



Committee Record BC6 - Human Research Ethics Committee

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1. Purpose

The WEHI Board (Board) established the Human Research Ethics Committee (Committee) to provide ethical oversight, review and approval of research involving humans, human tissue, data or their derivatives at WEHI in compliance with the National Statement on Ethical Conduct of Human Research (2018) and any amendments (National Statement or NS), and to advise the Board on these activities. The Board has established the Committee under clause 26(m) of WEHI's Constitution dated 27 November 2000.

This Charter outlines the role and responsibilities of the HREC and meets the requirement of 5.2.1 and 5.1.27 of the National Statement.

This Charter should be read in conjunction with the National Statement. Where inconsistencies exist between this Charter and the National Statement the National Statement prevails.

2. Authority and Responsibilities

2.1 General authority

Authority

The role of the Committee is advisory .

The Committee has authority to provide support and guidance on the matters identified under **clause 2.2 Responsibilities** and make recommendations to the Board about decisions and proposals within the scope of those responsibilities requiring board approval under WEHI's [Board Reserve Powers Policy](#).

The Board may set and vary priorities and otherwise provide policy guidelines as it sees fit. The Committee will exercise its discretion within those parameters.

Access to staff and advisors

At its discretion, the Committee may seek advice concerning matters under its area of responsibility, including seeking information required from members of staff or WEHI's professional advisers to meet its obligations.

2.2 Responsibilities

The Committee is responsible for the following areas:

- To confirm on behalf of the WEHI that human research is conducted consistently with NS 5.1.2.
- To evaluate human research projects submitted to the HREC for review according to the National Statement.
- To oversee the ethical review processes of human research at the WEHI.
- To comply with all guidelines and legislation relevant to the research proposals considered.
- To protect the welfare, rights and safety of participants in the research projects it reviews.

2.2.1 Responsibilities: HREC Review

The following types of research require review by an HREC.

- all research that involves more than low risk
- women who are pregnant and the human fetus (NS Chapter 4.1)
- people highly dependent on medical care who may be unable to give consent (NS Chapter 4.4)
- people with a cognitive impairment, an intellectual disability, or mental illness (NS Chapter 4.5)
- Aboriginal and Torres Strait Islander Peoples (NS Chapter 4.7).

WEHI currently accepts the review of the following human ethics committees:

- the WEHI HREC
- an HREC registered with the NHMRC and certified under the HREC National Certification Scheme.

2.2.2 Responsibilities: Out of session review (low-risk research)

Research involving no more than low risk that does not fall within a category under NS section 4.1 may be reviewed out of session.

Applications for out of session reviews are made in the Human Research Database.

Out of session reviews are to be conducted by at least

- Chair
- Scientific Secretary or other member of the committee with an appropriate research background
- Any other personnel as deemed necessary by the Chair

Considerations for out of session review

In assessing out of session review applications the following must be considered

- NS Section 1, 3 and 4 (NS5.1.19 (b))
- take account of researcher's judgements as to whether their research is suitable for review by a non-HREC process (NS 5.1.19 (c))
- have due regard to privacy legislation (NS 5.1.19(d)).

Documenting out of session review

The HREC Convenor is responsible for maintaining records of all discussions related to out of session reviews and decisions.

Reporting

All decisions assessed through Out-of-session review are to be reported to the next HREC meeting.

3. Membership

3.1 Membership

The Committee will include the following members (NS 5.1.30):

- Chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement.
- At least two lay people (one man and one woman) who have no affiliation with WEHI and who do not currently engage in medical, scientific, legal or academic work
- At least one person with knowledge of and current experience in the professional care, counselling or treatment of people
- At least one person who performs a pastoral care role in the community
- At least one lawyer, where possible one who is not engaged to advise the institution

At least two people with current research experience that is relevant to the research proposals to be considered at the meetings they attend. These two members may be selected according to need from an established pool of inducted members with relevant expertise.

Diversity and inclusion

Selection of Committee members will be consistent with the WEHI's policies regarding gender equity, diversity and inclusion.

3.2 Appointment of the Chair and members

Chair

The Board will appoint a non-executive member of the Board as Chair of the Committee.

Members

The Board appoints members of the Committee which is constituted in accordance with NS 5.1.29-30.

In the case of a vacancy, the Committee will make recommendations to the Board on external member and Faculty committee members.

The minimum membership of the HREC is eight and as far as is possible consist of an equal number of men and women. At least one third of the members should be from outside the WEHI (NS 5.1.29).

The HREC will appoint one of its members as the Scientific Secretary. This will be an individual with relevant clinical and research experience. The Scientific Secretary's responsibilities include explaining the science, procedures and/or treatments if necessary to lay committee members. The Scientific Secretary also acts as a valuable conduit to researchers offering and giving advice as necessary.

Term of appointment

Members are appointed for three year terms with a maximum appointment of twelve years. All members to the HREC are to be provided with a written notice of appointment that states the terms of their appointment.

Remuneration

All appointments to the Committee are voluntary.

3.3 Attendees

Ex-officio

The following roles may attend meetings but do not have voting rights:

- Head of Governance, Risk and Compliance
- Human Research Ethics, Governance and Integrity Manager
- Human Ethics Officer and Committee Convener, to take minutes

The ex-officio attendees may appoint a delegate to attend any meeting in their place.

Ad-hoc attendees

The Committee may invite other people to attend meetings or parts of meetings at their discretion.

3.4 Obligations of members

Induction and training

All members must participate in the HREC induction program. Each member is responsible for becoming familiar with the National Statement and consult other guidelines relevant to the review of specific research proposals. HREC members are expected to attend continuing education or training programs in research ethics at least every three years (NS 5.2.3). WEHI will pay for any conferences, training or similar undertaken in this manner.

All new members to the HREC will be provided with a mentor from the current membership to assist them in their transition to the committee.

Obligations in reviewing applications

Each member of the HREC is responsible for deciding whether, in their judgement, a proposal submitted to the review body meets the requirements of the National Statement and is ethically acceptable.

Membership of HREC to be made public

The membership of the HREC will be made public on the WEHI's website and intranet (NS 5.1).

4. Meetings

Frequency

The Committee will meet at least five (5) times per year at times that allow prompt reporting to the Board at their scheduled meetings.

Annual Plan

The Committee will review projects and relevant policies as they arise in a timely manner at meetings.

Agenda and papers

Each meeting's agenda and papers will be circulated at least five (5) working days before each meeting, unless agreed otherwise by the Chair.

4.1 Quorum

As far as possible, each HREC meeting should be arranged to enable at least one member in each membership category to attend (NS 5.2.30). There is no minimum quorum for the meeting.

Decisions

The following applies to decision making at the HREC consistent with NS 5.2.30-5.2.33.

Decisions by the HREC about whether a research proposal meets the requirements of the National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership. This exchange should ideally take place at a meeting with all those members present.

Where a member is not able to attend a meeting, they are encouraged to forward comments in writing to the HREC Convenor prior to the meeting to aid committee deliberation.

Where there is less than full attendance of the minimum membership at a meeting the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

Decisions by general agreement

The HREC should endeavour to reach decisions by general agreement. This need not involve unanimity.

Timeliness

The consideration and review of applications should be done in a timely manner.

Decision outcomes

The HREC will promptly notify researchers about decisions relating to outcomes. Decisions relating to approvals, rejections or withdrawal of ethical approval should be in writing and link the decision to the National Statement (NS 5.2.24).

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 **Conflicts of Interest Policy**.

Types of interest may include:

- personal involvement or participation in research
- financial or other interest or affiliation
- involvement in competing research.

Where a conflict exists, the person may not participate in the deliberation on whether or not the project can be approved and will leave the room while the item is discussed.

Refer to NS 5.2.11, Chapter 5.4 and any guidelines issued by the NHMRC for more guidance on the management of conflict of interest.

6. Conduct of Members and Attendees at Meetings

Each member and attendee must act with:

- respect to members and attendees at each meeting
- care and diligence
- discharge 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 is responsible for providing secretarial support to the Committee.

They are responsible for:

- Supporting the scheduling of HREC meetings.
- Circulating electronically meeting papers to HREC members, at least seven (7) days prior to the meeting.
- Preparing and circulating draft minutes to HREC members within seven (7) days of the meeting.
- Maintaining the register of approved human research projects consistent with NS 5.2.26.
- Overseeing that researchers submit required reports on time.
- Supporting the development of appropriate policies and procedures to support the HREC.
- Coordinate the provision of education initiatives for HREC members and staff in relation to the ethical conduct of research involving humans.
- Ensuring that researchers are notified in writing of the Committee's decision as soon as practicable after the meeting at which the proposal was considered.
- Ensuring that all relevant reports are submitted on behalf of the WEHI in a timely fashion.
- Reviewing annual progress reports from HREC approved research projects. This review is to ensure the projects continue to conform to all ethical guidelines and legislation and that no new ethical issues have arisen (consistent with NS 5.5.2-5.5.5).

9. Reporting

The Chair will report to the Board after each Committee meeting through a Chair's report and provide copies of approved minutes for noting.

10. Term of Committee

The Committee is an ongoing committee that is required to act in a manner consistent with the National Statement.

11. Review

The Board will review the role of the committee as a Board committee each year.

12. Supporting Information

12.1. Charter Management

Delegation Authority	Board
Responsible Division/Department	Governance, Risk and Compliance
Annual Board report required	First meeting of the calendar year

Review Cycle

Initial Review	1 Years
Ongoing Review	1 Years
Next Review	2022

Version History

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Head, Research Governance, Risk and Compliance	4/10/2021	25/03/2021	New Charter	1