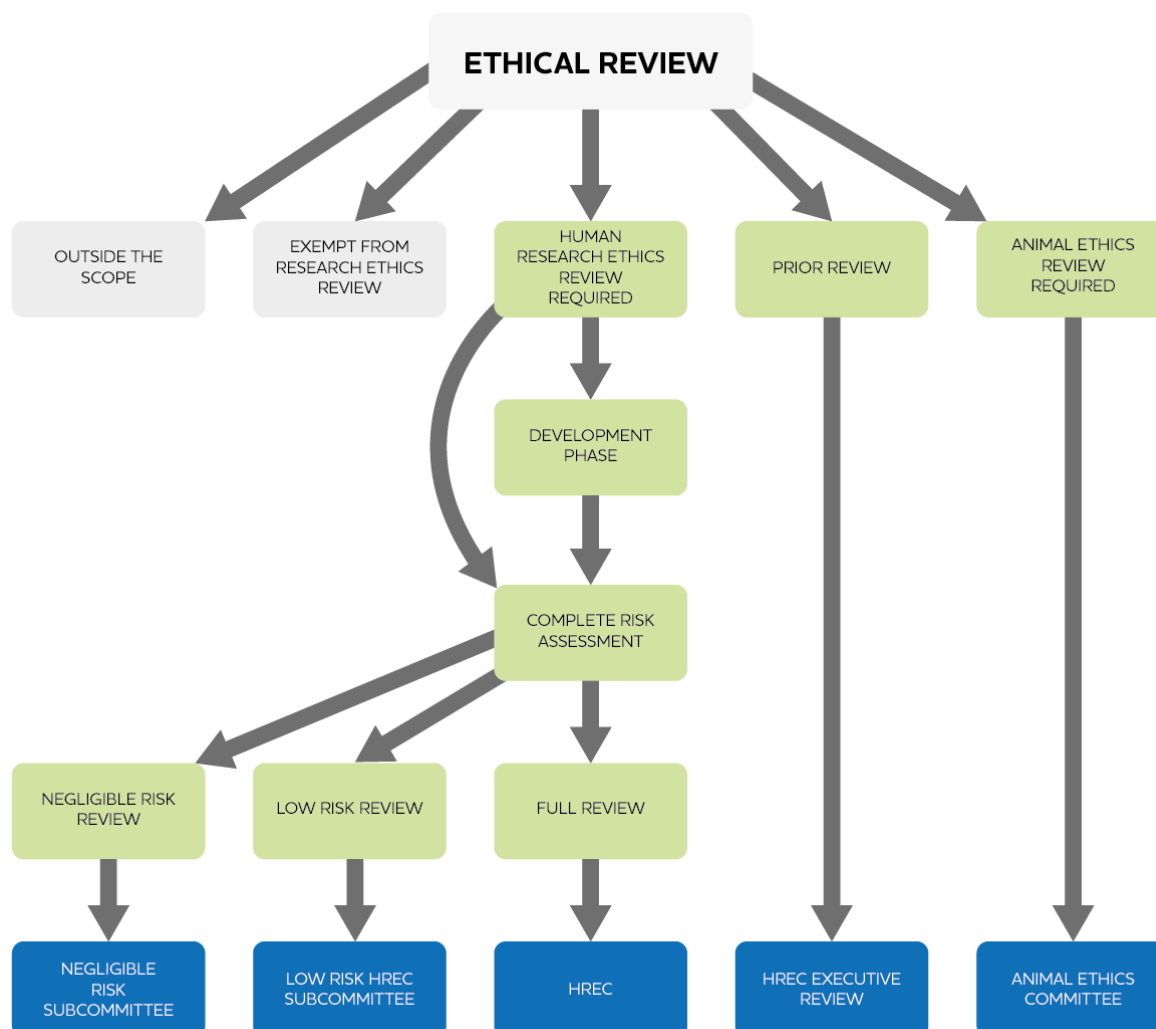


Figure 2: Research Ethics Management System (REMS)

The Proportional Review Checklist initially determines whether an application for human or animal research ethics approval is necessary. If review is required, the PRC asks further questions designed to determine the level of risk associated with the research. All questions are based on the [National Statement on Ethical Conduct in Human Research \(National Statement\)](#).

HREC Terms of Reference

1. Establishment

The HREC has been established by ECU to ensure the conduct of human research in accordance with the highest scientific and ethical standards.

The ECU HREC acts under the delegated authority of the ECU Academic Board (AB) and has executive authority conferred upon it to fulfil the roles and carry out the functions detailed in its terms of reference.

The ECU AB may consider and implement changes to the structure and operations of the HREC including dissolution, streamlining, re-configuration and establishment as deemed appropriate from time to time, provided that any changes do not compromise the capacity of the HREC to meet all relevant regulatory compliance requirements, research ethics standards and procedures.

The ECU HREC will act in accordance with the terms of reference as amended from time to time. The HREC terms of reference are to be read in conjunction with Section 5 of the *National Statement* which outlines processes of research governance and ethical review and includes responsibilities of the institution and the HREC.

2. The scope of responsibility

The HREC has been established to review and approve research ethics proposals for:

- Human research to be undertaken by ECU staff or students at, or under the auspices of, ECU, AND/OR
- Human research received by the HREC in the exercise of review processes accepted, accredited or certified for the purposes of any other system designed to eliminate unnecessary duplication of ethics review of human research, where these standards are consistent with the *National Statement*.

3. Roles

The roles of the HREC are to:

- Ensure that the design and conduct of any human research that it reviews conforms with the [National Statement](#) (National Health and Medical Research Council [NHMRC], Australian Research Council, and Universities Australia) and other relevant national and state codes (the [Australian Code for the Responsible Conduct of Research, 2018](#)) relevant legislation and the ethical standards to which ECU is committed (ECU values and Code of Conduct).
- Ensure that participants in any human research that the HREC reviews and approves are accorded the respect and protection that is due to them.
- Facilitate and foster human research that is of benefit to communities.
- Ensure that any decision it makes complies with relevant laws.
- Provide advice to the University about the design and conduct of ethical research.
- Facilitate and support a culture of research excellence, through involvement in the University's communication, education and training strategies.
- Provide advice to the Deputy Vice Chancellor (Research), as requested, on potential breaches of the University's research ethics arrangements and/or relevant external

regulations, codes and guidelines.

- Oversight and provide quality assurance in respect of determinations made by HREC Subcommittees and Research Services with respect of determinations by administrative reviews.

4. Functions

In fulfilling these roles, the HREC will:

- Provide independent review, approval and ethical oversight and advice in respect of human research projects.
- Provide competent, timely review of human research projects to ensure the project meets the requirements of the *National Statement*, and all other relevant Acts and legislative requirements for that type of research.
- Ensure that it is sufficiently informed on all aspects of a research proposal, including its merit and integrity, before deciding whether a proposal is both acceptable on ethical grounds and conforms with the *National Statement*.
- Ensure both the privacy and confidentiality of human research participants is protected by requiring that researchers appropriately manage the security, storage and disposal of data and bio-specimens collected during the conduct of the research in accordance with the ECU Research Data Management Policy (PL049), and/or the Privacy and Copyright Acts.
- Advise researcher applicants whether or not reviewed research proposals meet relevant ethical standards and have or have not been approved and provide reasons, linked to the *National Statement*, for those decisions.
- Determine, in relation to each reviewed and approved research project, that there will be mechanisms to monitor the conduct of the research and that the effectiveness of those mechanisms appropriately minimize the risk to participants.
- Offer relevant advice and assistance to other institutions without formally constituted HREC's.
- Implement systems adopted by ECU to promote the efficient ethical review of multicentre research projects to minimise unnecessary duplication of ethical review of human research.
- Be responsible and accountable for the activities and recommendations of non-HREC levels of review, which have been established by ECU in accordance with the *National Statement*.

5. Membership

The ECU HREC will be constituted in accordance with the terms of the *National Statement* and comprise of at least eight (8) members including:

- A chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the *National Statement*.
- At least two members who are laypeople, who have no affiliation with ECU and who are not currently engaged in the medical scientific, legal or academic work of ECU.
- At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people.
- At least one person who performs a pastoral role in a community.
- At least one lawyer, who, where possible, is not engaged to advise ECU.
- At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

Wherever possible, the Vice Chancellor and/or the ECU AB will ensure that one or more of the

appointed members are experienced in the professional practise of ethical decision-making.

The ECU Academic Board will also appoint from the appointed members one member to serve as Chairperson, and one member to serve as Deputy Chairperson on such terms and conditions and for such a period as the ECU Academic Board determines.

ECU will ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership. The Chair should ensure that this does not affect confidentiality.

Where required, the HREC Chair may invite a member of the ECU research community to join the HREC as an invited guest to fill a temporary vacancy or to assist as a discipline expert as required. Any invited guest will contribute to the review of all applications however will not hold voting rights without their appointment first being ratified by AB as outlined in Section 6 below.

6. Appointment

ECU may recruit members for the HREC in such manner and shall appoint them for such periods as indicated below:

- ECU will adopt open and transparent processes including advertising for applications for new membership and making appointments of members. The process for appointing and reappointing members is described below:
 - *New members* will be sought through expressions of interest and recommendations made by the HREC through the Chair. The HREC, through the Chair, will endorse the new member then make a formal recommendation to the Manager, Research Governance for the new member. This recommendation will be tabled at Research and Higher Degree Committee (RHDC) for endorsement and Academic Board (AB) for appointment.
 - *Members seeking to be reappointed* will be recommended by the HREC Chair to the Manager, Research Governance and this recommendation will be tabled at Research and Higher Degree Committee (RHDC) for endorsement and Academic Board (AB) for appointment.
 - *Reappointment of the current Chair* will be recommended by the HREC to the Manager, Research Governance and this recommendation will be tabled at Research and Higher Degree Committee (RHDC) for endorsement and Academic Board (AB) for appointment. The Chair of the HREC must always be an ECU staff member.
 - *Appointment of a new Chair* (where the current Chair no longer seeks re-appointment) will be overseen by the Manager, Research Governance. An expression of interest will be distributed to the ECU research community and the applicants along with a recommendation will be tabled at Research and Higher Degree Committee (RHDC) for endorsement and Academic Board (AB) for appointment.
 -
- Members will be appointed by the ECU AB for a term of three years, or an alternate term as recommended by the HREC, and are eligible for re-appointment.
- Where a member is appointed to fill a casual vacancy (casual member) that appointment shall expire at the time when the previous member's term would have expired. The casual member shall then be eligible for appointment for the following term.
- All recommendations for membership will be provided to the ECU AB, which will make the appointments.

- Members will receive a formal notice of appointment in writing from the Chair of the ECU AB.
- ECU provides indemnity for all appointed HREC members in respect of any liability that may arise in the course of the professional conduct of their duties as members.
- Members who are absent from three successive meetings of the HREC without the approval of the Chair will cease to be members.
- Members of the HREC who seek to resign or take a leave of absence for an extended period are required to provide written notice to the HREC Chair.
- The appointment of any HREC member may be terminated if the ECU Academic Board is of the opinion that:
 - it is necessary for the proper and effective functioning of the HREC; or
 - the person has failed to carry out their duties as a HREC member; or
 - the person is not a fit and proper person to serve on a HREC.

Any such decision will be provided to the member in writing by the ECU AB.

7. Members Responsibilities

Each member is responsible for deciding whether, in his or her judgment, an application submitted to the HREC meets the requirements of the *National Statement* and is ethically acceptable.

All hard copies of any protocols and/or HREC proceedings and correspondence are to be disposed of through a confidential recycling bin. It is the responsibility of members to delete electronic records of proceedings and correspondence.

Each member will be provided with an induction and orientation to the functions of the HREC and be offered the opportunity of being assisted by a current HREC member as a mentor.

Each member is responsible for:

- disclosing to the HREC any conflict of interest that may affect the HREC's review of a research proposal.
- ensuring the confidentiality of information received in the exercise of his or her duties is maintained at all times.
- maintaining a working knowledge of the *National Statement* and consult other guidelines relevant to the review of such research proposals.
- preparing for, and attending, HREC meetings or, if unavailable, providing opinions on the ethical acceptability of the research applications.
- undertaking continuing education in human research ethics once every three years in accordance with the *National Statement*.

8. Chair and Deputy Chair Responsibilities

In addition to the responsibilities of the general HREC members, the Chair and Deputy Chair will have the following responsibilities.

8.1. Chair

The Chair must not be accountable for other ECU functions that will impair the HREC's capacity to fulfil the obligations under the *National Statement* and carry out the functions set out in these Terms of Reference.

The Chair is responsible for ensuring that HREC decisions are informed by an exchange of views from members, whether in full attendance or through the receipt and consideration from some of those members who cannot be present (*National Statement* Section 5.2.29–30).

Achieving such decisions requires that the Chair:

- Actively engages all members;
- Elicits their views; and
- Communicates their responses to other members.

As the HREC endeavours to reach decisions by general agreement, which need not be unanimous (*National Statement* Section 5.1.31), the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of general agreement has been reached.

The Chair is responsible for guiding the manner in which the HREC communicates with investigators (*National Statement* Section 5.2.13–14, 5.2.22) and the decisions about inviting investigators to attend HREC meetings (*National Statement* Section 5.2.18).

8.2. Deputy Chair

The Deputy Chair should support the Chair in the performance of, and be capable of fulfilling, the responsibilities of the Chair whenever the Chair cannot attend meetings or perform any other function.

The Chair and Deputy Chair should consider issues referred by the ECU AB and, where appropriate, provide advice to the ECU AB especially on policy issues with ethical implications.

The Chair and Deputy Chair should provide a forum in which staff concerns regarding ethical issues in research can be considered and investigated.

9. Accountability

The HREC is accountable to Academic Board, for the exercise of its functions and the fulfilment of its roles.

The HREC will provide an annual report of its activities to Academic Board. The HREC annual report will contain a summary account of:

- The number of research ethics proposals received, reviewed, approved and rejected;
- Any complaints received from either:
 - researchers about the conduct of the HREC, or
 - participants or others about the conduct of research approved by the HREC;
- Any adverse events that occur during the conduct of research and how they were managed;
- Any changes in membership of the HREC; and
- Any changes in the procedures used for the performance of its functions.

The annual report will also include an evaluation of the performance of the HREC identifying any factors that have affected or may affect the integrity and efficiency of the HREC's performance. The HREC Chair is responsible for the conduct of this evaluation.

The Chair of the HREC will review and approve any reports of activities of the HREC, whether to the ECU AB, or to the NHMRC.

The HREC, through the Chair, may at any time bring to the attention of AB or its delegate any issues of significant concern that merit prompt consideration and attention.

10. Meetings

The HREC will meet each month, with the exception of January, and will publish the dates of its meetings and submission closing dates for applications on the ethics website.

As far as possible, at least one member of each category of membership (e.g., Chair, lay member, counselling member, pastoral care member, legal member) should attend a meeting in order to form a quorum. Where a meeting is inquorate, decisions can be made where the Chairperson is satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

Decisions at meetings must be made following an exchange of opinions from each of the members who constitute the minimum membership, whether at a face to face meeting, by teleconference or videoconference or where one of those members is absent, by the receipt and consideration of that member's views. Decisions need not involve unanimity.

The HREC will record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions linked to the relevant sections, chapters or paragraphs of the *National Statement* and/or as reflected in the ECU Research Ethics Manual booklets.

11. Procedures

The HREC shall establish, implement, document and notify ECU's AB (if required) of its working procedures concerning:

- Frequency of meetings.
- Attendance at meetings (including non-members and researchers).
- Conduct and structure of meetings and deliberations.
- Preparation of agendas and minutes.
- Timely distribution of papers prior to meetings.
- Presentation of applications for ethical review.
- Timely consideration and review of applications.
- Identification, declaration and management of any conflicts of interest.
- Prompt notification of decisions to researchers.
- Record keeping.
- Reporting and handling of adverse occurrences.
- Receipt and handling of complaints.
- Advising external institution(s) or organisation(s) of decisions to withdraw ethical approval of a research project.

12. Appeals and complaints

12.1. Appeals regarding HREC status 'not approved'

If the ECU HREC does not approve an application, the researcher may:

- Apply the feedback provided by the ECU HREC and submit this as a new application for ethics approval.
- Appeal to the ECU HREC Chair by providing a written appeal that specifies the grounds of appeal.

The HREC Chair will respond directly to the researcher in writing.

12.2. Appeals regarding HREC approval

If the ECU HREC has approved an application for research ethics and any party subsequently determines that the decision was made erroneously, that party may appeal to the ECU HREC Chair, through the Research Ethics Team by providing a written appeal that specifies the grounds of appeal.

12.3. Appeals to the Deputy Vice-Chancellor (Research)

Where a party consider that the HREC has failed to follow due process in regards to an appeal submitted at 2.12.1 and 2.12.2, that party may lodge an appeal with the Deputy Vice Chancellor (Research), via the Ethics Team. The Deputy Vice Chancellor (Research) may refer the matter to an external HREC or seek expert advice.

12.4. Complaints about the conduct of HREC members

Any party may make a formal complaint about a HREC member directly to the Deputy Vice Chancellor (Research). The Deputy Vice Chancellor (Research) will notify the ECU HREC Chair of the complaint in writing.

12.5. Complaints about the conduct of an approved research project

Any complaint in relation to an approved research project is managed in accordance with the ECU Research Misconduct Policy (PL232; ac091) and other ECU policies deemed relevant to the occurrence (e.g., Australian Code for the Responsible Conduct of Research).

13. Suspension and discontinuance of research

Where it is determined that there is reason to believe that the continuance of a research project will compromise participants' welfare, the following process will be engaged in to ensure that researchers and participants are treated fairly and with respect:

- The Ethics Team will notify the HREC Chair and Deputy Chair who will determine if urgent suspension of research is necessary before an investigation commences.
- Where the decision of the HREC Chair and Deputy Chair is to urgently suspend research, an instruction to cease data collection will be provided by the HREC Chair in writing.
- The Ethics Team will commence gathering relevant information.
- The HREC Chair and Deputy Chair will interview parties deemed relevant.
- The HREC Chair will write a report summarizing the nature of the issues identified.
- The HREC Chair will convene a HREC meeting to deliberate on the matter.
- A final report with a recommended course of action will be submitted to the Director of the Research Services for endorsement of the Executive decision.

If the decision is to suspend or discontinue a research project, the researcher, institutions(s) and where possible, the participants will be informed in writing by the HREC Chair and notification will be forwarded to the Director of Research Services.

The researcher may not resume data collection until it has been determined by the HREC Executive that:

- Continuance will not compromise the welfare of participants; and
- The research has been modified sufficiently to protect participants.

14. Review and amendments of the Terms of Reference

The HREC terms of reference shall be reviewed every three [3] years and may be amended in consultation with the HREC and Academic Board.

School Based Low Risk Subcommittee

Purpose

The School Based Low Risk Subcommittee has been established to ensure the conduct of human research in accordance with the highest scientific and ethical standards, and the efficient review and approval of low risk ethics applications and Unit Licenses.

The School Based Low Risk Subcommittee acts under the delegated authority of the Manager, Research Governance and has executive authority conferred upon it to fulfil the roles and carry out the functions detailed in its terms of reference.

All low risk ethics applications will be reviewed by the School Based Subcommittee unless:

- The research project is deemed *out of scope* or *exempt* through the proportional review pathway.
- The human research project has *prior review* by another Institution's HREC (reviewed administratively by the Research Ethics Team and HREC Chair).
- The human research project is deemed negligible risk (reviewed administratively by the Negligible Risk Subcommittee).
- The human research project is deemed greater than low risk (reviewed by the ECU HREC).
- The research project involves the use of animals only (with no human research) for scientific purposes (reviewed by the ECU Animal Ethics Committee).

Approval decisions of the School Based Low Risk Subcommittee are ratified by the Chair of the Low Risk Subcommittee.

The Low Risk Subcommittee operates in accordance with the following terms of reference.

Low Risk Subcommittee Terms of Reference.

1. Membership

Each School within ECU will form a Low Risk Subcommittee. All members of the Low Risk Subcommittees will be appointed by the Executive Dean or nominee.

1.1. Chair

The Low Risk Subcommittee will be Chaired by a senior research-active staff member of the School. The appointment is made by the relevant Executive Dean in consultation with the Manager, Research Governance. Where required, an Executive Dean may also appoint a Deputy Chair, who will also be a senior research-active member of staff.

1.2. Members

Each School Based Low Risk Subcommittee will comprise at least two research-active members representing each of the research disciplines of the School. There is no upper limit to the number of committee members.

The Chair of the Subcommittee is responsible for ensuring that members of the Subcommittee receive the resources and training provided by the University to enable them to fulfil their role.

The Chair will be responsible for conducting a final review of all applications reviewed by the Subcommittee members to provide a final sign off on its approval.

Members will declare any actual or potential Conflict of Interest relating to an ethics application they have been asked to review.

1.3. Appointment

The Executive Dean or nominee of each school is responsible for appointing members to their School Based Low Risk Subcommittee for such periods and on such terms and conditions as it determines. A maximum of three, three-year terms can be served.

1.4. Role

Each member of School Based Low Risk Subcommittee is responsible for deciding whether an application submitted to the Subcommittee meets the requirements of the *National Statement* and is ethically acceptable. This includes members becoming familiar with the *National Statement* and consulting other guidelines relevant to the review of specific applications for ethics approval.

Each member should provide opinions on the ethical acceptability of research ethics applications in a timely manner and should keep all information received as part of their role, confidential.

Each member should attend continuing education or training programs in research ethics at least every three years.

Each member also serves effectively in the role of Research Ethics Advisor (REA) to staff and students within the School. A REA supports the work of the Research Ethics Team by providing localised, discipline-specific support for researchers as they consider and conduct ethical research involving humans. Each REA within a School should be the first point of contact for a researcher or teaching team conducting human research, following their consultation with the ECU Research Ethics Manual (ECU-REM). The REA should offer advice, suggestions or guidance to researchers on the ethical design and conduct of their project. This advice should be based upon the ECU Research Ethics Manual, appropriate external reference points such as the National Statement on Ethical Conduct in Human Research, relevant regulations and legislation nationally and for Western Australia, and an understanding of the principles of ethical conduct in the broad disciplinary area.

2. Meetings

The School Based Low Risk Subcommittee will meet (face to face or via teleconference) at least once per year. All business, including the assessment of applications, will be conducted electronically between members.

3. Reporting

The Low Risk Subcommittee members and Chair report to the Manager, Research Governance in their capacity as a reviewer of low risk research.

All decisions made by members of the School Based Low Risk Subcommittee must be sent to the Research Ethics Team for noting. Monitoring of approved research projects will be conducted by the Research Ethics Team with referral to the Subcommittee Chair where required.

Standard conditions of ethics approval for research projects include completion of an annual ethics report (for projects longer than one year) and a final ethics report (at the completion of a project). The School Based Low Risk Subcommittee will be involved in the review of these reports and any requests for amendments.

4. Resources and budget

Research Services will provide administrative support for the School Based Low Risk Subcommittee. There will be no additional budget provided to the School Based Low Risk Subcommittee.

5. Review

The Chair of each School Based Low Risk Subcommittee will attend at least one HREC meeting and meet on an annual basis with the Manager Research Governance to review the roles and operation of the Subcommittee. The Manager Research Governance will report to the Director, Research Services in relation to roles and operation on an annual basis.

The Director, Research Services also reserves the right to periodically examine applications reviewed and approved by the School Based Low Risk Subcommittee to monitor quality and/or compliance with these Terms of Reference. The School Based Low Risk Subcommittee will provide any requested information regarding review of applications. The Chair of the School Based Low Risk Subcommittee must also report any adverse events, suspected ethics violations and complaints to the Manager, Research Governance in Research Services.

Negligible Risk Review Subcommittee

Purpose

In accordance with the NS sections 5.1.18 to 5.1.23, research with low risk can be assigned a level of ethical review other than HREC. In accordance with the NS section 5.1.22, negligible risk research can only be exempted from ethical review if it involves the use of existing data or records that contain only non-identifiable data about human beings. At ECU, negligible risk research is broader in scope than that which is outlined by the NS and therefore requires the establishment of a non-HREC level of ethical review. Negligible risk is defined within the *National Statement* as research where the only foreseeable risk is that of inconvenience.

Role

The role of the Negligible Risk Subcommittee is to review and approve applications that are of negligible risk.

Terms of Reference

The Negligible Risk Subcommittee's terms of reference are to oversee, review and approve ethics application of negligible risk; and to therefore determine if the research meets the requirements of the *National Statement* and is ethically acceptable.

1. Membership

The Negligible Risk Subcommittee shall comprise of the:

- Chair: Manager Research Governance; and
- Members: Research Ethics Support Officers

2. Meetings

The Negligible Risk Subcommittee shall not meet formally. The review and approval of ethics applications will occur on a daily basis. Decisions will be ratified by the Chair of the Negligible Risk Subcommittee.

3. Reporting

The Negligible Risk Subcommittee members and Chair report to the Director, Research Services in their capacity as a reviewer of negligible risk research.

The Director of Research Services also reserves the right to periodically examine applications reviewed and approved by the Negligible Risk Subcommittee to monitor quality and/or compliance with these Terms of Reference. The Negligible Risk Subcommittee will provide any requested information regarding review of applications and will report any adverse events, suspected ethics violations and complaints to the Director, Research Services.

Assessing, Monitoring and Auditing

The ECU Internal Audit and Assurance Charter provides for ECU's outsourced internal audit provider to undertake a range of strategic, financial and operational audits in line with the approved Strategic and Annual Internal Audit Plans. It is expected that research ethics processes would be included in the Strategic Audit Plan and be subject to an audit across a five-year cycle.

The objective and scope of such audits will be developed by the outsourced internal audit provider in consultation with the Director Research Services and other staff as required. Outcomes of audits are reported to the Vice-Chancellor and the Quality, Audit and Risk Committee of Council.

At any time, Management may request additional audits to be conducted by contacting the Enterprise Risk Unit, which will schedule the requested audits taking into consideration available resources and timing.

Version History

Version	Date approved	Approver	Academic Board Approval	Next Review Date
V1	6 April 2018	HREC	April 2018	April 2021
V2	7 August 2020	HREC	1 October 2020	October 2023

Appendix A

Ethics Procedure Documents

Documents will be added to this section as they are developed. The purpose of adding them is to ensure consistency in decision making and to ensure decisions are transparent. The types of procedures to be developed are:

- Process for recruiting and appointing members.
- Process for training- new members, reviewers.
- Process for auditing the PRP.
- Process for auditing approved applications.
- Process for the management of complaints.
- Process for the management of breaches.