**Procedural and operational matters, including meeting conduct, review pathways, record keeping, and complaints management, are governed by Vial Australia HREC Standard Operating Procedures (SOPs), which are maintained as separate but complementary documents*

1. Purpose

This document outlines the scope of the Vial Australia Human Research Ethics Committee, Vial Australia HREC ("Vial HREC").

2. Background

Vial Australia HREC is set up to review internal research applications from Vial Australia Ltd. which is an Australian entity of Vial. Vial Australia HREC **exclusively reviews applications from Vial Australia Pty Ltd.** and **will not accept submissions from external researchers.** This exclusivity policy will be **explicitly stated on the Vial Australia HREC website** to ensure transparency.

This document provides scope for Vial Australia HREC operations to ensure that the company operates in accordance with the NHMRC (*National Health and Medical Research Council) National Statement on Ethical Conduct in Human Research (2023 and 2025).*

3. Defined Terms

1. Acronyms and Abbreviation

Vial Australia HREC	Vial Australia Pty Ltd Human Research Ethics Committee; also known as "Vial HREC"
NHMRC	National Health and Medical Research Council
AHEC	Australian Health Ethics Committee

2. Definitions

Adverse Event	A **pharmaceutical adverse event** (AE) is any undesirable or unintended effect experienced by a patient after taking a medication, regardless of whether the drug is considered the direct cause. Adverse events can range from mild reactions, such as headaches or nausea, to more severe outcomes like organ damage, life-threatening conditions, or death.

Clinical Trial	Any investigation in human subjects intended to discover or verify clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
Principal Investigator	The individual who takes overall responsibility for the research project and submits the project for ethical and scientific review.
Investigator's Brochure	Compilation of clinical and non-clinical data on the investigational product(s) relevant to the study of investigational product(s) and human subjects.
Multi-center Research	Research that is conducted at more than one site.
National Statement	The National Statement on Ethical Conduct in Human Research (2023)
Research Protocol	A document that details the objectives, design methodologies, statistical considerations and organization of the research project.
Safety Review Committee	An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy points, and to recommend to the sponsor whether to continue, modify, or stop a clinical trial.
Serious Adverse Event	Is any adverse medical occurrence that: 1. Led to a death 2. Led to a serious deterioration in health of a patient user 3. Led to a life-threatening illness or injury 4. Led to a permanent impalement of body function or permanent damage to body structure 5. Led to a condition requiring hospitalization or increased length of existing hospitalization

	6. Led to a condition requiring unnecessary medical or surgical intervention 7. Led to a fetal distress, foetal death or congenital abnormality / birth defect 8. Might have led to death or a serious deterioration in health had suitable action or intervention not taken place 9. Is a result of a malfunction of a device such that it has to be modified or temporarily / permanently taken out of service 10. Is a result of a factor or deterioration in characteristics or performance found on examination of the device
Sponsor	Is the company, institution or organization, body or individual that takes overall responsibility for the conduct of the trial and usually initiates, organizes and supports the clinical trial.
Therapeutic Good	Defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic uses (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989). Therapeutic means a product for use in humans in connection with: 1. Preventing, diagnosing, curing or alleviating a disease, defect or injury 2. Influencing, inhibiting or modifying a physiological process 3. Testing the susceptibility of persons to a disease or ailment 4. Influencing, controlling or preventing conception 5. Testing for pregnancy 6. Used as an ingredient or component in the manufacture of therapeutic goods 7. Replacement or modification of parts of the anatomy

4. Objectives

The objectives of the Vial Australia HREC are to:

1. Protect the mental and physical welfare, rights, dignity and safety of participants of research

2. Promote ethical principle in human research related to diagnostics

3. Review research in accordance with the National Statement on Ethical Conduct in Human Research (2023 and 2025) incorporating all updates

4. Facilitate ethical research through an efficient and effective review process

5. Functions

The Vial HREC's functions are to:

1. Provide independent oversight of human research projects that are focused in drug trials

2. Provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active

3. Determine the compliance of a human research project with the National Statement on Ethical Conduct in Human Research (2023 and 2025) and grant, withhold or withdraw ethical approval

4. Provide advice on strategies to promote awareness of the ethical conduct of human research

6. Accountability

The Vial Australia HREC or Vial HREC is directly accountable to Vial, its subsidiary, Vial Australia Pty Ltd, and the Research Governance Office (RGO) under which it is constituted.

Vial HREC provides a report in accordance with the requirements of the National Health and Medical Research Council (NHMRC) as referenced in the National Statement paragraph 5.8.4.

The minutes of each Vial HREC meeting will be available to the Chief Executive or delegate of Vial incl. senior leadership following confirmation.

The Vial HREC provides a report to the Chief Executive or delegate of Vial incl. senior leadership annually.

The Vial HREC brings to the attention of the Chief Executive or delegate issues of significant concern, when appropriate such as a complaint (more details are outlined in Complaints Process).

The Vial Australia HREC provides a report in accordance with the requirements of the National Health and Medical Research Council (NHMRC).

7. Scope of Responsibility

1. Vial HREC provides ethical and scientific review of all internal research with a full HREC committee for all applications initially.

2. The Chairperson, who will be filled by a designated member of the HREC, is responsible for the conduct of Vial HREC business and for ensuring that Vial HREC reaches decisions on all matters.

   If needed, a Deputy Chairperson will also be a designated member appointed on an ongoing basis. A Deputy Chairperson is assigned when the Chairperson is unavailable. The meeting will be chaired by the Deputy Chairperson if available, or by an alternate Deputy Chairperson, if the original Deputy Chairperson is also unavailable.

3. The HREC has an Executive Committee, comprising at least the Vial Australia HREC Chairperson (or their delegate) and at least one other HREC member. The Executive Committee is delegated to undertake expedited review and approval of business that does not require full Vial Australia HREC review, in accordance with the National Statement and relevant institutional guidelines. This includes, but is not limited to:

   a. Reviews of lower-risk research proposals

   b. Minor amendments or administrative amendments and renewals to current Vial Australia HREC-approved projects

   c. Responses to Vial Australia HREC queries, as referred and pre-approved by the full Vial Australia HREC for Executive Committee review and approval

   d. Annual progress reports and final reports

   e. Review of Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) reports.

   Decisions made by the Executive Committee will be noted and ratified at the next full meeting of the Vial HREC.

4. To support efficient operations, Vial HREC may delegate decision-making authority to the Chairperson; however, such delegation is strictly limited to the types of business outlined in subsection (c) — that is, business that does not require full Vial HREC review. This delegation may be applied on a case-by-case basis or for a defined category of decisions and must always align with the principles and requirements of the National Statement.

   In exercising this delegated authority, the Chairperson must act in a manner consistent with the values and perspectives of the Vial

HREC's membership and ensure that decisions reflect appropriate ethical consideration. The delegation may include signing relevant documentation on behalf of the Vial HREC.

Where necessary, the Chairperson may authorise another member of the Vial HREC to perform administrative tasks or make limited decisions on behalf of the HREC, provided that such delegation is clearly documented in a permanent record, including any limitations or conditions placed on the delegated authority.

All decisions made by the Chairperson or any authorised delegate under this delegation will be noted and ratified at the subsequent Vial HREC meeting.

8. Vial Australia HREC / "Vial HREC" Composition

The composition of the Vial HREC is in accordance with the **2023 and 2025 National Statement on Ethical Conduct in Human Research**, Section 5.1.30. The minimum membership comprises **at least eight members**, including representatives from the following categories:

1. A **Chairperson** with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement

2. **Two people who bring a broader community or consumer perspective** and who have **no paid affiliation with Vial or its subsidiaries**, including Vial Australia Aus Pty Ltd

3. **One person with knowledge of, and current experience in, the professional care or treatment of people**; for example, a nurse, counsellor, or allied health professional

4. **One person who performs a pastoral care role in a community**, including but not limited to, an Aboriginal and/or Torres Strait Islander elder, or a community leader, chaplain, or minister of religion or other religious leader

5. **One qualified lawyer**, who may or may not be currently practicing and, where possible, is not engaged to advise Vial or its subsidiaries, including Vial Australia Aus Pty Ltd, on research-related or other institutional matters

6. **Two people with current research experience** that's relevant to the research proposals to be considered at the meetings they attend

Where appropriate, more than one person may be appointed to any of the above categories to ensure that the Vial HREC is equipped to consider the full scope of research under review. **However, no member will be appointed in**

more than one category.

At least one-third of Vial HREC members will be external to Vial and its subsidiaries, including Vial Australia Aus Pty Ltd., supporting the independence and integrity of the committee's ethical review process. Vial HREC actively promotes **diversity of membership**, including gender balance and a range of cultural, social, and professional backgrounds, to ensure that a broad range of perspectives are reflected in the committee's deliberations.

All members are required to declare any interests relevant to the research under review, including institutional affiliations or personal relationships. All declared interests will be assessed, and potential conflicts of interest will be identified and appropriately managed in accordance with institutional policy and the National Statement.

9. Membership Selection Criteria

General Criteria:

1. Experience of a broad range of community activities
2. Able to understand/learn and apply research ethics principles
3. Interest in health and health research issues
4. Able to read and understand Vial Australia HREC application documents
5. Able to appreciate the interest of potential research participants and the potential risks and benefits of research proposals, and assess the balance between the two
6. Able to attend meetings and able to participate in and respond to delegated Vial Australia HREC applications when required

Specific Criteria

1. Members who bring a broader community or consumer perspective
    a. Demonstrated interest in and awareness of health consumer issues
    b. Not currently involved in health research or the delivery of health services
    c. Not directly affiliated with the institution or research being reviewed
    d. Not a qualified lawyer, minister of religion, or health professional

2. Member with legal experience
    a. Legal qualifications and experience in the practice of law
    b. Interest in and knowledge of legal issues to health services or health research is desirable

3. Member with pastoral care experience:
    a. Experience as a minister of religion, spiritual leader or aboriginal elder
    b. Interest in a knowledge of religious or spiritual issues relevant to health services or health research is desirable

4. Member with knowledge of and current experience in the professional care / counselling and treatment of people:

a. Experience in the delivery of health or community services
b. Particular experience of service delivery in a hospital setting on community setting, depending on the vacancy being filled

5. Members with health research experience:
    a. Experiencing the conduct of health research
    b. Experience in clinical, social sciences, epidemical or laboratories research, depending on the vacancy being filled

10. Appointment of Members

Vial HREC members are recruited by direct approach, nomination, or by advertisement through an open and transparent process. Prospective members may be invited to observe a Vial HREC meeting.

Prospective members are asked to provide a copy of their curriculum vitae to a selection committee, composed of the Chairperson and at least one other Vial Australia HREC member. The selection committee interviews prospective members, consults with other Vial HREC members and makes a recommendation on new appointments.

Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organization, group or opinion.

Vial HREC members shall receive payment in accordance with reasonable value, based on expertise and experience, and reimbursement of any approved out of pocket expenses, such as a car parking cost.

Upon appointment, members are asked to sign a statement undertaking:

1. All matters of which they become aware during the course of their work on as a member of Vial HREC will be kept confidential

2. Any relevant interests which exist or may arise during their tenure on the Vial HREC will be declared. All declared interests will be assessed, and potential conflicts of interest will be identified and appropriately managed.

Members are appointed for up to 3 years and may serve a total of nine years. This is consistent with the tenure provisions in the *Health Service Act for Directors of Victorian Public Health Services*. Members are advised when their term is due to expire. Reappointment is by application to the Chairperson of the HREC.

The HREC Chairperson will review membership at least every three years. New and renewed appointments allow for continuity, development of expertise within the Vial HREC, and input of fresh ideas and approaches.

All members complete a declaration of interests, which is maintained in their personnel file. Potential conflicts of interest are identified and managed in line with institutional policy and the National Statement.

Membership lapses if a member fails to attend:

1. Three consecutive meetings without reasonable excuse / apology or exceptional circumstances

2. At least 2/3 of all Vial HREC meetings in each year, barring exceptional circumstances

The Chairperson notifies the member of lapse of membership in writing. Steps are taken to fill the vacancy.

Members seeking to resign or take a leave of absence for an extended period from the Vial HREC are asked to give notice to the Chairperson. Steps are taken to fill the vacancy.

The appointment of any member of the Vial HREC may be terminated if the Chairperson is of the opinion that:

1. It is necessary for the proper and effective functioning of the HREC

2. The person is not a fit and proper person to serve on the HREC

3. The person has failed to carry out their duties as an HREC member

11. Training of Members

New HREC members are provided with training, involving the following:

1. Introduction to other Vial HREC members prior to their first official Vial HREC meeting

2. Informal meeting with the Chairperson to explain the responsibilities as a Vial HREC member, as well as the processes and procedures

Each member is expected to become familiar with the National Statement and consult other guidelines (listed below) relevant to the review of specific research applications and encouraged to attend continuing education or professional development activities in research ethics at least once annually.

1. National Statement on Ethical Conduct in Human Research (2025)
2. NHMRC Australian Code for the Responsible Conduct of Research (2018)
3. Therapeutic Goods Administration “Note for Guidance on Good Clinical Practice (CPMP/ ICH/135/95)” (2000)

Training and education on ethical review should occur at least annually and a register of all training provided to committee members will be maintained.

12. Agenda

The finalised agenda (not including late and urgent items) will be distributed to all members and attendees at least five business days before the HREC meeting. Records of the Vial HREC’s activities including agendas and minutes of all meetings will be maintained.

13. Quorum Requirements

A quorum is required at each Vial HREC meeting to reach a final decision on any agenda item. A meeting is considered quorate when **each of the eight minimum members from each category**, as specified in the National Statement, is present either in person or via videoconference or telephone.

14. External Expert Reviewers

Where Vial HREC lacks sufficient expertise to assess an application, the HREC committee, the HREC Chairperson, or HREC administrative officer may identify and consult an appropriate external expert. The procedures for engaging external reviewers are detailed in SOP2, Section 8.

15. Declaration of Interest

A Vial HREC member declares to the Vial Australia HREC any interest they have in relation to an application for ethical and scientific review or any other matter for consideration at that meeting. Relevant interests include financial interests, personal, professional, or institutional benefits, and / or advantages that depend significantly on the research outcomes (NS 5.6.7).

Researchers should disclose any interest that may constitute a conflict of interest, as referenced in National Statement 5.6.6 (Declaration and management of interests is governed by SOP3)

16. Confidentiality

The confidentiality of Vial HREC proceedings is essential as applications need to be discussed freely and may have commercial implications / sensitive information.

Vial HREC meetings are held in private, and members are encouraged to raise matters of concern. Confidentiality is addressed in the following ways:

1. The Vial HREC Terms of Reference

2. Members must sign a statement of undertaking upon appointment; attendance of visitors or observers at a meeting, as appropriate and approved by the Chairperson, is conditional on the attendee signing a confidentiality agreement.

3. Application documents and all supporting documentation and correspondence are treated confidentially

4. External expert reviewers providing advice to the Vial HREC are asked to sign a confidentiality agreement

5. Vial HREC correspondence is addressed to the Principal Investigator and the relevant contact person identified on the application form; correspondence is not released to the sponsor or any other party

6. If necessary, the Principal Investigators can forward information about matters raised in the ethical review to the Sponsor or another party

17. Decision Making

Members present in the HREC meetings are allowed a reasonable opportunity to express relevant views on matters on the agenda.

Applications to Vial HREC are reviewed in accordance with SOP: *HREC Research Review and Monitoring.* The Vial HREC endeavours to reach a decision concerning the ethical and scientific acceptability of a research project by unanimous agreement.

Where a unanimous decision is not reached, the Chairperson will need to facilitate the expression of opinion of all members, identify points of agreement and of disagreements, and judge when sufficient degree of general agreement has been reached. Any significant minority view (i.e., two or more members) is noted in the minutes.

Discussions of significant issues and decisions are recorded in the minutes. Where members wish, a record of their formal dissent from the decision of the Vial HREC is recorded in the minutes.

To encourage free and open discussion and to emphasize the collegiate character of the Vial HREC, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

An HREC member unable to attend a meeting must submit comments in writing on agenda items to the Chairperson prior to the meeting, Submission of written comments is recorded in the minutes.

18. Decisions Available to Vial HREC

The Vial HREC selects one of the following decisions on any application reviewed at a meeting and the decision is recorded in the minutes:

1. Approve the application as being ethically and scientifically acceptable

2. Request modification or further clarification

3. Seek further advice from external expert reviewer(s)

4. Reject the application

The Chairperson ensures that one of the above decisions is made on every application considered at an HREC meeting. Where the Vial HREC decides that further information or clarification is required, the Chairperson ensures that:

1. Further information or clarification required is specifically identified at the meeting

2. Delegation of responsibility for considering the further information or clarification, once collected, and confirming the final Vial HREC opinion is clearly agreed

19. Complaints

Complaints about the Conduct of a Research Project
If a participant, researcher, or third party wishes to raise a complaint about the conduct of a research project:

1. They may contact the **Principal Investigator** directly

2. Submit the complaint to the **Vial HREC** via the Research Governance Officer

If the complaint specifically concerns the **conduct of the Principal Investigator**, it must be directed to the **RGO or the RGO administrator.**

Additionally, for complaints are specifically related to the **HREC's conduct or processes**, please contact the **RGO or the RGO administrator.**

The RGO is responsible for conducting preliminary investigations involving Principal Investigators and will work in collaboration with the HREC as needed.

Where appropriate, matters may be referred for institutional disciplinary review. All complaints and outcomes are documented and tabled for the next HREC meeting if applicable. Complainants are informed of outcomes via phone or email.

Complaints About the Conduct or Operations of the HREC

Any individual may lodge a complaint about the **conduct, operation, or decision-making** of the Vial HREC. These are not limited to rejection or delays in application review, but may also relate to process transparency, ethical integrity, or procedural fairness. **Such complaints should be submitted directly to the RGO at rgo@vial.com.**

The RGO will conduct an initial investigation and, where necessary, consult with additional personnel. If a conflict of interest or serious concern is identified, the complaint may be escalated to leadership **at Vial or its subsidiary, Vial Australia Pty Ltd.**, who may initiate a formal review process.

Detailed procedures for complaints and appeals are outlined in **Section 8 of SOP3** and are available on the Vial Australia HREC website.

20. Vial Australia HREC Reporting Requirements

Vial HREC will submit a report to Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Statement (5.8.4)

21. Review of Standard Operating Procedures and Terms of Reference

The Vial HREC Standard Operating Procedures and Terms of Reference shall be

reviewed at least every two years and amended as necessary. The SOPs and Terms of Reference may be amended by following the procedure below:

The proposal must be in writing and approved by the Chairperson and where necessary, the views of the other HREC members should be discussed at the next scheduled meeting, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.

The proposal shall be ratified if two thirds of the members agree to the amendment.

22. Fees for Ethics Review

Vial HREC operates as an internal HREC under the RGO of Vial and its Australian entity, Vial Australia Pty Ltd. Its primary function is to review and provide ethical oversight exclusively for research applications submitted by Vial Australia Pty Ltd.

As Vial HREC has been established to support the ethical governance of research conducted by Vial Australia Pty Ltd., it does not function as a commercial or external review service. Instead, it is an integrated part of the research governance framework within Vial and its Australian entity. Therefore, Vial Australia HREC does not charge any fees for ethical review of research applications submitted by Vial Australia Pty Ltd.

Version History

Version Number	Version Date	Author	List of Changes
1.0	October 12, 2024	Amna Ali	N/A : Initial Release
2.0	January 5th, 2026	Nikolajs Zeps	Reformatted for more accessible readability / structure. Updated to match the most up-to-date National Statement (2025). Clarification of finer details of the ToR per NHMRC's request, incl. Verbiage and clarification of personnel and respective responsibilities