

**Definitions**

In these 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 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 procedures outlined in this document.

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 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 all ethics reviews, but lower risk levels of review are delegated to the Lower Risk Research Ethics Review Panel (“LRP”) in alignment with the National Statement 5.1.10.

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

- The HREC Chair will not be a member of the senior management of the University (known as the University Executive). They will be an ECU research-active Level E academic with a strong track record of sustained conduct of human research with integrity. Under exceptional circumstances, a Level D appointment may be considered by the DVCR. This person's name is to be published on the externally-facing ECU webpages.
- The HREC Chair is appointed for 3 years in the first instance and will be subject to an annual DVCR performance review, the parameters of which will be outlined by the DVCR to the HREC Chair at the start of each year. The HREC Chair will be eligible for re-appointment for a maximum of one additional 3-year term. Under exceptional circumstances, and subject to formal approval from the DVCR or VC, a HREC Chair may be appointed for a third 3-year term.
- The university service workload allocation for the HREC Chair is up to 0.4FTE, depending on the committee's plan of work.
- The HREC Chair represents the HREC at the RHDC in accordance with the HREC and RHDC Terms of Reference.
- The HREC Chair shall meet annually with LRP Chairs in a format to be determined by the HREC Chair and facilitate the attendance of LRP Chairs for at least one meeting of the HREC annually.
- The person elected as Deputy Chair will hold office for a period not exceeding 3 years and will be eligible for re-election. The relevant School has responsibility for determining university service workload allocation. They will be an ECU research-active Level E or Level D academic with a strong track record of sustained conduct of research with integrity. Under exceptional circumstances, a level C academic might be considered for this role.
- The HREC Chair and Deputy Chair shall constitute the HREC Executive. The HREC Executive will conduct executive reviews pursuant to the Executive Review Procedures.
- Expressions of interest for new HREC members will be sought via the RET. The HREC Chair will make a recommendation to the RHDC for formal approval and appointment.
- HREC members will be appointed for a duration of 3 years. In exceptional circumstances, and at the discretion of the HREC Chair, HREC members may be recommended for endorsement to the RHDC for appointment for shorter terms. There is no limitation to the number of terms served by HREC members.
- The HREC Chair will recommend HREC members seeking to be reappointed. This recommendation will be endorsed at the RHDC for re-appointment.
- ECU staff HREC members should be provided with a university service workload allocation as determined by the relevant School. Non-ECU HREC members will be offered remuneration for their service (including but not limited to meeting attendance, provision of feedback and reviews out of session).
- Where a member is appointed to fill a short-term or 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.
- HREC members will receive a formal notice of appointment in writing from the RHDC Chair.
- Prior to commencement of the role, each HREC member is required to attend an induction facilitated by the RET and Research Ethics Advisor (REA).
- ECU provides indemnity for all appointed HREC members in respect of any liability that may arise during the professional conduct of their duties as members.
- HREC members who are absent from 3 successive meetings of the HREC or who do not provide written feedback, and/or complete other duties, will cease to be HREC members at the recommendation of the HREC Chair, and endorsed by the RHDC.
- 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 via the RET.

- The appointment of any HREC member may be terminated by the RHDC on the recommendation of the HREC Chair if they reach the conclusion 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 deemed to be no longer a fit and proper person to serve on an HREC.

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

## 2. Election of Chair and Deputy Chair

Appointment of a new Chair

- The Deputy Vice-Chancellor (Research), DVCR, will adopt a process to identify a new Chair in consultation with the outgoing Chair. The recommendation of the DVCR will be tabled at RHDC for discussion and ratification. The Chair is appointed for 3 years, with one further 3-year extension, and will be subject to DVCR annual performance review. Under exceptional circumstances, and subject to formal approval from the DVCR or VC, a Chair may be appointed for a third 3-year term. The Chair of the HREC must always be an ECU staff member and meet the requirements of a Chair as outlined in the National Statement (5.1.30a)

Reappointment of the current Chair:

- Where an HREC Chair seeks to be reappointed, the DVCR will consider the reappointment, and if they support the re-appointment, they will table the recommendation at RHDC for discussion and ratification.

Appointment of Deputy Chair:

- The HREC shall nominate from amongst its ECU membership, through an expression of interest process, a Deputy Chair. The HREC Chair will recommend to the RHDC for ratification. The Deputy Chair is appointed for 3 years, with one further 3-year extension.

## 3. Composition

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

- A Chairperson (level E/D research active academic), with suitable experience, including previous membership of a HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the [National Statement](#).
- Two people who bring a broader community or consumer perspective and who have no paid affiliation with ECU.
- A person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional.
- A person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader.
- At least one lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise ECU on research-related or any other matters; and
- Two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

ECU members should be level E or D and research active. In exceptional circumstances, a research active level C may be appointed as a member so long as no greater than 33% of ECU members are level C. Every effort will be made to ensure Athena Swan and Gender Equity, Diversity, and Inclusion (GEDI) principles for committee membership.

The HREC may admit observers to its meetings.

#### 4. Meeting and responsibilities

- The HREC will meet each month, with the exception of January, and will publish the dates of its meetings and agenda closing dates for applications on the ECU ethics website. The meetings can be held in person, online or through a hybrid approach.
- As far as is practicable, each HREC meeting should be arranged to enable attendance of all members of the minimum membership categories (i.e., Chair, community member, counselling member, pastoral care member, legal member, and researcher member) and other relevant appointed members, either in person or via available technology, for example, videoconference. Where there is less than full attendance of members from the minimum membership categories at a meeting, the Chair must be satisfied that the views of the members who are not present have been received and considered by all members of the HREC participating in the meeting, as far as is practicable, before a decision is made.
- Decisions at meetings must be made following a respectful 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 receipt and consideration of that member's views. Decisions need not involve unanimity but still require a majority (greater than 50%). Dissenting opinions, if requested by the HREC member, will be noted in the minutes. Members cannot delegate their role to a proxy.
- The HREC will maintain a record of decisions about approval, amendments or rejection of proposals, with reasons for those decisions linked to the relevant sections, chapters or paragraphs of the [National Statement 2025](#)
- In the event the Chair and Deputy-Chair are unavailable to attend a meeting, the HREC may appoint an HREC member to Chair the meeting in their absence. This HREC member must be an ECU staff member and will no longer be identified in their membership category.
- The HREC notes approval decisions, HREC Executive and Exempt/Out-of-Scope notifications, investigation outcomes, as well as annual and final reports.
- The HREC will document all conflicts of interest raised by HREC member, along with their resolutions, in the HREC meeting minutes
- The HREC has oversight of the LRP to which it has delegated the ethical review of research that is considered to be of lower risk to participants. This includes noting of:
  - Approval decisions of the LRP.
  - Outcomes of complaint processes, including but not limited to suspensions and discontinuations of approved lower-risk projects.
  - Decisions relating to the appointment and termination of membership and chairpersonship of the LRP, including the resolution (decision and actions taken) of all complaints and conflicts of interest raised against LRP members.

Each HREC member is responsible for:

- Disclosing to the HREC any conflict of interest that may affect the member's review of a research proposal, as outlined in the HREC Terms of Reference.
- Preparing for, and attending, HREC meetings or, if unavailable, providing feedback on the ethical acceptability of the research applications in advance to be tabled at the meeting.
- Re-reviewing application resubmissions and amendments as required.
- Promptly notifying the RET if unable to meet the review deadline.
- Undertaking continuing education in human research ethics once every 3 years in accordance with the [National Statement](#).
- Have an awareness of and adherence to ECU's guidelines or policies for research integrity.
- Ensuring the confidentiality of information received in the exercise of their duties is maintained at all times.

- Maintaining a working knowledge of the National Statement and other guidelines as relevant to the review of such research proposals. Members need to have an understanding of:
  - The ethical issues that can arise in the research under review.
  - Issues associated with the collection, use and management of data and information in research.
  - The privacy guidelines that may apply to the research under review.
  - Other legal standards that may apply to the research under review include legislation relating to guardianship or the use of human biospecimens.
- HREC responsibilities do not extend to the assessment of, and determinations on, research governance matters. Examples of areas of responsibility that do not extend to HREC responsibility include, but are not limited to, foreign interference risk, some areas of controversial research, insurance and legal compliance (e.g., Privacy and Responsible Information Sharing Act). These are outlined in the induction provided to HREC members. The HREC Chair, with the support of the RET, ensures feedback to researchers does not include governance matters; however, the HREC reserves the right to draw attention to potential governance matters that need addressing, as ECU does not have a Research Governance Review Process.
- In line with University practice, research ethics applications that involve Aboriginal and Torres Strait Islander persons, populations and/or communities, but not pertaining to their health and wellbeing, undergo pre-review by Kurongkurl Katitjin.
  - An application will then progress to ethical review against the National Statement upon written communication from Kurongkurl Katitjin that includes:
    - Confirmation that the application has satisfactorily addressed relevant sections of the National Statement
    - Advice on assessed risk to participants.
  - The review pathway is determined by the level of assessed risk in accordance with the National Statement (Chapter 2.1); this will be guided by advice from Kurongkurl Katitjin. Higher-risk applications are reviewed by the HREC and lower-risk applications by the appropriate LRP, pursuant to the respective Procedures.
- Research ethics applications that pertain to the health and well-being of Aboriginal and Torres Strait Islander persons, populations and/or communities are required to undergo review by the Western Australian Aboriginal Health Ethics Committee (WAAHEC). Upon approval, researchers are required to use the Proportional Review Checklist (PRC) within REMS to lodge their application. This will allocate the application to the Executive Review pathway for reciprocal approval pursuant to the Executive Review Procedures.

## 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.
- Maintain a record of training status and regular updates on induction and ongoing ethics training and provide to the HREC Chair on request.
- Provide advice and executive support to the HREC Chair or Deputy Chair as requested.
- Provide advice and executive support to the HREC 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 the Committees, to promote ethics literacy.

- Offer relevant advice and assistance to other institutions, which may include but is not limited to, queries regarding ethics approval for ongoing projects.
- Implement systems adopted by ECU to promote efficient ethical review.
- Provide an annual report to RHDC on both lower-risk and higher-risk applications reviewed by school LRPs and the HREC, in line with the annual RHDC reporting requirements and schedule.

## 6. Complaints Processes

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

- Complaints or enquiries regarding higher-risk ethics 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 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 or a member of the RET, if the REA is unavailable, will consult with the HREC Chair or Deputy Chair, if the Chair is unavailable, to agree on any suspension recommendations.
  - If suspension is required, the REA or a member of the RET, if the REA is unavailable, on behalf of the HREC Chair (or Deputy Chair, if the Chair is unavailable), 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 HREC Chair (or Deputy Chair, if the Chair is unavailable), REA, and/or RET members will discuss and gather further information or interview parties deemed relevant.
  - If interviews are deemed necessary for the investigation of the matter at hand, the REA or a member of the RET, if the REA is unavailable, will invite the party/parties deemed relevant by the HREC Chair to attend interviews in the format deemed appropriate, including but not limited to individual or group meetings.
  - The invitation will identify the proposed attendees and provide an opportunity for relevant parties to raise any conflicts of interest in line with Section 6e of these procedures.

- An interviewee will have the opportunity to attend the meeting with an appropriate support person per University guidelines, noting the confidential nature of these meetings. A summary of meetings will be compiled and circulated to confirm accuracy.
- The REA or a member of the RET, if the REA is unavailable, in consultation with the HREC 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 HREC Chair (or Deputy Chair).
- Complaint outcomes will be confidentially communicated to the ED and line manager, as per ECU process, the ED will be confidentially copied on investigation outcomes.
- In cases where projects have been suspended, the research team must not resume any research activities until the HREC 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 HREC 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 raised against HREC members

- Any complaint against an HREC member, including the HREC Chair or Deputy-Chair, that brings into question their fitness and propriety to serve on the HREC, 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 1 of these procedures, will be made by RHDC upon the advice of the HREC Chair.
  - Where a complaint against the HREC Chair or Deputy-Chair is upheld, the DVCR will be informed, and a decision to terminate the individual's chairpersonship and panel membership, pursuant to section 1 of these procedures, will be made by RHDC upon the advice of the DVCR.
  - All complaints, along with their resolutions (decision and action taken), will be documented and noted at the next appropriate HREC meeting.

#### 6e. Conflicts of Interest raised against HREC members

- For avoidance of doubt, this subsection applies to externally raised conflicts of interest concerns regarding HREC members (including the Chair and Deputy Chair). It does not replace the standard process by which HREC members disclose item-specific conflicts of interest themselves during HREC meetings or out-of-session deliberations, which are managed at the time by HREC decision in accordance with the HREC Terms of Reference and these Procedures (Section 4) and in alignment with the National Statement (Chapter 5.6).

#### Externally raised COIs relating to HREC *in-session* matters

- When an individual(s) external to the HREC committee believes a conflicts of interest, actual, potential or perceived, exists for an HREC member pertaining to an item under review at a forthcoming HREC meeting, it must be raised using the prescribed process outlined below and

managed in accordance with HREC processes (including National Statement (Chapter 5.6)) and ECU's Conflicts of Interest Policy and associated institutional processes.

- An externally raised COI concerning a member participating in an HREC meeting item (including agenda items for review, complaints, or committee business) must be raised in writing via either an email to the REA/RET or through ECU's prescribed process. The concern must be provided to the HREC Chair (or Deputy Chair, if the Chair is the subject of the concern) for tabling at the earliest appropriate HREC meeting (or out-of-session HREC determination, for example, but not limited to, an electronic circulation).
  - The COI concern must be considered before deliberation on the substantive matter proceeds.
  - The HREC will determine any appropriate COI management actions in accordance with standard HREC processes and ECU's Conflict of Interest Policy and Procedure (including whether the member should be excused from deliberation and/or decision-making on that matter).

#### Externally raised COIs relating to HREC *out-of-session* matters

- When an out-of-session meeting (including but not limited to an investigation interview) is convened, the invitation should identify the proposed ECU/HREC attendees and provide a reasonable opportunity for relevant parties to raise any COI concerns in advance through the formal process outlined below.
- If conflicts of interest, actual, potential or perceived, are believed to exist for an attendee at an out-of-session meeting, this is raised in writing via either an email to the Manager, Research Governance, or through ECU's prescribed process.
- To preserve procedural fairness and prevent misuse of process, where an externally raised COI concerns a member proposed to participate in an out-of-session meeting, interview, or investigation process (including matters under section 6c), the COI concern must be assessed before that meeting/process occurs.
- If the COI concern is assessed and an actual, potential, or perceived COI is identified, the involved meeting participant must not engage in deliberations or decision-making and must not influence the outcome of the relevant matter.
- Where the COI concern relates to the HREC Chair, the out-of-session matter will be managed by the Deputy Chair (or other appropriate delegate); where the concern relates to the Chair and/or Deputy Chair such that independent management is required, the matter will be referred to the Manager, Research Governance (or nominee) for determination of process and interim arrangements; where the matter relates to the REA or member of the RET, an alternate member of the RET will be used.
- All externally raised COI matters, and their resolutions (including any interim management steps, decisions, and actions taken), will be documented and noted at the next appropriate HREC meeting, subject to confidentiality requirements.

## 7. Approval History

<b>Procedure approved by:</b>	Research and Higher Degrees Committee (RHDC)
<b>Date Procedure first approved:</b>	26 August 2025
<b>Date last modified:</b>	24 March 2026

<b>Revision history:</b>	<p>26 August 2025</p> <p>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.</p> <p>10 February 2026</p> <p>Revision and clarification of process for the review of research ethics applications that involve Aboriginal and Torres Strait Islander persons, populations and/or communities. Revision of language around process for the investigation of ethical concerns raised. Minor edits for consistency and to tighten process for the assessment of conflicts of interest to ensure procedural fairness.</p> <p>24 March 2026</p> <p>Tightening of processes for management of conflicts of interest raised by external parties.</p>
<b>Next revision due:</b>	26 August 2028