

# Vial HREC Complaints Process

## Overview

Vial Australia HREC (“Vial HREC”) is committed to upholding the highest standards of ethical research. If you have a concern or wish to make a complaint regarding any aspect of research reviewed by Vial HREC, or about the operation of the committee itself, please contact us using the information below.

## Types of Complaints We Handle

1. Concerns about the decision of the HREC
2. Concerns about the conduct of the researcher or research team (research integrity)
3. Concerns about the conduct of the research project (breaches of approved protocol or research integrity)

## Who to Contact

### General Inquiries

**Contact Name:** Amna Ali

**Email:** [contact@vialhrec.com](mailto:contact@vialhrec.com)

### Complaints or Concerns from Researchers and Participants

(i.e., regarding Ethics, the Researchers, the PI and / or the Sponsor)

**Contact Name:** Dr. Tahir Yayha

**Email:** [tahir.yayha@vialhrec.com](mailto:tahir.yayha@vialhrec.com)

**Phone:** +61 29 0995786

### Concerns Regarding the HREC

**Contact Name:** Research Governance Office

**Email:** [rgo@vial.com](mailto:rgo@vial.com)

**Phone:** +61 29 0995797

## What Happens Next

1. Complaints will be acknowledged within two working days

2. Preliminary review is conducted by the RGO or the HREC Chairperson, dependent on the nature of the complaint and adjusting for potential conflicts of interest
3. If warranted, such as severe breach of research protocol that can affect the physical, mental, and / or emotional well-being of patients, complaints are escalated for formal investigation(s) by an independent investigator
4. All parties are informed of the outcome in writing or by phone
5. Where complaints are against both the RGO and the HREC simultaneously, the Sponsor, Vial or its subsidiary, Vial Australia Pty Ltd, will assign the complaint to an independent investigator

## More Information

For detailed procedures on complaints handling, please refer to:

1. Section 8 of the Vial HREC Standard Operating Procedures (SOP3)
2. Section 19 of the Vial HREC Terms of Reference

Vial HREC follows the National Statement on Ethical Conduct in Human Research (2025), Chapter 5.7, in managing all complaints.

## 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	Recategorization of complaints. Clarification on formal investigations and what is considered a severe breach of research



			protocol. Added a footer and version control.
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