Human Research Ethics Committee
Terms of Reference

Date Effective:	**June 2019**	**Version:**	**V9**
Review Date:	**June 2020**	**Last Reviewed:**	**November 2017**
Associated NSQHS Standards:	S1 – Governance for Safety and Quality in Health Service Organisations S2 – Partnering with Consumers		
Compliance requirements:	The West Moreton Health Human Research Ethics Committee (WMH HREC), is a committee established by the West Moreton Health (WMH) of Queensland Health and is constituted and functions in accordance with the National Health and Medical Research Council (NHMRC) '*National Statement on Ethical Conduct in Human Research' (2007 updated 2018 – the National Statement'* and complies with the '*the Australian Code for the Responsible Conduct of Research' (2018)* and '*QH Research Management Policy' (QH-POL-013:2010 Version 1.2).*		

The standardised WMH Committee Guidelines should be applied in the completion of this content and an associated Work Plan supports this 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.
- To ensure that all clinical and health research is conducted ethically and responsibly.

2.2 HREC Functions and Responsibilities

- Provide independent, competent and timely review of research projects in respect of their ethical acceptability.
- Monitor approved research studies for which the HREC has granted approval and provide advice as required to the West Moreton Health Chief Executive (CE) through the relevant Research Ethics & Governance Officer (REGO) and coordinating Principal Investigator.
- Obtain expert opinions (internal or external) as required to provide scientific / technical assessment on human research protocols and evaluation of research clinical trials / studies and compliance with regulatory requirements.
- 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 proposals 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 accreditation 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:

- report on human research ethics to the WMH CE through the Clinical Safety and Quality Council;
- submit quarterly Committee Governance Reports to WMH Corporate Governance, via the CE;
- submit an annual Committee Evaluation Report to WMH Corporate Governance via the CE;
- submit a report annually to the NHMRC to maintain accreditation and registration as a compliant human research ethics committee;
- liaise with the Office of Health Innovation, Investment and Research Office (HIIRO), other Hospital and Health Services (HHSs), Universities, research institutes, research facilities and research personnel as appropriate;
- process the charging of fees to the sponsors of commercial research, as per the QH Research Management Policy (QHRMP), both for the processing (initial application and amendment submissions) and consideration of the protocols; and
- acknowledge that the CE or appointed delegate of the Hospital and Health Service will have the right to refuse approval of a research project within its jurisdiction.

The CE is the Executive Sponsor and responsible for reporting HREC activity to the WMH Board as deemed appropriate.

3. Membership:

Chair:

- Director of Service Evaluation and Research (The Park – Centre for Mental Health)

Secretary

- Research Ethics and Governance Officer

Members

- Please see Section 3.1

A quorum shall be half the membership plus one.

3.1 HREC Composition

3.1.1 The HREC membership appointment will be constituted in accordance with the National Statement and will include the following as a minimum:

a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement**;**

b) at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;

c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;

d) at least one person who performs a pastoral care role in the community, for example, an Aboriginal elder, a minister of religion;

e) at least one lawyer, where possible one who is not engaged to advise the institution; and

f) at least 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.

3.1.3 As far as possible there should be equal numbers of men and women.

3.1.4 At least one third of the members should be from outside the institution for which the HREC is reviewing research.

3.1.5 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

3.1.6 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 received 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 and other senior Health Service officials, as deemed appropriate.

3.2.2 Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.

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

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

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

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

3.2.7 Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. 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.

3.2.8 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.

3.2.9 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.

3.2.10 Before appointment, members acknowledge in writing their acceptance of the terms of reference by WMH HREC and any requirements for confidentiality and conflict of interest required by Queensland Health.

3.2.11 Members will be provided with a letter of appointment 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.

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

3.2.13 Members will be required to sign a statement outlining:

- that all matters of which he / she becomes aware during the course of his / her work on the HREC will be kept confidential;

- that any conflicts of interest, which exist or may arise during his / her tenure on the HREC be declared; and
- that he / she has not been subject to any criminal conviction or disciplinary action, which may prejudice his / her standing as a HREC member.

3.3 Education for HREC Members

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 two years.

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 Members of the sub-committee may not be members of the HREC.

3.4.3.1 The Queensland Health Research Ethics and Governance Unit (QH REGU) co-ordinates a substantial pool of available experts in a wide variety of research areas. These experts will provide reports on specific studies upon request. This talent pool may be accessed at any time the HREC requires additional scientific expertise. The HREC will make use of this resource at any time where an application is to be considered and the HREC deems it desirable that specific additional expertise be sought.

3.4.3.2 External expert review can be sought by contacting the QH REGU.

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.

Queensland Health extends this indemnity to reviewers providing expert opinion drawn from the pool of expert reviewers managed by QH REGU.

4. Frequency, and duration, of meetings:

Frequency: 6-8 weeks

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 written standard operating procedures (SOP). These procedures shall be reviewed at least every three years and amended and updated as necessary.

4.1.2. All HREC members shall have access to and / or be provided with copies of the SOP and shall be consulted with regard to any changes.

4.2. Submissions

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 low or negligible risk will require submissions to be in a standard format using the Low or Negligible Risk (LNR) form or Human Research Ethics Application (HREA) form which is available from the Ethical Review Manager website https://au.forms.ethicalreviewmanager.com/.

4.2.5. The HREC Chair will review and provide a decision on low or negligible risk applications and consult with the HREC and sub-committee 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) available on the Ethical Review Manager website: https://au.forms.ethicalreviewmanager.com/

4.2.7. The HREC requires researchers to electronically upload all supporting documents against the HREA / LNR via the Ethical Review Manager website.

4.2.8. The HREC will also require the researcher to submit hard copies of the submission as per the HREC requirements, available on the REGU website.

4.2.9. The Chairperson / Deputy Chairperson and REGO will determine if any expert advice is required.

4.2.10. 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 six to eight weeks on 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 given to members for the current year.

4.3.4. A copy of the agenda, previous minutes, new protocols for consideration, including the HREA/ LNR, protocol, patient information and consent form, budget, questionnaire or other relevant correspondence (where applicable) and the written advice review sheet for any meeting will be forwarded to all members at least ten (10) and preferably fourteen (14) days before 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. Where there is less than full attendance of the minimum membership at a meeting, the Chairperson must be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.

4.3.7. 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.

4.3.8. 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, Health Services Act 1991 and any other requirements of relevant Commonwealth or State / territory laws; and
- where relevant, overseas regulatory requirements.

4.3.9. Meetings will normally be held in a designated room of Dawson House at The Park, Wacol or at Ipswich Hospital. Teleconference linkage to individual members unable to be present in person will be made available and considered acceptable participation processes.

4.3.10. The Principal Investigator or a representative for the Investigator may be invited to attend the relevant meeting or be available via phone to discuss a proposal but would be required to leave the meeting before any decision is taken.

4.3.11. Members of the HREC will be required to declare any conflict of interest prior to or at any time during a meeting, 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.

4.3.12. In general, decisions of the HREC will be reached by general agreement rather than simple voting majorities.

4.3.13. 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.

4.3.14. The Chairperson may reschedule a HREC meeting or convene additional meetings of the full HREC or of sub – committees to consider urgent matters or to facilitate approval of submitted studies.

HREC Decisions

4.3.15. Meeting minutes will be kept by the REGO of the WMH HREC.

4.3.16. 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.

4.3.17. Draft minutes will be made available to the WMH HREC as soon as practical after the meeting for review.

4.3.18. Action following decisions recorded in the draft minutes will be initiated no sooner than 48 hours after circulation of draft minutes. Members who object to the progress of any actions recorded should contact the REGO within that time frame.

4.3.19. As much as possible, electronic communication will be used to communicate with 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.

4.4. Monitoring

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 them 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 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 come via the WMH 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 WMH 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 WMH HREC and in addition if appropriate to the patient liaison officer.

4.5.3. Consent forms and participant information sheets 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.

4.5.6. The Chairperson / Deputy Chairperson of the WMH HREC will determine the action to be taken.

4.5.6.1. This may necessitate a special meeting of the WMH HREC, which may be called without the usual 10 – 14-day requirement of notice, to consider such a complaint. The Chairperson / Deputy Chairperson and / or REGO shall notify the CE of the complaint and recommended action plan.

4.5.6.2. This may also require consultation with the Queensland Health Office of Health Innovation, Investment and Research Office (HIIRO). WMH HREC may delegate the complaint process to OHMR in its stead if it deems necessary.

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 addressed by the REGO. The REGO will liaise with the reviewing (lead) HREC.

5. Governance pathway and reporting:

The Executive Sponsor for this Committee is:
Chief Executive of West Moreton Health

The Committee reports to:

Position/Committee	Method of reporting	Frequency of reports
Chief Executive of WMH		Quarterly

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 by HREC member

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

6.1.2 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 his / her views in writing.

6.1.3 The proposal shall be ratified if two thirds of the members agree to the amendment

6.1.4 The Chairperson shall send the TOR amendment to the WMH CE for review and approval if appropriate.

6.2 Proposed amendments by 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 (mandatory)

8. Annual Agenda and Work plan:

The committee Work Plan 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:

Position:

Signature:

Date:

Executive Sponsor:

Position:

Signature:

Date: