HREC Standard Operating Procedure (2)

1. Purpose

This document provides standard operating procedures for the conduct of Vial Australia Human Research Ethics Committee (Vial Australia HREC) meetings, including meeting procedures, decision-making processes, record keeping, complaints handling, and review processes. It ensures that Vial Australia HREC operates in accordance with the National Statement on Ethical Conduct in Human Research (2025) incorporating all updates by the National Health and Medical Research Council, Australian Research Council and Universities Australia.

2. Meeting Procedures

2.1 Frequency of Meetings

The Vial Australia HREC is scheduled to meet monthly, either in person or through an online meeting platform. Meeting dates and application closing dates are discussed via teleconference.

2.2 Attendance at Meetings

At the full committee meeting, a record of which members attended the meeting will be documented and the category in which each member belongs to, per the National Statement.

2.3 Quorum

A quorum shall consist of at least eight members, including the required number from each of the minimum membership categories as defined in the National Statement (Section 5.1.30) (i.e., two members are required for some categories):

- Chairperson with suitable experience, including prior HREC membership
- Two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution
- One person with knowledge and current experience in the professional care or treatment of people (e.g., nurse, counsellor, or allied health professional)
- One person who performs a pastoral care role in the community (such as an Aboriginal and/or Torres Strait Islander elder, minister of religion, or chaplain)
- One qualified lawyer, preferably not currently engaged to advise the institution on research-related matters
- Two people with current research experience relevant to the proposals being considered

If any required member cannot attend, quorum may still be met provided their written comments are received and considered prior to decision-making, as permitted under

Sections 5.2.29–30 of the National Statement.

3. Conduct and Structure of Meetings

3.1 General Conduct

Vial Australia HREC meetings are conducted in a structured format to ensure rigorous, ethical review and transparent decision-making in accordance with the National Statement (2025).

A meeting is considered quorate when at least eight members are present, including the required number from each minimum membership category as specified in Section 5.1.30 of the National Statement (i.e., two people are required for some categories).

If a required member cannot attend, the meeting may still proceed if the Chairperson confirms the member:

- Received the agenda and papers in advance
- Was provided an opportunity to submit written comments
- Had those comments tabled and considered during deliberations

3.2 Meeting Agenda

The meeting agenda typically includes:

- Attendance and apologies
- Declaration and management of relevant interests
- Confirmation of previous minutes
- Review of applications for ethical and scientific acceptability
- Review of amendments, annual progress, and final reports
- Reports of serious or unexpected adverse events
- Review of items approved under delegated authority (for ratification)
- General business

3.3 Chairperson Responsibilities

The Chairperson facilitates discussion of each agenda item, ensuring:

- All members are given a fair opportunity to contribute
- Ethical principles and National Statement guidelines are followed
- Decisions are made by consensus wherever possible

Where consensus cannot be reached, the Chairperson will determine whether there is sufficient general agreement to proceed. Any dissenting opinions or significant minority views (i.e., two or more members) are recorded in the minutes.

The Secretariat documents all discussions and decisions in formal minutes, which are confirmed at the following meeting.

3.4 Preparation of Agendas and Minutes

The preparation of the agenda and minutes is undertaken by either Vial's leadership, administration officer, or an appointed delegate.

The minutes from the meeting will include an overview of the committee discussion of each application and a detailed list of concerns to be addressed. The minutes will also record any conflicts of interest, detailed discussions of policy discussions, complaints, matters arising, general discussion items and any applications brought back to the full committee for final approval.

The HREC Chair, in consultation with the Research Governance Office, may choose to accept a late application or incident report if there is a demonstrable risk or urgency to the application or report.

3.5 Distribution of Papers Prior to Meetings

Agendas and review materials will be distributed to members at least seven business days prior to each meeting in an electronic format.

3.6 Attendance of the Principal Investigator

At the request of the HREC Chairperson, the Principal Investigator (PI) may be invited to attend a Vial Australia HREC meeting to:

- Provide a presentation or summary of the proposed research project
- Clarify specific aspects of the protocol or consent process
- Respond to questions or concerns raised by the committee

Where the PI is unavailable, another key investigator or collaborator may attend with prior approval from the Chairperson. Representatives of the sponsor are not permitted to attend in place of the PI, but may accompany them where appropriate and approved by the Chairperson.

Any such attendance must be conducted in accordance with confidentiality obligations and must not interfere with the independence of HREC deliberations.

4. Presentation of Applications for Ethical Review

After a full committee review, the researcher will receive an email with the minutes from this meeting, outlining any questions or changes required from the committee.

The Vial Australia HREC will request any additional documentation they require to assist in the review of the application.

5. Managing Conflicts of Interest

All Vial Australia HREC members must declare any interests that may be relevant to matters under consideration at a meeting. Interests include, but are not limited to:

- Financial, professional, or personal relationships with any parties associated with a research project
- Institutional affiliations
- Prior involvement in the project under review

Declared interests are recorded, and potential conflicts of interest (COIs) are then identified and managed in accordance with institutional policy and the National Statement (Sections 5.4–5.6).

Where a potential conflict is identified:

- The member may be asked to leave the meeting during discussion of the relevant item
- The absence and reason are recorded in the minutes

This ensures that Vial Australia HREC decisions are made independently and transparently.

6. Communicating with Researchers

After each meeting, the researcher will be informed by email of the approval level and a detailed list of committee concerns that need to be addressed before full ethical approval will be granted. It is standard practice to have the minutes provided to researchers within 7 days from the meeting to allow a timely response to the minutes.

All correspondence to the researchers is securely stored electronically in the ERMS.

The Research Governance Officer can only communicate with the sponsor in relation to administrative matters.

7. Record Keeping and Duration of Approval

7.1 Project Records

Vial Australia HREC prepares and maintains a confidential electronic record for each application received and reviewed and records the following information:

- Unique project identification number
- Principal Investigator(s)
- Title of the project
- Ethical approval or non-approval with date
- Approval or non-approval of any changes to the project
- Terms and conditions, if any, of approval of the project
- Whether approval was by delegated review
- Action taken by the Vial Australia HREC to monitor the conduct of the research

The file contains a copy of the application, including signatures, relevant

correspondence including that between the applicant and the Vial Australia HREC, all approved documents and other material used to inform potential research participants.

7.2 Minutes

A HREC member or secretariat is to prepare the minutes of the Vial Australia HREC meeting in consultation with the Chairperson and other members as necessary. The minutes are subsequently approved by the Chairperson within 1 working day of the meeting.

The minutes reflect each item listed for discussion on the agenda:

a. Attendance and apologies

b. Declarations of relevant interests relating to agenda items. Any identified potential conflicts of interest and their management are documented.

c. Confirmation of minutes of the previous Vial Australia HREC meeting

d. Business arising since the previous meeting(s) that the Vial Australia HREC indicated it wished to reconsider

e. Minutes of meetings and any issues for noting and/or approving from the Vial Australia HREC Executive Committee, and external expert reviewers

f. Amendments to documents or modifications to applications and research projects (including renewals)

g. Annual progress reports and final reports

h. Reports of serious adverse events and suspected unexpected serious adverse reactions

i. Vial Australia HREC deliberations and decisions on new applications, whether in the main text of the minutes or in attachments:

- Submission of written comments by members
- Summaries of the advice given by expert or lead reviewers
- Summaries of the main issues considered
- Decisions of the Vial Australia HREC on the application
- Formal dissent from the decision of the Vial Australia HREC by a member and the reason for it and/or any significant minority views (i.e., 2 or more members)

j. General business

k. Notification of the date, time and venue of the next scheduled meeting

The minutes are submitted at the next meeting of the Vial Australia HREC for ratification as a true record. Members are given the opportunity to seek amendments to the minutes prior to their finalisation.

The minutes are confidential to the Vial Australia HREC and are not disclosed to

investigators or sponsors.

The minutes of Vial Australia HREC meetings are made available to Vial's leadership, an administration officer or their appointed delegate and, upon request, to the Research Governance Officer.

7.3 Record Retention

All relevant records of the Vial Australia HREC, including applications, membership, minutes and correspondence, will be kept as secure confidential electronic files in accordance with Policy: Vial Australia HREC Record Keeping.

To ensure confidentiality, any documents provided to Vial Australia HREC members, which are no longer required, are disposed of in a secure manner, such as shredding or placed in confidential bins.

Data pertaining to research projects is held for sufficient time to allow for future reference. Records will be retained for 15 years following the completion of the research.

The database of all the applications received and reviewed is maintained in accordance with the NHMRC National Statement on Ethical Conduct in Human Research.

7.4 Duration of Approval

Vial Australia HREC approval applies for a maximum of 2 years, except where action is taken to suspend or terminate the decision.

The request to extend the duration of the research project is submitted by the Principal Investigator as an amendment for review by the Vial Australia HREC in the first instance.

Vial Australia HREC approval for an extension applies for a maximum of 2 years, except where action is taken to suspend or terminate the decision.

8. Relevant Expertise on Committee

The leadership at Vial and Research Governance are responsible for maintaining the number of scientific and ethical reviewers on the committee to ensure that all applications are reviewed by those with appropriate experience.

9. Complaints

9.1 Receiving and Handling of Complaints

The Vial Australia HREC may receive complaints relating to the conduct of research, researchers or research staff, research participants, or the operation and conduct of the HREC itself. Complaints may be submitted by participants, researchers,

members of the public, or any party involved in or affected by the research or the HREC's processes.

Complaint Handling Procedure:

- Upon receipt of a complaint, the HREC Chairperson or the RGO will gather preliminary information and assess the complaint.
- Where the complaint relates to a Principal Investigator, the HREC Chairperson will lead the investigation in line with institutional research integrity policies. Where the complaint relates to the HREC, the RGO will lead the investigation in line with institutional research integrity policies.
- Complaints are handled confidentially and independently of the party or project in question.
- Possible outcomes include:
    - No further action (with rationale)
    - Clarification or correction
    - Meeting with relevant parties
    - Placing conditions on the research
    - Suspension or withdrawal of ethical approval
    - Referral to institutional leadership or external review

All complaints and outcomes are documented and, where appropriate, tabled at the next Vial Australia HREC meeting.

All complainants will be notified of the outcome via email or phone once a resolution has been reached.

9.2 Complaints about the Conduct of the HREC

Section 5.7 of the National Statement (2025) states that institutions need to establish processes to handle complaints concerning research. This process specifically outlines a process for managing complaints made by ethics applicants for decisions made by a Vial Australia Human Research Ethics Committee (HREC).

Complaints about the conduct of the Vial Australia HREC may relate to procedural fairness, ethical oversight, timeliness, or any matter other than specific review decisions. Such complaints may be submitted by researchers, participants, or any other affected parties. These complaints should be directed to the Research Governance Officer.

General complaints not specifically related to HREC conduct should be sent to rgo@vial.com. All HREC-related complaints will be reviewed in consultation with the Research Governance Office (RGO). If a conflict of interest is identified, an alternative senior officer within VIAL will oversee the investigation.

9.3 Appeals Regarding HREC Decisions

If a researcher is dissatisfied with a decision made by Vial Australia HREC (e.g., rejection of a proposal or conditions imposed):

a. They may submit a revised application addressing the HREC's concerns; or

b. Where (a) does not apply, they may lodge a written appeal with the HREC

Chairperson, specifying the grounds. The Chairperson will investigate and recommend next steps within 4 weeks.

9.4 Escalation to Vial's Leadership

If the researcher believes the HREC has not followed due process or remains unsatisfied, they may escalate the complaint to the leadership at VIAL.

A panel may be convened including:

- Any leadership personnel or appointed delegate
- Two independent nominees (not HREC members)
- One member with ethics expertise
- Relevant external subject matter expert(s)

The panel's decision and rationale will be shared with both the HREC and the complainant. The panel may recommend referral to an independent HREC but cannot override Vial Australia HREC's decision.

10. Review Process

10.1 Lower Risk Applications

Lower risk applications, including audit-based research, may be reviewed out of session by the Chair, the Deputy Chairs, and a lay member or committee member with relevant qualifications or experience, in accordance with the lower risk review pathway described in SOP1 Section 5.4.

10.2 Higher Risk Applications

Higher risk applications are always reviewed at full committee. These include:

- Clinical drug trials
- Device trials
- Research involving new interventions or randomisation
- Research involving participants who may experience increased risk (as described in Section 4 of the National Statement)
- Registries and databanks
- All interventional research
- Research requiring waiver of consent
- Opt-out requests
- Genomic research
- Biobanks
- Exploration of any sensitive personal or cultural issues

10.3 Prompt Notification of Decisions

The Office for Research aims for its decisions to be relayed to the researchers within 7 days of the meeting at which it was discussed.

Version History

Version Number	Version Date	Author	List of Changes
1.0	October 12, 2024	Amna Ali	N/A: Initial Release (as SOP3)
2.0	January 5th, 2026	Nikolajs Zeps	Renumbered from SOP3 to SOP2 following consolidation of former SOP1 and SOP2. Updated to match the most up-to-date National Statement (2025). Updated all NS references. Revised risk terminology to "lower risk" and "higher risk" per continuum model. Replaced "vulnerable populations" with "participants who may experience increased risk." Harmonised distribution period for agenda and review materials to seven business days.