







Human Research Ethics Committee

Terms of Reference

Date Effective	September 2024	Version	V11				
Review date	September 2026	Last Reviewed	November 2021				
<p>Compliance requirements</p> <p>These may be legislative requirements or internal requirements (such as approved plans, frameworks and actions relevant to the Committee).</p> <p>Meeting minutes must reflect compliance considerations and their part in any decision-making process.</p>	<ul style="list-style-type: none"> • <i>Human Rights Act 2019 (Qld) (mandatory)</i>: Consider human rights, and act and make decisions compatible with the <i>Human Rights Act 2019</i>, in order to achieve equitable health outcomes in our community. • WMH Strategic Plan 2021-25 (mandatory) • The West Moreton Health Human Research Ethics Committee (WMH HREC), is a committee established by the West Moreton Hospital and Health Service (WMHHS) of Queensland Health and is constituted and functions in accordance with the National Health and Medical Research Council (NHMRC) '<i>National Statement on Ethical Conduct in Human Research 2023</i>' (National Statement) and complies with the '<i>Australian Code for the Responsible Conduct of Research</i>' (2018), '<i>QH Research Management Policy</i>' (QH-POL-013:2022 Version 3). The WMH HREC is registered with the NHMRC – EC00184 for review and approval of single site research proposals. 						
<p>Associated NSQHS Standards</p>	<table border="1"> <tr> <td></td> <td>Clinical Governance</td> </tr> <tr> <td></td> <td>Partnering with Consumers</td> </tr> </table>				Clinical Governance		Partnering with Consumers
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The standardised West Moreton Health (WMH) Committee Guidelines should be applied in the completion of this content and an associated Work Plan (if required) supports these Terms of Reference.

1. Purpose

The purpose and main function of this Committee is to:

- Advise West Moreton Health on ethical issues relating to human research;
- Evaluate and approve suitable human research proposals in line with NHMRC guidelines and Queensland Health policies; and
- Monitor and review approved human research proposals.

2. Scope and functions

This Committee undertakes to:

2.1 HREC Objectives

- Protect the mental and physical welfare, rights, dignity and safety of participants of research.
- Facilitate ethical research through efficient and effective review processes.
- Promote ethical standards of human research.
- Ensure that all research approved by the Committee is conducted ethically and responsibly.

2.2 HREC Functions and Responsibilities

- Provide independent, competent and timely review of research studies in respect of their ethical acceptability.
- Monitor approved research studies which have been granted approval by the HREC and provide advice as required to the WMH Chief Executive (CE), the relevant Research Ethics and Governance Officer (REGO) and the coordinating Principal Investigator.
- Obtain expert opinion (internal or external) as required to ensure scientific / technical assessment of human research studies and compliance with regulatory requirements. This includes seeking expert opinion / reviews from members of other HRECs to meet quorum requirements.
- In the instance that the HREC reviews a proposal for research with Aboriginal and / or Torres Strait Islander People(s) / Communities, the HREC will obtain an expert opinion from an Aboriginal and / or Torres Strait Islander representative. The HREC will also require evidence of support from the relevant Aboriginal and / or Torres Strait Islander Community.
- Register on the Ethical Review Manager System (ERM) all research applications and associated documents submitted to the HREC, any monitoring or reporting requirements and any ongoing approval status of studies including amendments.
- The HREC will ensure that relevant training is provided for HREC members to enable the HREC to meet its obligations under its NHMRC registration and as a committee within Queensland Health.
- The HREC will be responsible for ensuring that adequate recruitment is undertaken to meet the minimum membership requirements under Section 5.1.30 of the National Statement.

2.3 Relationships and Reporting

The WMH HREC will:

- Submit an activity report annually to the NHMRC to maintain registration as a compliant HREC;
- Liaise with the Queensland Department of Health's Office of Research and Innovation (ORI), other Hospital and Health Services (HHSs), universities, research institutes, research facilities and research personnel as appropriate;
- The REGO, on behalf of the HREC will ensure the charging of fees, as required, to the sponsors of research, as per the WMH Schedule of Fees for HREC and Research Governance Review, both for the processing (initial application and amendment submissions) and consideration of the protocols; and
- Acknowledge that the CE or appointed delegate of the HHS will have the right to refuse approval of a research project within their jurisdiction.

3. Membership

Chair:

- The person appointed to the role of WMH HREC Chair, Position ID 32111065.

3. Membership

Deputy Chair:

- As recommended by the Chair and/or HREC and appointed by the WMH CE.

Secretary

- The people appointed to the roles of Research Ethics and Governance Officers, Position ID 32022852.

Members

- Please see Section 3.1

A quorum shall be the minimum membership (see 3.1.1). As per National Statement 5.2.5, where there is less than full attendance from the minimum membership categories in 3.1.1, the Chairperson should be satisfied that all HREC members have received the meeting papers and have had an opportunity to review and provide their views.

3.1 HREC Composition

3.1.1 Membership of the HREC will be in accordance with the National Statement and will include the following as a minimum:

- a) 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;
- b) two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution;
- c) a person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse, counsellor or allied health professional;
- d) a person who performs a pastoral care role in the community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader;
- e) a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters; and
- f) two people with current research experience that is relevant to 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.

3.1.2 The minimum membership of an HREC is eight as per the categories above. More than the minimum membership can be appointed to each category; however no individual may represent more than one category at any individual meeting.

3.1.3 Where the appointed chair is unavailable and the deputy chair is designated as the chairperson, the minimum membership category filled by this member, if any, should be filled by another HREC member.

3.1.4 As far as practicable:

3.1.4.1 the HREC membership at each meeting will have diversity, including gender diversity; and

3.1.4.2 at least one third of members participating in each meeting are external to WMH.

3.1.5 At least one third of the members should be external to the organisation for which the HREC is reviewing research.

3.1.6 At any one time, at least half the members appointed in the minimum membership categories listed under the National Statement (5.1.30) will have two or more years' experience on a HREC.

3. Membership

3.1.7 Annually the HREC Chair will assess the categories and quantities of research received and align, as required, the expertise of the HREC with the research studies being considered for review.

3.2 HREC Appointment of Members

3.2.1 The WMH CE shall appoint members of the HREC, in consultation with the HREC chairperson and other senior Health Service officials, as deemed appropriate.

3.2.2 Prospective members of the HREC should be appointed using an open and transparent process.

3.2.3 Prior to their recommendation for appointment, a criminal history check will be completed for all prospective members external to Queensland Health. All prospective members employed by Queensland Health will have had a criminal history check as part of their employment onboarding.

3.2.4 Appointments will allow for continuity, development of expertise within the HREC, and regular input of fresh ideas and approaches.

3.2.5 Members are appointed for a period of three (3) years and may serve consecutive terms as approved by the WMH CE.

3.2.6 The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the WMH CE.

3.2.7 Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the WMH CE.

3.2.8 Membership of the HREC will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three (3) consecutive meetings of the HREC. The Chairperson will notify the member in writing of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.

3.2.9 A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.

3.2.10 The WMH CE may terminate the appointment of any member of the HREC if the WMH CE is of the opinion that:

- it is necessary for the proper and effective functioning of the HREC;
- the person is not a fit and proper person to serve on a HREC; and / or
- the person has failed to carry out their duties as an HREC member.

3.2.11 Before appointment, members acknowledge in writing their acceptance of the WMH HREC Terms of Reference (TOR) and any requirements for confidentiality and conflict of interest required by WMH and/or Queensland Health.

3.2.12 Members will be provided with a letter of appointment written acceptance of obligations which will include date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member. Members are required to return the signed acceptance of obligations to the REGO before commencing their duties as a HREC member.

3.2.13 Members will not be offered remuneration for services to the HREC.

3.2.14 Members will be required to sign a statement outlining:

- that all matters of which they become aware during the course of their work on the HREC will be kept confidential;
- that any conflicts of interest, which exist or may arise during their tenure on the HREC be declared; and
- that they have not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as a HREC member.

3.3 Education for HREC Members

3. Membership

- 3.3.1 Newly appointed members shall be provided with adequate orientation, induction and mentoring.
- 3.3.2 Throughout their tenure, members will be encouraged to attend conferences and workshops relevant to the work and responsibilities of the HREC.
- 3.3.3 Members will attend continuing education and training in research ethics at least every three (3) years, although more regular attendance is encouraged.

3.4 HREC Sub-Committees

- 3.4.1 The HREC may appoint such sub-committees as it sees fit or as required from time to time to carry out a scientific or technical review of a research proposal or ethical review of low or minimal risk research submitted to the HREC.
- 3.4.2 The Chair of any such sub-committee will be appointed by the WMH CE.
- 3.4.3 Although members of the sub-committee will often be members of the HREC, membership of the HREC is not mandatory, .
- 3.4.4 All reports from sub-committees must be tabled at the next full HREC meeting for consideration.

3.5 HREC Liability Coverage

- 3.5.1 Queensland Health provides indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his / her duties as a member in good faith. Indemnity is provided through Queensland Government Insurance Fund (QGIF).
- 3.5.2 Queensland Health provides indemnity for external expert reviewers for any liabilities that arise as a result of the reviewer exercising his / her duties in good faith. Such indemnity is provided through QGIF.

3.6 Management of the HREC

- 3.6.1 The REGOs will maintain a database on the Queensland Health instance of REDCap to document and manage HREC membership, including recruitment and selection, on-boarding, training, meeting attendance and any other matters as required.
- 3.6.2 Consent will be sought from existing HREC members for their information to be entered into the REDCap database, with consent to utilise REDCap being included as a condition for the appointment of all new members.

4. Frequency and duration of meetings

Frequency: Up to 8 meetings per year (4-8 weeks) as required

Duration: 2 hours but will be determined by the number of proposals to be reviewed.

4.1 Standard Operating Procedures

- 4.1.1. The HREC will perform its functions, including monitoring of research and handling of complaints, according to the Queensland Health HREC Administrators Standard Operating Procedure (SOPs). These procedures shall be reviewed periodically and amended and updated as necessary by Queensland Health's Office of Research and Innovation.
- 4.1.2. All HREC members shall have access to and / or be provided with a copy of the SOPs and shall be informed of any changes.

4.2. Submissions

4. Frequency and duration of meetings

- 4.2.1. Excluding exceptional circumstances, the HREC will consider every application which it receives, at its next available meeting following receipt, provided that the application is valid, includes the necessary documentation and is received by the relevant closing date.
- 4.2.2. When a submission, including amendments, is accepted by the HREC, the HREC administrator / REGO will continue the process of HREC review and approval as per the HREC SOP.
- 4.2.3. Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Research Ethics Committee (FSS-HEC) for ethical and legal approval.
- 4.2.4. Research considered to be of lower risk will require submissions to be in a standard format using the Human Research Ethics Application (HREA) form via Ethical Review Manager (ERM) <https://au.forms.ethicalreviewmanager.com/>.
- 4.2.5. The HREC Chair and/or Deputy Chair will review and provide a decision on low risk applications out-of-session of regular HREC meetings in consultation with HREC members and/or sub-committees as required.
- 4.2.6. All other research applications will require submissions to be in a standard format using the Human Research Ethics Application (HREA) via ERM: <https://au.forms.ethicalreviewmanager.com/>
- 4.2.7. The HREC requires researchers to electronically upload all supporting documents as attachments accompanying the HREA via ERM.
- 4.2.8. The Chairperson / Deputy Chairperson and REGO will determine if any expert advice is required to be sought prior to the HREC meeting. The HREC may also make the recommendation for expert advice to be sought following review of an application.
- 4.2.9. The final decision on approval or rejection of an application will be within a period of sixty (60) days, excluding time waiting for responses from researchers.

4.3. Meetings

- 4.3.1. Meetings will be held every four to eight weeks at a pre-scheduled time and place.
- 4.3.2. Meeting dates are available at: https://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp.
- 4.3.3. Notice of meetings will be provided to members in December of the current year for the following year.
- 4.3.4. A copy of the agenda, previous minutes, new applications for consideration and all relevant documents, will be forwarded to HREC members at least ten (10) and preferably fourteen (14) days prior to the meeting.

Meeting Protocols

- 4.3.5. Decisions by the WMH HREC as to whether the research project meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members that constitute the minimum membership of the HREC.
- 4.3.6. Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via submission to either the Chairperson or REGO prior to the meeting.
- 4.3.7. Before granting approval for a research study involving humans, the WMH HREC must review the study protocol and other documentation to satisfy itself that the study complies with:
 - the NHMRC National Statement;
 - where relevant, the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) adopted by the TGA;
 - *Public Health Act 2005* (Qld), *Hospital and Health Boards Act 2011* (Qld), *Human Rights Act 2019* (Qld) and any other requirements of relevant Commonwealth or State / territory laws; and
 - where relevant, overseas regulatory requirements.

4. Frequency and duration of meetings

- 4.3.8. Meetings will be held virtually via Microsoft Teams (or other teleconference technology as approved for use in WMH), or a hybrid of virtual and in-person attendance at either The Park – Centre for Mental Health, Wacol, the Hayden Centre, Ipswich or Ipswich Hospital. Virtual attendance of a meeting will be considered an acceptable level of participation.
- 4.3.9. The Principal Investigator or a representative for the Investigator may be invited to attend the relevant meeting or be available via phone and/or Microsoft Teams to discuss a study proposal but would be required to leave the meeting before any decision is taken.
- 4.3.10. Members of the HREC will be required to declare any conflict of interest prior to or at any time during a meeting or out-of-session review, such as where the member is associated with a research protocol under review by the HREC. The Chairperson in discussion with the committee will determine the action to be taken, such as inviting the exclusion of the member from the meeting for deliberation of the particular protocol. Conflicts declared by members of the committee who hold a supervisory role will be considered based on the level of involvement with the researcher and/or the protocol under review.
- 4.3.11. In general, decisions of the HREC will be reached by general agreement rather than simple voting majorities.
- 4.3.12. The appointed Chairperson or Deputy Chairperson will chair every meeting when present. On occasions when either are absent or excluded because of a conflict of interest, the meeting attendees will appoint a Chairperson.
- 4.3.13. The Chairperson may reschedule a HREC meeting or convene additional meetings of the full HREC and/or of sub-committees to consider urgent matters or to facilitate approval of submitted studies.

HREC Decisions

- 4.3.14. Meeting minutes will be kept by the WMH REGOs.
- 4.3.15. Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol, application, or associated documents, linking those reasons to the National Statement.
- 4.3.16. Draft minutes will be approved by the HREC Chairperson within three (3) business days following the HREC meeting.
- 4.3.17. Action following decisions recorded in the draft minutes will not be initiated until the HREC Chair has approved the minutes.
- 4.3.18. Draft minutes approved by the Chairperson will be submitted to the next meeting of the HREC for ratification as a true and accurate record. Any necessary revisions will be incorporated into the final version of the minutes which should be signed and dated by the Chairperson.
- 4.3.19. As much as possible, electronic communication will be used to communicate with the Chairperson, members and researchers.
- 4.3.20. Advice to applicants regarding the ethical consideration and approval of protocols will include details of reporting requirements and monitoring processes.
- 4.3.21. A copy of any communication with the research applicant will be dated, labelled with the protocol number and kept in the appropriate protocol file.
- 4.3.22. The REGOs have the delegation to sign correspondence on behalf of the Chairperson where the Chairperson and/or HREC have made a decision on a submission.
- 4.3.23. The REGOs have the delegation to undertake review and approval of matters / submissions considered administrative in nature (e.g. amendments to documents that require no interpretation of the ethical impact of the amendment).

4.4. Monitoring

4. Frequency and duration of meetings

4.4.1. The WMH HREC acts in accordance with the National Statement in relation to monitoring approved research and requires the principal researcher to:

- complete all necessary forms accurately and in a timely fashion;
- keep adequate records (hard copy and / or electronic) and provide access to these by the HREC when requested;
- provide progress reports at intervals specified by the WMH HREC and at the completion of any research;
- notify the HREC of significant events, side effects or complications occurring at any time during the research including the course of action taken;
- notify the HREC of any complaints received from participants, staff, observers, third party or the community;
- provide prospective advice of any proposed changes to be made to the protocol and obtain approval of these prior to their implementation;
- notify the HREC if the research is to be discontinued before the expected date of completion; and
- provide a copy of published results, presentations at conferences etc to the HREC.

4.4.2. The WMH HREC representing the institution may request:

- researchers to amend research procedures to protect participants;
- interviews with the researchers, research participants or use other forms of feedback from these and other key parties if required;
- access to research data and records if required;
- opinion of external experts if considered necessary;
- reports from researchers;
- reports from independent agencies (such as data and safety monitoring board).

4.4.3. The WMH HREC may conduct random inspections of research sites, data, data storage or consent documentation.

4.4.4. Where the WMH HREC finds reason to believe the continuance of a research project will compromise participants' welfare, it may establish whether ethical approval should be withdrawn.

4.4.5. Where the WMH HREC considers that urgent suspension of research is necessary in line with the National Statement, the instruction to cease the study will be sent to the Principal Investigator by the REGO following the recommendation of the Chairperson / Deputy Chairperson of the WMH HREC.

4.5. Complaints

4.5.1. In the first instance, all complaints received will go to the Chairperson / Deputy Chairperson and / or the REGO of the HREC concerned, who will address and monitor the complaints.

4.5.2. Any complaints received by the researcher must be forwarded to the Chairperson / Deputy Chairperson and / or REGO of the HREC and in addition, if appropriate, to the Consumer Liaison Officer (CLO).

4.5.3. Participant information sheets and consent forms must include contact details of the WMH REGO to allow such complaints to be made.

4.5.4. Complaints on the process, conduct or decisions of the WMH HREC should be made in writing to the Chairperson / Deputy Chairperson and / or REGO of the WMH HREC.

4.5.5. All complaints will be acknowledged within seven (7) days.

4. Frequency and duration of meetings

4.5.6. All complaints will be handled in accordance with the Queensland HREC Administrators SOP.

4.5.7. The complainant will be advised of the decision of the WMH HREC within 30 days of obtaining all necessary information to proceed with complete review of the complaints.

4.5.8. If the complainant does not accept the decision of the WMH HREC, the complaint may be forwarded to the WMH CE whose decision will be final. In multi-centre research where the WMH HREC is not the reviewing HREC, all complaints received will be actioned in accordance with the Queensland Health Research Governance Officer (RGO) SOP.

5. Governance pathway and reporting

The Executive Sponsor of this Committee is:

- Chief Executive of West Moreton Health

The Committee reports to:

Position/Committee	Method of reporting	Frequency of reports
Clinical Governance Committee	Annual report in the format specified by the Committee	Annual

The Committee oversees the:

Committee	Reports received	Frequency of reports

6. Staff Communications

The Secretariat is responsible for completing meeting minutes and distributing them within seven business days of the meeting taking place.

The Chair will consider appropriate methods of communicating any significant outcomes to staff affected via email, printed publications, Staff Connect, or any other communication tool deemed suitable.

6.1 Proposed amendments to the TOR

6.1.1 The proposal may be initiated by the Chairperson, Deputy Chairperson, REGOs or HREC members.

6.1.2 The proposal must be in writing and circulated to all HREC members for their consideration.

6.1.3 The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register their views in writing.

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

6.1.5 The REGO, on behalf of the Chairperson, shall send the TOR amendment to the Clinical Governance Committee for endorsement prior to the WMH CE for review and approval as appropriate.

6.2 Proposed amendments to the TOR by the CE

6.2.1 Proposals made by the CE will be sent to the WMH HREC and any relevant person to seek their views.

7. Evaluation

The committee will undertake an annual performance self-assessment and the outcome will be reported via the defined governance pathway.

The self-assessment will be against:

- The endorsed terms of reference (mandatory)
- Meeting regularity and attendance (mandatory)
- Evidence of appropriate escalation of issues (mandatory)
- Timely achievement of activities in the annual work plan, if one is required.

8. Annual Agenda and Work plan

The committee Work Plan, if required, will be approved by the Executive Sponsor at the same time as the Terms of Reference.

9. Authorisation

The Terms of Reference for the Human Research Ethics Committee are formally endorsed by the Committee and approved by the Executive Sponsor:

Chair: Dr Thomas Meehan

Position: WMH HREC Chairperson

Signature: 

Date: 11/09/2024

Executive Sponsor: Joanne Johnson

Position: A/Health Service Chief Executive

Signature:

Date: