



Metro North Hospital and Health Service *Putting people first*

Royal Brisbane and Women's Hospital

Royal Brisbane and Women's Hospital Human Research Ethics Committee (EC00172)

Terms of Reference

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Accountability and Role

The Royal Brisbane and Women's Hospital (RBWH) Human Research Ethics Committee (HREC) is a Committee established by the Royal Brisbane & Women's Hospital, Metro North Hospital and Health Service, Queensland Health. The Institution is accountable for its HREC to the National Health and Medical Research Council (NHMRC) under registration requirements (NHMRC Registration No: EC00172), and through NHMRC certification as a lead HREC under the National Approach to Single Ethical Review of Multi-Centre Research. The Committee is established and practises in accordance with the National Statement on Ethical Conduct in Human Research 2007 (National Statement). The Committee is certified for single ethical review of multicentre studies involving adults: specifically for Phase I, II, III & IV clinical trials; population health; clinical interventional research other than clinical trials; qualitative health, mental health, health services, and molecular biology research.

The RBWH HREC facilitates the review and oversight of human research to protect the mental and physical welfare, rights, dignity and safety of participants in research and to promote ethical standards of human research in Queensland Health.

Before granting approval to a research study involving humans, the RBWH HREC reviews the study protocol and other documentation to satisfy itself that the study complies with:

- The NHMRC National Statement;
- The World Medical Association "Declaration of Helsinki";
- where relevant, the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMH/ICH-135/95) adopted by the TGA;
- Public Health Act 2005, Hospital and Health Boards Act 2011 and other relevant requirements of Commonwealth and State/Territory laws;
- Other policies and guidelines, including where relevant, overseas regulatory requirements.

The RBWH HREC is assisted by expert reviewers external to the Committee who provide advice on scientific, technical and clinical aspects of human research protocols and clinical trials and on compliance with regulatory requirements.

Membership of the Committee is approved by the Executive Director, Royal Brisbane & Women's Hospital.

Mechanisms of reporting

- The RBWH HREC Chairperson reports to the RBWH Executive Director of Medical Services (EDMS) regarding the constitution and function of the RBWH HREC and the ethical acceptability of research applications submitted for consideration;
- The RBWH HREC reports on a quarterly basis to the RBWH Executive;
- The RBWH HREC submits an Annual Compliance Report to the NHMRC to be provided to the Australian Health Ethics Committee (AHEC) and the Office of the Australian Information Commissioner;
- The RBWH HREC submits a Certified Institutions Annual Report to the Research Integrity Unit, NHMRC.

Scope of responsibilities

The RBWH HREC is responsible for ensuring human research submitted for review:

- is designed with respect for participants and is not compromised by the aims of the research, by the way it is carried out, or by the results [National Statement Section 1.1 (d)];
- is justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities [National Statement 1.1(a)];

- meets the requirements of the National Statement on Ethical Conduct in Human Research, 2007 (updated in May 2015) and other updates as they are released;
- takes into account Commonwealth and State/Territory statutory and legislative requirements.

The RBWH HREC is responsible for:

- Reviewing and approving research including those projects submitted by affiliated and non-affiliated researchers in line with its certification via single ethical review for multi-centre research and in accordance with Queensland Health policies and procedures, and Memoranda of Understanding between Queensland Health and public sector health services in other States and Territories, and Mater Health Services, Brisbane;
- Considering the need for additional external expert review [National Statement 5.1.33];
- Advising the responsible principal investigator and, as necessary, the RBWH Executive via the EDMS, of advice on the ethical acceptability of submitted research;
- Providing advice on ethical issues related to research.

The RBWH HREC is responsible for:

- Maintaining a record in accordance with the National Statement within the local register (Queensland Health AU-RED database) of all research applications submitted to the HREC, which includes details such as date of approval, monitoring and reporting requirements and protocol amendments [National Statement 5.2.24];
- Overseeing the monitoring of research in accordance with the National Statement and the Australian Code for the Responsible Conduct of Research 2007, and the NHMRC Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research;
- Arranging or recommending to the Institution additional monitoring of approved research studies as required;
- Providing advice to the responsible Institution at any time when the RBWH HREC considers that ethical approval for research should be withdrawn;
- Completion of annual compliance reports to the NHMRC to be provided to AHEC and the Federal Privacy Commissioner;
- Completion of Certified Institutions' Annual Reports to the Research Integrity Unit, NHMRC;
- Liaising with other Queensland Health Hospital and Health Services, Mater Health Services, other research facilities, HRECs and research personnel as appropriate;
- Notifying the Institution of applications for which a fee may be levied to the sponsors of commercial research for the processing and consideration of research documentation, research monitoring, and review of amendments.

Indemnity

Queensland Health accepts legal responsibility for decisions made and advice given, and indemnifies all members of the HREC and expert reviewers.

Composition and appointment

The RBWH HREC Chairperson and Deputy Chairperson

- Both the Chairperson and Deputy Chairperson of the RBWH HREC are appointed by the Executive Director or delegate.
- In the absence of the Chairperson, the Deputy Chairperson will perform the duties of the Chairperson.

- In the absence of both the Chairperson and Deputy Chairperson, the Chairperson/HREC Coordinator may appoint an Acting Chairperson.

The RBWH HREC Coordinator

- The HREC Coordinator is an employee of Queensland Health and provides administrative advice on the Institution's processes of ethics review of research projects.
- The HREC Coordinator reports to the Chairperson of the RBWH HREC in matters related to the activities of the Committee and supporting Office.
- The primary role of the Coordinator is to provide leadership in directing and managing the Office of the HREC at the RBWH in accordance with the National Statement and other relevant policies, guidelines and legislation pertaining to human research in Australia.
- The Office of the HREC is responsible for the administration of applications made by researchers to the HREC, and for the support of the HREC, and expert reviewers.

RBWH HREC Members (National Statement sections 5.1.29 – 5.1.32, 5.1.34 – 5.1.36)

- Prospective members of the HREC may be recruited by expressions of interest, direct approach, nomination and advertisement, and are appointed in accordance with National Statement [Section 5.1.34 - 5.1.36].
- The membership of the RBWH HREC is constituted according to the National Statement [Section 5.1.30] and includes the following:
 - A chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
 - 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;
 - 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;
 - at least one person who performs a pastoral care role in a community, for example, an Aboriginal Elder, a Minister of Religion;
 - at least one lawyer, where possible one who is not engaged to advise the Institution; and
 - 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.
- Additional members are included to ensure optimal functioning, taking into account:
 - the spread of disciplinary expertise across the Committee;
 - age and gender balance;
 - the balance between institutional/non-institutional and medical/non-medical members;
 - that not less than one-third of the committee should consist of members who are not employed by Queensland Health [National Statement 5.1.29 (b)].
 - The HREC may also access a pool of inducted members in each membership category. These members may attend meetings as needed to meet minimum HREC requirements, and may also be available to provide expertise for the research under review [National Statement 5.1.31].

Period of appointment

- Membership appointments to the RBWH HREC will be considered for review every three years [National Statement 5.1.34].

- A member may be re-appointed for further three year periods.

Conditions of appointment (National Statement sections 5.1.34 – 5.1.36)

- Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience not as representatives of any organisation, group or opinion [National Statement 5.1.35].
- Before appointment, members acknowledge in writing their acceptance of the terms of reference of the RBWH HREC and any requirements for confidentiality and conflict of interest required by Queensland Health.
- Members will be provided a letter of appointment including the date of appointment, length of tenure, assurance that indemnity will be provided by Queensland Health in respect of the conduct of their duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.
- Members should inform the Chairperson if a leave of absence is required. If unable to attend three or more consecutive meetings, or unable to provide reviews as one of a pool of inducted members, members should consider their availability to remain on the Committee.
- All essential and necessary expenses incurred by members in carrying out their RBWH HREC duties will be paid for or reimbursed by the RBWH on production of original receipts.
- Parking and refreshments will be provided at Herston to facilitate members' attendance at meetings.
- Members agree to attend continuing education and training in research ethics at least every three years [National Statement 5.2.3 (c)].

Induction, mentoring and training

- New members are provided induction material and mentoring via the Chairperson or other members of the HREC [National Statement 5.1.28(b)].
- Members are required to attend continuing education and training in research ethics at least every three years [National Statement 5.2.3 (c)].
- Throughout their tenure, members are given the opportunity to attend conferences and workshops, supported by the Institution, that are relevant to the roles and responsibilities of the HREC [National Statement 5.1.28].

Confidentiality and conflict of interest

Members will be required to sign an agreement and declaration at the time of appointment and thereafter every three (3) years or earlier should their situation change, undertaking:

- Any conflicts of interest, which exist or may arise during tenure on the RBWH HREC will be declared [National Statement 5.2.4]; and
- All matters of which they become aware during tenure on the RBWH HREC will be kept confidential.

Applications

- The RBWH HREC requires new applications to be submitted on the online Queensland Health Human Research Ethics Application (HREA) or Low and Negligible Risk (LNR) form and to include, in all cases, a protocol, in addition to other relevant documentation such as participant information sheets and consent forms, data collection sheets, Investigator Brochures, questionnaires (where applicable), as set out in the checklist for submission;
- Submissions are to be provided in both hard and electronic media;
- In the first instance, the HREC Chairperson and Coordinator will determine if additional expert review is required;
- 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].

- Low or Negligible Risk research applications considered by the RBWH HREC secretariat to be low or negligible risk and not excluded by virtue of National Statement 5.1.6(b), will have delegated review with reporting to the HREC as set out in the Metro North Hospital and Health Service Low and Negligible Risk Review Guideline [National Statement 5.1.20(c)].
- Those low or negligible risk applications requiring approval of an opt-out process of consent or a waiver of consent will be provided to the full Committee in order that these may be approved in accordance with the National Statement [National Statement Chapter 2.3].

Meetings (National Statement sections 5.1.37, 5.2.28 – 5.2.31)

- Meetings will be held monthly, except for January when there will be no scheduled meeting [National Statement 5.1.37].
- A timetable for meetings will be promulgated by November of the preceding year and published on the Metro North Hospital and Health Service Ethics and Governance internet page.
- A hard or electronic copy of the applications for consideration will be forwarded to members approximately two (2) weeks before the meeting.
- Expert reviewers and absent HREC members provide their reviews for inclusion in the Reviews and Tabled Items document to assist the HREC in the review of applications at its monthly meetings.
- 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.
- Members who are unable to attend a meeting will be encouraged to contribute and advise their opinion via electronic submission to the Chairperson or Coordinator prior to the meeting.
- Meetings will normally be held in the Lower Ground Floor, Dr James Mayne Building, RBWH and teleconference linkage to individual members unable to be present in person will be acceptable.
- The Principal Investigator or a representative of the investigator may be invited to attend the relevant meeting to discuss an application but would be required to leave the meeting before a decision is made on the outcome.
- Members of the Committee associated with a research protocol being considered by the Committee will be excluded from the meeting for consideration of that particular application.
- Members of the Committee will be required to declare any conflict of interest prior to or at any time during a meeting. The Chairperson will determine the action to be taken.
- Questions or issues raised should be linked by members to the relevant section of the National Statement.
- Decisions by the Committee about 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 RBWH HREC.
- In general, decisions of the RBWH HREC will be reached by general agreement rather than by a majority vote.
- The appointed Chairperson will chair every meeting when present. On occasions when the Chairperson is absent or excluded because of a conflict of interest, the meeting will be chaired by the Deputy Chairperson or an appointed Acting Chairperson.
- The Chairperson may reschedule a HREC meeting or convene additional meetings of the full HREC or of sub-Committees comprising HREC members to consider urgent matters or to facilitate approval of submitted studies.
- The Agenda; content of applications; documents associated with submissions; deliberations of the HREC, sub-Committees of the full Committee, and expert reviewers; and Minutes; will remain confidential and confined to the Committee, those responsible for the administration of the HREC office and those with authority to access the HREC AU-RED database.

Levels of ethical review

- Requests for exemption will be considered by the RBWH HREC Chairperson, with the assistance of HREC members as required, and noted by the full Committee.
- Multi-centre research applications of all risk levels will be reviewed by the RBWH HREC in accordance with its certification and Memoranda of Understanding between Queensland Health and health services in other States and Territories, and Mater Health Services Brisbane.
- Low risk studies requiring approval of a waiver of consent or opt-out consent, and greater than low risk single site research, will be reviewed by the RBWH HREC.
- Amendments, safety and other reports may be reviewed and approved, actioned or noted by the Chairperson between meetings. Substantial amendments or serious safety issues may require full Committee review and / or subsequent ratification.

Administrative support

- Administrative support will be provided by staff of the Office of the Human Research Ethics Committee, RBWH, in accordance with the National Statement and the Queensland Health Standard Operating Procedures for HREC Administrators.
- Staff will receive research documentation, prepare the meeting agenda, and communicate with researchers and Committee members as required.
- Electronic media will be used to communicate with researchers and HREC members wherever possible.
- The Coordinator will attend and record the Minutes of the meeting. In the absence of the Coordinator, the Assistant Coordinator may act in this role.
- To assist with the preparation of Minutes, the proceedings of HREC meetings may be audio-recorded.
- Minutes will record major issues discussed, concerns expressed, decisions taken, recommendations for changes in the application and reasons for rejection, linking those reasons to the National Statement.
- Draft minutes will be forwarded to the Chairperson within 48 hours of the meeting.
- The Minutes will be finalised within five (5) working days of the meeting.
- HREC recommendations, usually in the form of the relevant meeting minute, will be forwarded by email to researchers within six (6) working days of the HREC meeting, or notification will be sent advising of a delay.
- Advice to applicants regarding the ethical consideration and approval of applications will include details of reporting requirements and monitoring processes.

Monitoring (National Statement chapter 5.6)

Where the RBWH HREC is the reviewing (lead) Committee, the Coordinating or site Principal Investigator is required to conform to conditions set out in the formal approval letter. These include:

- Keeping adequate records regarding the research and providing access to the RBWH HREC when requested.
- Providing collated progress reports at intervals specified by the RBWH HREC and at completion of the research.
- Notifying the HREC of significant events, side effects or complications occurring at any time during the research including the course of action recommended to be taken and outcome.
- Notifying the HREC of any complaints received from participants, staff, observers or the community.
- Providing advice on any proposed changes to be made to the protocol and awaiting HREC approval of these prior to implementation.
- Notifying the HREC if the research is to be discontinued before the expected date of completion.

- Providing a copy of published results and presentations at conferences etc. to the HREC.
- With respect to information provided during monitoring, the RBWH HREC may:
 - Request an interview with the researchers if required.
 - Request access to research data and records if required.
 - Request the opinion of external experts if considered necessary.

Handing complaints (National Statement chapter 5.6)

Single site research or multi-centre research where the RBWH HREC is the reviewing committee

- All research ethics complaints should be forwarded to the HREC Chairperson via the Coordinator.
- Participant Information Sheets must include HREC contact details to allow such complaints to be made.
- The Chairperson will consider the complaint and will determine a course of action. This may include, via the agreed governance route, referral to the Institution's Patient Liaison Officer, or to the Health Quality and Complaints Commission.
- All complaints will be acknowledged by the RBWH HREC office within seven (7) days.
- The complaint and the proposed action will be reported to the next meeting of the RBWH HREC, and depending on the nature of the complaint to the RBWH Executive via the EDMS or to a relevant site contact, such as Research Governance Officer, at another institution.
- In the event that the response to the complaint has not been finalised within sixty (60) days the complainant will be notified in writing of progress.
- If the complainant does not accept the decision of the RBWH HREC the complaint will be escalated in accordance with the Queensland Health Standard Operating Procedure for HREC Administrators [Section 11.16-24].
- Complaints on the process, conduct or decisions of the RBWH HREC should be made in writing to the RBWH Executive Director of Medical Services, or to the Chief Executive of Metro North Hospital and Health Service.
- Where a complaint has not been resolved, the complainant will be referred to Health, Innovation, Investment and Research Office (HIIRO), Queensland Health [National Statement 5.6.7].

Multi-centre research where the RBWH HREC is not the reviewing (lead) committee

- For multi-centre research where the RBWH HREC is not the reviewing HREC, all complaints received will go to the local Research Governance Office (RGO) to be addressed. The RGO will liaise with the reviewing (lead) HREC.
- Participant Information Sheets must include RGO contact details to allow such complaints to be made.

Bibliography

National Statement on Ethical Conduct in Human Research. National Health & Medical Research Council, 2007 (Updated in May 2015).

The Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. World Medical Association, 2008.

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments. Therapeutic Goods Administration, 2000.

Public Health Act 2005 (current as at 20 May 2013).

Hospital and Health Boards Act 2011 (current as at 1 July 2013).

For further information, please use the contact details below:

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