



Committee Record MC23 - Human Research Ethics Committee (HREC)

Version

1 **APPROVED**

Author(s)

GRC Coordinator

Owner

Human Research Ethics, Governance and Integrity Manager

Department

Governance, Risk & Compliance

Approval Authority

Ethical Practice and Integrity Committee

Key Words

Hrec



Approved

04 Nov 2024



Effective

01 Nov 2024



Review

2025

1. Purpose

The WEHI Board established the Human Research Ethics Committee (HREC) as a Management Committee on March 2024.

The Committee was established by WEHI to support the appropriate ethics review of human-based research within the guidelines of the National Statement on Ethical Conduct in Human Research 2023 (National Statement/NS) and is guided by the Australian Code for the Responsible Conduct of Research 2018 (the Code).

The HREC is registered with the National Health and Medical Research Council (NHMRC), and the HREC NHMRC registration is number EC00255

These terms of reference meet the requirements of section 5.2.29 of the National Statement.

Oversight of the committee is provided by the Ethical Practice and Research Integrity Committee (EIC) and these Terms of Reference should be read in conjunction with the [EIC Charter](#).

2. Authority and Responsibilities

Authority

The Committee has authority to conduct ethics reviews of Australian research that does not include applications for:

- Multisite research
- Requires Therapeutic Goods Administration registration
- Interventions on patients.

For more information on the process for the ethical review pathways at WEHI refer to **Human Research Ethics Review Procedure** (Procedure).

The Committee also has the authority to provide ethical oversight for the various ethical pathways listed in the procedure.

Responsibilities

It is a condition of the HREC exercising its authority that it:

Undertaking research ethics review following the National Statement

When undertaking ethics reviews, the HREC must follow the requirements of the National Statement, particularly in Chapters 5.1 and section 5.1.24-5.1.28.

Decision making

The HREC may approve, request modification of, reject or withdraw approval for a research proposal following section 5.2.7 NS.

Providing feedback on matters relating to human ethics at WEHI

The HREC is encouraged to engage with management on the operation of human ethics at WEHI, consistent with Chapter 5.2 of the National Statement. The Head of Governance, Risk and Compliance (GRC) is the primary contact, but the WEHI Director should be contacted if the Chair is not satisfied with the response.

Role of the HREC Chair

The HREC Chair is responsible for Chairing the HREC meetings, coordinating the substance of the meeting papers with the GRC Human Ethics and Governance Team and provides guidance to the GRC Ethics and Governance Team on matters relating to human ethics review. This includes the development of policies and procedures relating to human ethics review. The Chair at their discretion or at the request of management may seek feedback on these activities from the HREC where they consider that this would be of benefit.

The Chair may at any time make recommendations to management or the Ethical Practice and Integrity Committee on the effectiveness of the Committee and its membership.

Ongoing monitoring of ethics projects

The HREC will be provided with the following reports at each meeting. Consideration of the reports and the ethical issues that they raise in the context of the National Statement:

- Approval through the exempt pathway and approval of new projects and amendments through the Lower Risk pathway.
- Adverse event reporting
- Approved annual reports since the last meeting
- Potential non-compliance reporting
- Results of any quality assurance reviews undertaken with a list of actions and timelines.

3. Membership

The HREC must be established consistent with the requirements of the National Statement 5.1.30.

Members are appointed for three years for a maximum of three consecutive terms.

3.1 Appointment of the Chair and members

3.1.1 Chair

The Chair of the HREC is appointed by the Ethical Practice and Research Integrity Committee following the process outlined in the [Ethical Practice and Research Integrity Committee Charter](#).

A competitive recruitment process is to be conducted to identify suitable candidates for the HREC Chair. The Chair of the EIC is to be consulted on the recruitment process and may, at their discretion, participate.

The HREC Chair is a paid WEHI employee. However, management may not interfere with the proper operation of their duties under the National Statement.

The HREC Chair is encouraged to resolve issues directly with management but may contact the WEHI Director or EIC Chair at any time with concerns.

3.1.2 Members

The members of the HREC are appointed by the WEHI Director on the recommendation of the HREC Chair and Head of Governance, Risk and Compliance.

Appointment of members must meet the requirements of section 5.1.30 of the National Statement. To ensure that the quorum requirements it is preferable that more than one person per category of membership be appointed at any time.

An open process for the appointment of HREC members is encouraged.

Appointment of new members are to be included in the regular management report to the Ethical Practice and Research Integrity Committee.

Member responsibilities

Members must meet the responsibilities detailed in sections 5.2.21-24 of the National Statement.

3.1.3 Management attendees

To support the efficient operation of the HREC, members of the Governance, Risk and Compliance team may attend the HREC meeting.

Management attendees may offer support to the committee but must not interfere with its correct operation.

The HREC may, at its discretion, meet for part of the meeting in-camera (without management present).

3.1.4 Ad-hoc attendees

Consistent with section 5.2.6 the HREC may request researchers to be present at meetings, seek advice from external experts or invite observers to attend meetings.

4. Meetings

4.1 General

Role of the Chair at Meetings

The role of the Chair is to ensure the effective management of the meeting, including:

- Reviewing the agenda at the start of the meeting to prioritise items in consultation with the members.
- Ensuring that the meeting outcomes are achieved.
- Everyone is given the opportunity to contribute.
- The meeting is run on time.

Frequency – Regular meetings

HREC meetings should be evenly distributed across the year between February and December. Generally, a minimum of five meetings will be held a year but the number and frequency should be determined by the GRC Human Ethics and Governance Team in consultation with the HREC Chair.

Format of meeting

The format of the meeting should be such to encourage the participation of members. Members are encouraged to attend in person where possible. For members who cannot attend in person, online access will be available through Microsoft Teams.

Decision making

Decisions should be made by general agreement or consensus following section 5.2.8 NS.

Dissenting decisions should be recorded in the minutes.

Quorum

Where possible the HREC should meet where the full minimum membership is available to attend (see NS section 5.1.30).

Where a category of member is unable to attend the meeting, they are encouraged to read the papers and provide written feedback to ensure that their views are considered in the HREC's decision making (see NS section 5.2.5)

4.2 Participating in meetings

Preparation

Members are expected to be prepared for the meeting to allow for an effective discussion.

4.2.1 Conduct

Each person at a meeting must act consistently with WEHI's Code of Conduct. At all times, members must act with:

- respect to members and attendees at each meeting
- care and diligence
- discharging their duties in good faith and honesty to the best to their ability.

4.3 Planning and administration

The documentation and recording of decisions at meeting must meet the requirements of sections 5.2.15-5.2.20 NS.

Agenda

The Convenor will coordinate the preparation of the agenda in consultation with the HREC Chair.

The agenda for each meeting shall include an item requesting conflicts of interest. The Chair is to determine the management of any conflicts consistent with the National Statement and WEHI [Conflicts of Interest Policy](#).

Papers

The papers must be circulated at least ten days before the meeting (including weekends).

Minutes

The activities of the meeting must be minuted.

Minutes of the meeting are to be approved at the next meeting or circulated no more than 30 days after the meeting to the members for review whichever is first.

Recording

The meeting may be recorded for the purposes of preparing the minutes of the meeting but must be destroyed after the minutes are drafted.

5. Conflicts of Interest

The agenda for each meeting shall include an item requesting conflicts of interest. The Chair is to determine the management of any conflicts consistent with the National Statement and WEHI [Conflicts of Interest Policy](#).

6. Conduct of Members and Attendees at Meetings

Each person at a meeting must act consistently with WEHI's Code of Conduct. At all times, members must act with:

- respect to members and attendees at each meeting
- care and diligence
- discharging their duties in good faith and honesty to the best to their ability.

7. Risk Management

The Committee will actively consider risk management in its recommendations and decisions, including:

- WEHI's risk profile
- identify risks and mitigating strategies associated with decisions made
- implement processes to allow the Committee to identify, monitor and manage critical risks associated with commercialisation projects.

8. Secretarial

The Human Ethics Officer and Committee Convenor will provide secretarial support to the HREC.

9. Reporting

The HREC Chair will provide a report on the HREC's activities at each Ethical Practice and Integrity Committee meeting. This is in addition to reporting requirements under the Human Ethics Review Procedure.

10. Term of Committee

The Committee is an ongoing committee subject to an annual review by the Director.

11. Review

Committee review

The Committee will review the Committee's Terms of Reference annually or when the National Statement is amended.

12. Supporting Information

12.1 Terms of Reference Management

Delegation Authority	Board
Responsible Division/Department	Governance, Risk and Compliance

Review Cycle

 Initial	 Ongoing	 Next
1 Year(s)	Annual	2025

Version History

Approved By	Approval Date	Effective Date	Approval Notes	Version
Ethical Practice and Integrity Committee	4/11/2024	1/11/2024	New TOR	1

Appendix

 This document does not have an appendix.