Royal Brisbane & Women’s Hospital Human Research Ethics Committee (EC00172) Terms of Reference

(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 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 the Scientific sub-Committee (SsC), which provides advice on scientific, technical and clinical aspects of human research protocols and clinical trials and on compliance with regulatory requirements (Appendix: SsC Terms of Reference). Additional review of applications is also conducted as required by experts outside the two Committees.

Membership of both Committees 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 two Committees and the ethical acceptability of research applications submitted for consideration;
- The RBWH HREC submits an annual report to the RBWH Executive via the EDMS;
- 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 March 2014);
- takes into account Commonwealth and State/Territory statutory and legislative requirements.
The RBWH HREC is responsible for:

- Reviewing and approving research including 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 office 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;
- 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 Report to the Research Integrity Unit, NHMRC;
- Liaising with other Queensland Health Hospital and Health Services, Mater Health Services, other research facilities 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 sub-Committees of the HREC.
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, its sub-Committees and expert reviewers.

RBWH HREC Members (National Statement sections 5.1.29 - 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) 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 women, 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 a 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."

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)].

**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 RBHWH REC 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 leave of absence is required. If unable to attend three or more consecutive meetings, 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 National Ethics Application Form (NEAF) 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].
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 RBWH internet.
- Notice of meeting will be given at least two (2) weeks before the HREC meeting.
- A hard or electronic copy of the applications for consideration will be forwarded to members approximately two (2) weeks before the meeting.
- The RBWH SsC members provide their reviews directly, or by meeting, 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 on 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 to consider urgent matters or to facilitate approval of submitted studies.

- The Agenda; content of applications; documents associated with submissions; deliberations of the SsC, 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 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 public sector health services in other States and Territories, and Mater Health Services Brisbane.

- Low risk studies requiring a waiver of 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 three (3) working days of the meeting.
• HREC recommendations, usually in the form of the relevant meeting minute, will be forwarded by email to researchers within four (4) 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 5.5)**

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.

**Handling 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.
- 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 may be forwarded to the EDMS, RBWH or to a relevant site contact at another institution.
- Complaints on the process, conduct or decisions of the RBWH HREC should be made in writing to the EDMS, RBWH.

Multi-Centre Research when 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


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

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

The RBWH Scientific sub-Committee (SsC) is a committee established by the Royal Brisbane & Women’s Hospital (RBWH), Metro North Hospital and Health Service, Queensland Health, and is accountable to the RBWH Human Research Ethics Committee (HREC). The SsC provides advice to the HREC on conformance of submitted research studies with the requirements of:

- The NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated March 2014) [National Statement];
- The World Medical Association “Declaration of Helsinki”;
- The “Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments” and any other relevant requirements of the Therapeutic Goods Administration;
- Other relevant policies and guidelines.

Mechanisms of Reporting

- The SsC Chairperson and members report to the RBWH HREC Chairperson on the function of the SsC and studies reviewed.
- The RBWH HREC Chairperson reports to the RBWH Executive Director of Medical Services regarding the function of the Committees.

If it meets, minutes of RBWH SsC meetings are reviewed and confirmed by the SsC Chairperson before being considered by the RBWH HREC at the subsequent meeting. SsC Minutes are electronically forwarded to RBWH HREC members 48 hours after the SsC meeting. In the majority of cases the SsC members do not meet but conduct reviews independently of other members and forward them directly to the Coordinator of the HREC for collation and inclusion in the Reviews and Tabled Items document for the next HREC meeting.
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Scope of Responsibilities

The RBWH SsC is responsible for providing advice regarding the acceptability of research submitted to the HREC in terms of:

- the scientific, technical and statistical aspects of the proposals, particularly the rationale, methodology, conduct and progress.
- whether additional expert advice is required for the proper consideration of a particular proposal.
- the research merit and safety of applications with respect to a consideration including:
  - whether the research is justifiable in terms of its potential contribution to knowledge based on the thorough study of current literature, prior observation and where relevant, laboratory and animal studies;
  - whether the methodology provides the rationale for selection of appropriate/experimental participants;
  - safety risks are balanced by the likely benefit gained;
  - the description of the interventions and/or observations to be conducted;
  - the sample size enabling demonstration of clinically / biologically and statistically significant effects;
  - the adequacy of provisions for dealing with contingencies;
  - whether Investigators' skills, facilities and resources are appropriate or should be prescribed in the case of multi-centre research;
  - whether academic supervision and support is available and suitable.

At the request of the RBWH HREC, the SsC will provide an opinion on the effect of changes to a research protocol on research merit and safety and how changes may relate to the ethical acceptability of a study.

Composition and Appointment:

The SsC Chairperson

- The Chairperson of the SsC is appointed by the RBWH Executive Director or delegate.
- When the SsC meets, the SsC Chairperson chairs meetings and reviews all new protocols.
- In the absence of the SsC Chairperson, the SsC Chairperson or HREC Chairperson may appoint another member as Acting Chairperson.
The RBWH SsC Secretariat

- The RBWH HREC Coordinator provides administrative support for the SsC and advice on the Institution’s process of review of research projects.

The RBWH HREC Coordinator directs the preparation of the SsC Agenda, provision of study documents for review to members, and attends and minutes meetings when they occur.

RBWH SsC Membership

- The membership is reviewed in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated in March 2014) by the RBWH HREC Chairperson, the RBWH SsC Chairperson and the RBWH Executive Director to ensure that the RBWH SsC is best able to perform its functions.

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

- RBWH SsC members are appointed by the RBWH Executive Director.

Period of Appointment

- RBWH SsC members are normally appointed for a three year term.

- A retiring member may be reappointed.

Conditions of Appointment

- Members are appointed for their expertise, in consideration of the research protocols submitted, and not in a representative capacity.

- Members receive a formal notice of appointment and an assurance that they will be covered by Queensland Health insurance policies as they relate to professional indemnity whilst undertaking reviews for the Institution.

- Before appointment, members acknowledge in writing their acceptance of the terms of reference of the SsC 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 an SsC member, SsC meeting attendance responsibilities and general responsibilities as an SsC member.
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- Members should inform the Chairperson if leave of absence is required. If unable to attend three or more consecutive meetings, members should consider their availability to remain on the Committee.
- Parking or transport costs and refreshments will be provided at Herston to facilitate members’ attendance at meetings.
- All members are appointed on a voluntary unpaid basis.
- All essential and necessary expenses incurred by members in carrying out the HREC SsC business will be reimbursed by RBWH on production of original receipts.
- Parking will be provided at Herston for members who are not co-located RBWH staff while on RBWH SsC business.

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 SsC will be declared; and
- All matters of which they become aware during tenure on the SsC will be kept confidential.

Meetings

- Meetings are held rarely as reviews of studies are conducted independently by individual members as required and submitted directly to the HREC office.
- Where they are held:
  - the SsC will meet within 1 week prior to the RBWH HREC meeting.
- Members are allocated specific studies for review.
- The RBWH HREC office distributes the Agenda and relevant research documentation by email or courier (USBs and/or hard copy) to all SsC members more than one (1) week prior to a meeting of either the SsC or HREC, allowing sufficient time for reading of protocols.
- In the case where an SsC meeting occurs, the quorum is:
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- Chairperson or Deputy Chairperson;
- Three members with experience or active in research involving humans.

- Members who are unable to attend a meeting are encouraged to contribute prior to the meeting via written comments emailed to the HREC office.

- If there is insufficient business or attendances for a formal meeting, the SsC Chairperson is authorised to hold a “virtual meeting”, in which members are invited to contribute their comments electronically. It is expected that the majority of meetings in any calendar year will be face-to-face meetings.

- Conflict of interest: Any member who has a duality of interest or a conflict of interest in a research protocol before the Committee, as defined by the QH Conflict of interest in Research Implementation Standard must declare the interest and its nature at the beginning of the meeting. When a research protocol involves a Committee member, that member, at the discretion of the Chairperson, may be required to leave the meeting before a recommendation is made.