Vial HREC Governance & Quality Assurance Policy

Vial Australia Research Governance

Vial Australia Pty. Ltd. ("Vial Australia") stands at the forefront of biotechnology innovation, pioneering transformative treatments for a variety of therapeutic areas. Founded in 2023 in Melbourne as a wholly-owned subsidiary of Vial Health Technology Inc., our organisation embodies a commitment to research excellence that transcends conventional industry standards and sets new benchmarks for scientific integrity, participant safety, and regulatory compliance.

The architectural foundation of Vial Australia's Research Governance Framework embodies principles of independence, accountability, transparency, and continuous improvement. This framework serves as the structural backbone supporting all research activities while ensuring separation between governance oversight and operational decision-making. The architecture reflects best practices from leading research institutions worldwide while incorporating innovations specific to biotechnology research and in alignment with the following Australian regulatory requirements:

1. National Statement on Ethical Conduct in Human Research 2025

2. Australian Code for the Responsible Conduct of Research 2018

3. Other relevant international standards including ICH Good Clinical Practice E6(R3)

The Research Governance Framework consists of:

1. **Board of Directors (BoD):** The Board provides oversight and ultimate accountability for research governance strategy, policy development, and resource allocation.

2. **Executive Leadership:** The Chief Executive Officer maintains executive accountability for research governance implementation while delegating operational oversight to the Research Governance Officer (RGO). This delegation structure ensures appropriate separation between commercial leadership and governance oversight while maintaining clear accountability lines.

3. **Research Governance Office (RGO):** The independent RGO serves as the primary interface between researchers, the sponsor and the HREC, ensuring separation of duties and alignment with governance and ethical requirements.

While the RGO is compensated by the Sponsor, the RGO maintains sufficient independence from operational functions to provide objective oversight. This is ensured as the RGO has no financial gain(s) / losses or conflict(s) of interest to make any particular decision on behalf of Vial. Vice-versa, Vial has no capacity to influence the RGO's decision. This structure allows the RGO to provide unbiased research guidance and support. Should it be required, any declaration of conflicts by the RGO will be captured in any and all meeting minutes or a repository for secure record-keeping.

4. **Human Research Ethics Committee (HREC):** The Vial Australia HREC ("Vial HREC") represents the cornerstone of our ethical oversight system, operating with complete independence from commercial, research, and operational functions. Our HREC structure incorporates arms-length governance principles, ensuring that ethical decisions remain free from commercial or researcher interests while maintaining appropriate expertise and efficiency. To mitigate against potential for any financial conflict of interest, the committee's independence is ensured via a separate entity, CMO Pro LLC. CMO Pro LLC is responsible for contract and financial management of HREC members, while the HREC Chair is responsible for appointing members to the committee. Additionally, the RGO and HREC work together independently of Vial to address any concerns that may arise through their review of research applications.

   For example, for all research and operational matters, the HREC interacts with Vial Australia via the RGO, which as mentioned above makes decisions independent of any influence from Vial and its subsidiary. For all other matters and to mitigate any potential financial conflict of interest(s), all contracts, financial, and payment decisions are delegated to the separate entity, CMO Pro LLC. These measures ensure that Vial has no decision-making capacity and no influence over any decision made by the HREC. Vice-versa, the HREC, including its chair and members are not obligated to make any specific decision on behalf of Vial and any of its subsidiary's influences. Should it be required, any declaration of conflicts by the HREC chair and / or member will be captured in any and all meeting minutes or a repository for secure record-keeping.

5. **Sponsor Team (Vial and its subsidiary, Vial Australia Pty Ltd / "Vial Australia"):** The Sponsor Team serves as the scientific and operational engine behind each research initiative, taking responsibility for the rigorous design of study protocols, preparation and management of regulatory submissions, and ongoing compliance with industry standards. This team oversees the end-to-end process of product development, setting the scientific strategy that guides each project while ensuring that R&D efforts align with both organizational priorities and evolving clinical needs. Additionally, the Sponsor Team centrally manages data capture, quality assurance, and study reporting, providing the robust analytical and regulatory foundation upon which the integrity and impact of all research findings rest.

6. **Research Team (Principal Investigator and on-site research team):** At the site level, the Research Team operates as the primary architect of trial execution, translating approved protocols into high-quality clinical activity and direct participant engagement. Led by the Principal Investigator, this team manages participant recruitment and consent, steers the day-to-day conduct of each study, and is responsible for precise, timely source documentation in compliance with established protocol requirements. By acting as the key liaison with the HREC, the Research Team ensures rigorous adherence to ethical standards and fulfills all site-specific safety, compliance, and reporting obligations, thereby safeguarding both data fidelity and participant welfare throughout the course of the trial.

7. **Administrative Support:** Administrative support including legal, finance, and quality provide resourcing on matters pertaining to their respective expertise. For example, Quality Management System (QMS) integration ensures that governance activities align with broader organisational quality objectives while maintaining specific focus on research requirements. This integration prevents duplication of effort, ensures consistent application of quality principles, and facilitates continuous improvement through regular monitoring, audit activities, and feedback mechanisms.

If you have any specific questions please direct them to:

The Research Governance Office,

Email: rgo@vial.com

Address: Level 7, Suite 12, Dymocks Building, 428 George Street, Sydney, NSW 2000

Vial Australia Quality Policy

Vial Australia is committed to conducting and overseeing high-quality clinical trials that comply with ethical, scientific, and regulatory requirements both in Australia and around the world.

Vial Australia is dedicated to:

1. Ensuring participant rights, safety, and well-being are protected at all times

2. Maintaining compliance with applicable Australian laws, regulations, and international standards

3. Promoting scientific integrity and ethical responsibility in all research
4. Supporting transparency, accountability, and continuous quality improvement

Vial Australia operates under a global Quality Management System (QMS) framework that is designed to flexibly accommodate regional compliance needs. For Australia, we maintain local policies, study-specific documentation, and ethical governance aligned with NHMRC and TGA expectations.

Vial Australia Independent Ethical Oversight

Overview

The independence of research governance functions from sponsor and research pressures represents a fundamental requirement for maintaining ethical research conduct and public trust. Vial HREC's independence structures incorporate multiple layers of protection designed to ensure that governance decisions prioritise participant welfare and scientific integrity above commercial considerations. These safeguards reflect best practices from leading research institutions while addressing unique challenges associated with biotechnology research and commercial drug development.

Vial HREC’s governance model is designed to uphold strict independence between core sponsor functions and those activities requiring impartial oversight to protect research integrity and participant welfare. All sponsor-driven roles, spanning strategic planning, investor relations, product development, protocol creation, manufacturing, regulatory submissions, monitoring, and commercial decision-making, are structurally and operationally separated from independent functions. These independent bodies, such as the Human Research Ethics Committee (HREC), Research Governance Office (RGO), safety and data monitoring boards, clinical labs and participant advocacy boards, maintain critical autonomy over decision making, operations, personnel decisions, financing, communications, and record-keeping. Independent functions do not have remuneration tied to any commercial success in relation to sponsor functions, they are only compensated for their operational performance tied to compliance with regulatory requirements and international guidelines. This deliberate division ensures that all ethical, scientific, and safety-related judgments are made without commercial influence, enabling objective audit, compliance, and participant protection while sustaining public trust and regulatory confidence in Vial Australia’s research activities.

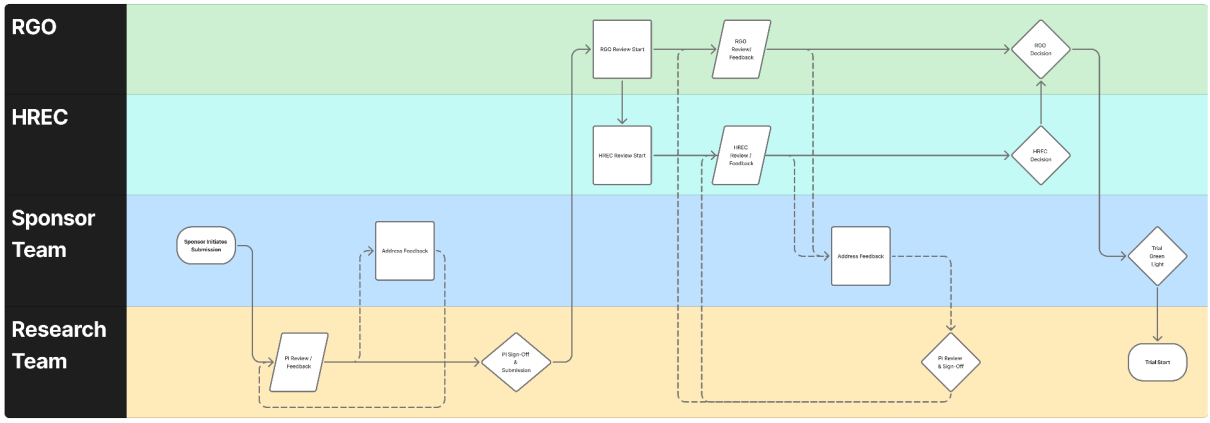

Figure 1. Governance Model (incl. Vial HREC, the Research Governance Office, and the Sponsor and Research teams). Vial HREC's governance model is designed to enable independence between the parties involved; for example, this diagram shows a clear delineation between activities and responsibilities of the Sponsor, Vial and its subsidiary, and the Research team(s) and activities that require impartial oversight (outside the Sponsor and Research teams) in order to maintain research integrity and protect the welfare and safety of all research participants.

Research Governance Office

Our Research Governance Office operates as the central coordinating body for all governance activities, providing day-to-day oversight, policy implementation, and support for research personnel. Staffed by experienced professionals with expertise in research ethics, regulatory affairs, and quality management, the RGO serves as the primary interface between researchers, the sponsor and the HREC, ensuring separation of duties and alignment with governance and ethical requirements. The RGO is headed by the Research Governance Officer, who provides independent assessment of research activities and compliance with organisational policies and regulatory requirements, and is supported by an administrative assistant.

Vial Human Research Ethics Committee

Vial HREC operates independently to ensure that all human research conducted under the company's sponsorship complies with the ethical principles outlined in the *National Statement on Ethical Conduct in Human Research*. Its primary responsibilities include reviewing research proposals to assess risks and benefits, safeguarding the welfare, rights, and dignity of participants, monitoring ongoing ethical compliance, and ensuring that all research is scientifically and ethically justified. The HREC also ensures that conflicts of interest are transparently managed and that participant privacy is protected in accordance with Australian regulatory requirements.

The committee is maintained by the HREC Chair and is composed entirely of individuals who are independent of the Company and are qualified in accordance with s5.1.30-5.1.43 of the National Statement on Ethical Conduct in Human Research 2025.

The HREC operates with the following independence:

1. **Structural Independence:** Vial HREC operates under its own charter with clearly defined authority and responsibility that cannot be overridden by commercial considerations. When and if relevant, should Vial HREC seek external consultation to review any internal research submitted by the Sponsor, that review process will also remain independent from the Sponsor.

2. **Financial Independence:** Vial HREC operates under a dedicated budget that is quarantined from commercial research revenues, ensuring that committee operations and member compensation remain independent of research approval decisions. Multi-year funding commitments provide stability and predictability while protecting against potential manipulation through budget restrictions.

3. **Operational Independence:** The HREC chair ensures that governance functions maintain control over their own procedures, meeting schedules, and decision-making processes. Ethics committee members maintain control over meeting agendas, review processes, and communication with regulatory authorities. Committee deliberations occur in closed sessions without commercial representatives present.

4. **Personnel Independence:** Independent recruitment processes run by the Chair of the HREC ensures that the most qualified candidates are selected based on relevant expertise rather than commercial considerations. Performance evaluation focuses on governance effectiveness and regulatory compliance rather than commercial outcomes.

Contact Information

For any inquiries, complaints, or concerns, please contact us:

General Inquiries
Contact Name: Amna Ali
Email: contact@vialhrec.com

Complaints or Concerns from Researchers and Participants
(i.e., regarding Ethics, the Researchers, the PI and / or the Sponsor)
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Concerns Regarding the HREC
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Vial Australia is committed to transparency, ethical rigor, and continuous improvement in all aspects of our research oversight.

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 incl. Page #s. Updated to match the most up-to-date ICH guidelines. Clarified HREC's committee independence. Clarified the purpose of the document and its relevance to HREC governance.