



Government of **Western Australia**
East Metropolitan Health Service

Royal Perth Hospital Human Research Ethics Committee Terms of Reference

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Preamble

These Terms of Reference (TOR) describe the functions and status of the Royal Perth Hospital Human Research Ethics Committee (RPH HREC) established by the East Metropolitan Health Service (EMHS) to conduct scientific and ethical review of proposed research projects.

The National Health and Medical Research Committee (NHMRC) National Statement on Ethical Conduct in Human Research (2007; Updated 2018) (National Statement) does not prescribe how HREC TOR are written nor is there a statutory authority invested in such HREC TOR. However, the *Therapeutic Goods Act 1989* requires that HRECs follow the guidelines laid out in the National Statement for the purposes of studies involving access to unapproved therapeutic goods and the NHMRC requires compliance with the National Statement for studies funded by the NHMRC. It is therefore important to provide a clear description of the functions, responsibilities and management of the HREC for the purposes of complying with the National Statement and TGA Act. Furthermore, all WA Health HRECs operate in accordance with the WA Health Research Governance Policy and Procedures (2012).

The RPH HREC's function is to determine the scientific merit and ethical acceptability of proposed research projects and to monitor the conduct of approved projects to their completion. On approval, the RPH HREC provides a letter to the project's Coordinating Principle Investigator (CPI) to be used by the CPI as evidence of ethical approval in support of site governance submissions. The decision to authorise (or not authorise) a research project ethically approved by the RPH HREC rests with the Executive Director (or delegate) of the project site(s).

1. Objectives

The HREC objectives are to:

- 1.1 Protect the mental and physical welfare, rights, dignity and safety of participants in research involving humans, their data or tissue.
- 1.2 Review and monitor approved research projects in accordance with the requirements set out in the National Statement.
- 1.3 Facilitate ethical research through efficient and effective review processes.
- 1.4 Promote ethical standards of human research.

2. Functions

The HREC functions are to:

- 2.1 Provide independent, consistent and timely review of the scientific merit and ethical acceptability of research projects involving humans, their data or tissue.
- 2.2 Provide ethical oversight, monitoring and advice for research projects involving humans, their data or tissue.
- 2.3 Provide advice to the EMHS on research ethics principles and policies to assist in the development of effective and ethical human research-related policies and procedures.

3. Scope of Responsibility

- 3.1. As the HREC established and maintained by the EMHS, the RPH HREC is primarily responsible for the ethical review and monitoring of human research projects conducted at EMHS sites.
- 3.2. The RPH HREC also reviews and monitors human research projects to be conducted at multiple WA Health sites under the WA Health Single Ethical Review of Multi-Centre Research Scheme.
- 3.3. Research involving humans includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records, as well as epidemiological, social, and psychological investigations.

4. Accountability

- 4.1. The HREC is accountable to the EMHS Chief Executive (CE) via the EMHS Area Director of Clinical Services (ADCS).
- 4.2. The HREC provides a financial year annual report to the EMHS Area Executive Group (AEG) and CE summarising:
 - HREC membership and training;
 - The number of new proposals reviewed and approved;
 - Monitoring activities;
 - A description of any complaints received and their outcome;
 - Any general issues arising and their capacity to acquit their objectives and functions.
- 4.3. After ADCS review and CE approval, the annual report is provided to the EMHS Area Executive Group (AEG)
- 4.4. The HREC may from time to time bring to the attention of the ADCS or CE issues of significant concern.
- 4.5. The HREC provides calendar year reports to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC and the Federal Privacy Commissioner in accordance with the requirements of the Privacy Act 1988 (Cwth)
- 4.6. The HREC TOR and membership list are available upon request and published on the EMHS website.

5. Membership

5.1 Composition

- 5.1.1. The composition of the HREC is in accordance with Section 5 of the National Statement.
- 5.1.2. Minimum membership is eight members, being as far as possible an equal number of men and women, and at least one third of the members should be from outside the institution for which the HREC is reviewing research. The minimum membership is:
 - a) a chairperson, with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
 - b) at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work
 - c) at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people, for example, a nurse or social worker
 - d) at least one member who performs a pastoral care role in a community, for example, a minister of religion or an Aboriginal elder
 - e) at least one member who is a lawyer, but not a lawyer engaged to advise the institution
 - f) at least two medically/scientifically qualified members with current research experience relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from a pool of further members (see TOR 5.1.6).
- 5.1.3. No member may be appointed in more than one category, but in each category proxy members may be appointed to ensure all categories required by the National Statement are present or available to provide comment for all meetings.
- 5.1.4. Where required, the HREC may seek advice from appropriate experts to assist with the review of a project. However, the HREC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) will be required to provide an undertaking of confidentiality and will not be entitled to vote on any matter.
- 5.1.5. In the interests of transparency and for training/mentoring, any person may request attendance at an HREC meeting as an observer. Attendance will be at the discretion of the Chairperson and the attendee must sign a confidentiality and conflict-of-interest declaration prior to the meeting. Observers may not participate in discussions about specific items on the agenda or HREC decisions.
- 5.1.6. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the core composition of the HREC will continue to reflect the diversity and balance of members, including gender and the relative proportion of institutional and non-institutional members, required by Section 5 of the National Statement (see TOR 5.1.2).

5.2 Appointment of members

- 5.2.1 Members are appointed as individuals for their knowledge, qualities and experience rather than as representatives of any organisation or group.
- 5.2.2 Prospective members may be recruited by direct approach, personal reference/nomination or following advertisement.
- 5.2.3 Prospective members are asked to provide a copy of their Curriculum Vitae and must agree to their name and profession being made available to the public, including being published on the EMHS website. They are asked to attend an HREC meeting as an observer to gain a direct understanding of what the role entails.
- 5.2.4 A selection committee, consisting at minimum of the Chairperson and HREC Coordinator, review the prospective member's CV and interview them before making a recommendation to the EMHS ADCS.
- 5.2.5 Members are appointed by the EMHS ADCS and receive a formal letter of appointment detailing the terms of appointment (see TOR 5.3).
- 5.2.6 The Chairperson is appointed by the EMHS ADCS following nomination by the HREC members. In the absence of the Chairperson at a meeting, a proxy Chairperson elected by the HREC members will perform the role and duties of the Chairperson.
- 5.2.7 The HREC Chairperson may delegate limited specified tasks to a Delegate of the Chair (DoC). The DoC is responsible for signing correspondence on behalf of the HREC and the review of HREC-requested changes to applications, administrative amendments and annual/final reports. Delegations are documented in writing, specifying the scope of delegated tasks.

5.3 Terms of appointment

- 5.3.1 The letter of appointment includes:
 - Date of appointment;
 - Term of appointment;
 - Category of membership;
 - 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;
 - Conditions of appointment.
- 5.3.2 Members are required to sign a confidentiality agreement and agree to the HREC conflict of interest policy and process.
- 5.3.3 Members are appointed for an initial period of three years, with renewal by mutual agreement. To ensure the development of expertise among HREC members, as well as continuity and consistency in decision making, there is no mandatory limit to the number of consecutive terms a member may serve. Members will be advised when their term is due to expire and they can opt to continue if they wish, after which a new appointment letter will be issued for a further three-year period.
- 5.3.4 A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps will be taken to fill the arising vacancy.
- 5.3.5 Members may take a planned leave of absence from the HREC for up to 6 months. Steps will be taken to fill the vacancy for the period or to recruit an additional permanent member.
- 5.3.6 Membership may lapse if a member fails to attend, or provide written comments for, three consecutive meetings of the HREC without explanation, unless exceptional circumstances exist.
- 5.3.7 EMHS provides indemnity for members of the HREC for any liabilities that arise as a result of the member exercising their duties as a member in good faith. Such indemnity is provided through RiskCover (Insurance Commission of Western Australia).

- 5.3.8 Members are not paid a sitting fee for attendance at HREC meetings. Members are reimbursed by EMHS for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses, by EMHS or free parking is provided.
- 5.3.9 Members should attend continuing education or training programs in research ethics at least every three years. EMHS will support access to such education and training.

5.4 Orientation and training of new members

- 5.4.1 New HREC members are provided with orientation, consisting of:
- An informal meeting with the Chairperson and Coordinator to explain their role as an HREC member and the HREC processes and procedures;
 - An opportunity to observe an HREC meeting before their appointment takes effect;
 - The opportunity to 'partner' with another HREC member in the same category for early reviews;
 - Coaching from the Chairperson and Coordinator.
- 5.4.2 New members receive an orientation package containing the following:
- HREC Terms of Reference;
 - A current list of members' names and key contacts (i.e., The Chairperson and Coordinator);
 - NHMRC National Statement on Ethical Conduct in Human Research (2007; Updated 2018);
 - The Australian Code for the Responsible Conduct of Research (2018);
 - WA Health Research Governance and Single Ethical Review Standard Operating Procedures;
 - Recent previous reports on the HREC's activities;
 - Any other relevant information about the HREC's processes, procedures and protocols.
- 5.4.3 New members are encouraged to undertake online training and/or attend WA Health and NHMRC education and training sessions as soon as practicable after their appointment. Reasonable costs associated with training and education sessions is available to be covered by EMHS, with requests submitted to EMHS Executive via the HREC Coordinator.

5.5 Subcommittees

- 5.5.1 The HREC may form subcommittees or panels as required to carry out a scientific or technical review of a research proposal submitted to the HREC or any other function determined by the HREC. The Chair of any such subcommittee will be appointed by the HREC. Members of the subcommittee need not be members of the HREC. Subcommittees report to and are responsible to the HREC.

6. Conduct of business

6.1 Procedures

- 6.1.1 The HREC performs its functions by adopting operating procedures that fulfill the requirements laid out in the National Statement. These procedures are available on the EMHS and the RGS websites and are available in hard copy on request.
- 6.1.2 Submission and other procedures are standardised to the extent possible with other WA Health HRECs and are regularly reviewed and updated to ensure compliance with the WA Health Research Governance Policy and Procedures (2012) and other relevant policy frameworks and guidelines.

6.2 Submissions, notifications and approvals

- 6.2.1 Applications for ethical approval must be submitted via the WA Health Research Governance Service (RGS) by the relevant meeting closing date.
- 6.2.2 Guidelines are provided to assist applicants to prepare applications and all submissions are pre-reviewed by the HREC Coordinator, who also provides general advice to WA Health staff and external researchers on research ethics principles and submission requirements.
- 6.2.3 The HREC Chairperson, in consultation with the Coordinator, may withhold submissions they deem incomplete or underdeveloped from the HREC meeting. The Chairperson and Coordinator are responsible for ensuring only submissions of sufficient quality and completeness are included on HREC meeting agendas and, to the extent possible, assisting applicants to meet the necessary standards.
- 6.2.4 Applicants are not routinely required to attend the HREC meeting. Applicants may request attendance but this is at the discretion of the Chairperson who will assess the potential benefits of the applicant's attendance to the review process.
- 6.2.5 The HREC may request the applicant supply further information in relation to an application and/or request the applicant attend the HREC meeting for the purpose of providing information to, and answering questions from, the members.
- 6.2.6 The HREC will consider every correctly completed application that it receives at its next available meeting following receipt of the application by the relevant closing date. The HREC Coordinator will circulate the completed application and associated documents received with a meeting agenda to attending HREC members at least 7 days prior to the meeting.
- 6.2.7 If the HREC delegates consideration of an application/other matter before it to a subcommittee or panel, EMHS Research Hub will forward papers to the subcommittee/panel members. The HREC may also obtain expert scientific/technical advice (see TOR 5.1.4).
- 6.2.8 In the interest of minimising duplication of scientific and ethical review, the HREC will take into account prior scientific review (such as conducted during a grant review process) and prior ethical review of applications.
- 6.2.9 The HREC will notify the applicant in writing, advising whether their application has received ethical approval and any conditions of that approval.
- 6.2.10 In addition to formal written communication with applicants, the HREC, its Chairperson and Coordinator will use informal methods of communication, including phone calls and face-to-face meetings, to resolve expeditiously outstanding issues or queries relating to an application.

6.3 Meetings

- 6.3.1 The HREC will meet monthly, a minimum of 11 times in a calendar year.
- 6.3.2 Meeting dates and deadlines will be published on the EMHS and the RGS websites no later than 1st September of the preceding year.
- 6.3.3 Consistent with the National Statement a quorum will be deemed to have been reached where the minimum membership described in TOR 5.1.2 has been provided with meeting papers and given an opportunity to provide comment in time for the meeting.
- 6.3.4 Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is the subject of consideration, the member will withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. The member will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter. All declarations of interest and absence of the member(s) concerned will be minuted.
- 6.3.5 The HREC will endeavor to reach a decision about the ethical acceptability of a proposal by unanimous consensus. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, provided the majority includes at least one layperson. The minutes will note any minority view.

6.4 Fees

- 6.4.1 A fee will be charged for HREC review of commercially sponsored projects and the schedule of fees published on the EMHS website. Fees will be in line with national trends and other WA Health HRECs.

6.5 Administrative support

- 6.5.1 The EMHS Research Hub will:
 - Provide general and project-specific advice about research ethics principles and requirements to EMHS staff/researchers, other WA Health service staff and external partners (e.g., university researchers) (See TOR 3, 6.2.2, 6.2.9-6.2.10);
 - Receive all applications and correspondence addressed to the HREC (See TOR 6.2, 6.7 & 7);
 - Pre-review new ethics applications, as well as monitoring reports, amendment requests and safety reports and preparing these for review by the HREC, the Chairperson or a delegate (as applicable) (See TOR 6.2 & 6.7);
 - Act as the primary source of communication between the HREC and researchers and ensure this communication is effective and timely throughout all stages of the review process and, subsequently, over the life-cycle of active projects (see TOR 6.2 & 6.7);
 - Organise the annual HREC meeting schedule and maintain an 'apologies calendar' to help ensure meetings are quorate (see TOR 5.1 & 6.3);
 - Compile meeting agendas and papers and ensure HREC members have access to any additional information, briefings or guidelines necessary to review the applications before it (see TOR 6.3);
 - Ensure the smooth running of HREC meetings (see TOR 6.3);
 - Efficiently draft the HREC meeting minutes and decision letters for review by the Chairperson and dissemination to researchers (see TOR 6.3);

- Arrange expert reviews or organise, coordinate and document the operations and decisions of any subcommittees/panels created by the HREC (see TOR 5.1.5 & 6.2.7)
- Maintain HREC records and register of applications (see TOR 6.6);
- Update the EMHS and RGS website records relating to the RPH HREC meetings and procedures (see TOR 6.1);
- Maintain up-to-date HREC member records (see TOR 5.1);
- With the Chairperson regularly review the HREC membership roster and arrange advertisements/expressions of interest for new HREC members (see TOR 5.1);
- Arrange interviews with potential new HREC members and coordinate the appointment, induction and orientation of new members (see TOR 5.4)
- Arrange and coordinate training opportunities for HREC members and keep them up-to-date with legislative or guideline updates relevant to the functions of the HREC (see TOR 5.4.3);
- Compile annual reports to the NHMRC and EMHS and respond to *ad hoc* requests for reports on HREC operations (see TOR 4.2-4.6).

6.6 Records

- 6.6.1 EMHS Research Hub will prepare and maintain electronic records of the HREC's activities, including agendas and minutes of all meetings and records of actions conducted out-of-session under delegation (see TOR 5.2.7).
- 6.6.2 EMHS Research Hub will prepare and maintain an electronic file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the HREC.
- 6.6.3 Files will be held securely and confidentially in accordance with the requirements of the *Health Services (Conciliation and Review) Act 1995 (WA)*, *The State Records Act (2000)* and the *Privacy Act-Cwth (1988)*.
- 6.6.4 Records will be held indefinitely in electronic format.
- 6.6.5 EMHS Research Hub will maintain a register of all the applications received and reviewed in accordance with the National Statement.

6.7 Post-approval monitoring

- 6.7.1 The RPH HREC will monitor approved projects in line with Chapter 5.5 of the National Statement by, at a minimum, requiring annual progress and final reports for all projects.
- 6.7.2 As a condition of approval of each project, the HREC will require that investigators immediately report anything that could adversely affect the safety or wellbeing of participants or materially impact on the continued ethical acceptability of the project, including:
- Proposed amendments to the research protocol, other documents or conduct
 - Unforeseen events that might affect continued ethical acceptability of the project (e.g. significant safety issues or serious breaches of the protocol)
 - Early termination or suspension of the project for any reason

7. Complaints

7.1 Complaints about the conduct of a research project

- 7.1.1 Complaints will be handled according to Section 2.18 of the WA Health Research Governance Policy and Procedures (2012). Complaints not related to the conduct of the research project will be referred to the institution at which the research is being conducted/the researcher is employed.
- 7.1.2 Complaints related to the conduct of research project approved by the RPH HREC may be reported directly to the HREC Coordinator or received via the Research Governance Office (RGO) responsible for a site at which the research is being conducted.
- 7.1.3 Complaints may be made in writing or recounted verbally to the HREC Coordinator or RGO. Complainants may choose to remain anonymous.
- 7.1.4 Once the complaint has been received either by the HREC Coordinator or RGO, the details will be entered into the RGS. A letter of acknowledgement will be sent within 7 calendar days to the complainant and a complaint notification letter sent by the HREC Coordinator/RGO to the CPI/Site Principle Investigator (PI) respectively.
- 7.1.5 The HREC will liaise with the relevant site RGO to resolve the complaint promptly. If the complaint is reported directly to the HREC, the Coordinator will inform the RGO at the site where the complaint originated as soon as possible.
- 7.1.6 The HREC Coordinator and Chairperson, along with the RGO, will instigate an investigation of the complaint and its validity, and make a recommendation on the appropriate course of action. This investigation must not take longer than 30 calendar days from the time of the notification of the complaint, unless exceptional circumstances exist. The HREC Coordinator and Chairperson will liaise with, and report to, the HREC as required, either at the next available meeting or out-of-session if the complaint requires an urgent reconsideration of the ongoing ethical acceptability of the project.
- 7.1.7 The outcome will be recorded in the RGS, including the date of review and by whom and any additional information that is required. More information will be requested from the complainant over the course of the investigation if required.
- 7.1.8 Once the complaint has been resolved a letter will be sent from the HREC to the complainant, CPI and RGO within 7 calendar days of the HREC meeting/determination.

7.2 Complaints about the HREC review

- 7.2.1 Complaints about the HREC review process will be handled according to Section 2.18 of the WA Health Research Governance Policy and Procedures (2012).
- 7.2.2 Any concern or complaint must be directed by the CPI to the HREC Chairperson via an RGS complaint form outlining the nature of the concern. The HREC Coordinator will send an acknowledgement of receipt via the RGS within 7 calendar days.
- 7.2.3 The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on any necessary action. This investigation must not take longer than 30 calendar days from the time of the notification of the complaint, unless exceptional circumstances exist.
- 7.2.4 The outcome will be recorded in the RGS, including the date of review and by whom and any additional information that is required. More information will be requested from the CPI over the course of the investigation if required.
- 7.2.5 Once the complaint has been resolved a letter will be sent from the HREC to the CPI within 7 calendar days of the HREC meeting/determination.
- 7.2.6 If the CPI is not satisfied with the outcome of the Chairperson's investigation, they can refer the complaint to the EMHS ADCS for review.

- 7.2.7 The ADCS will consider the complaint, ensuring that both the CPI and the HREC provide submissions, and determine whether there is to be a further investigation of the complaint. In considering the complaint, the ADCS will be concerned with ascertaining whether the HREC acted in accordance with the National Statement, these TOR, operating procedures or acted in an unfair or biased manner or were insufficiently timely in their review of the application.
- 7.2.8 Where no further investigation is to occur and the previous determination by the HREC Chairperson/HREC is upheld, the ADCS will inform the CPI and the HREC Chair.
- 7.2.9 If a further investigation is conducted, the ADCS will notify the CPI and HREC of the outcome and any arising recommendations.

8. Amendments to the Terms of Reference

These TOR will be reviewed every 3 years. Additionally, they may be amended as below:

- 8.1 Amendments may be proposed by interested parties (e.g., HREC members; the EMHS CE or ADCS) or required to comply with revisions to key guidelines (the National Statement; the WA Health Research Governance Policy and Procedures) or legislative changes.
- 8.2 Amendments proposed by individuals must be submitted in writing to the HREC Coordinator who will prepare a tracked copy of the TOR reflecting the proposed changes in consultation with the Chairperson.
- 8.3 Amendments required to comply with revised guidelines or legislation will be drafted by the Coordinator and HREC Chairperson.
- 8.4 The draft TOR will be ratified by the HREC members as follows:
- The draft TOR will be circulated with the papers for the next available HREC meeting.
 - The draft TOR will be discussed at the meeting and a vote taken. Any member unable to attend the meeting can provide comments and indicate their support or otherwise for the changes in writing.
 - The TOR revisions will be ratified if at least two thirds of the members support them.
- 8.5 The Coordinator will send the HREC-ratified TOR revisions to the EMHS ADCS and CE. The TOR will be considered effective from the date of EMHS CE approval.

HREC ENDORSEMENT	
Endorsed by RPH HREC at meeting held:	29 July 2020
APPROVAL	
Approved by EMHS Chief Executive	6 August 2020
Review Date	August 2023
These TOR are reviewed every 3 years or if required following revision of the National Statement or other relevant guidelines, policies or legislation.	