



Government of **Western Australia**
Department of **Health**

Department of Health Western Australia Human Research Ethics Committee

Terms of Reference

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Contents

1. Preamble	2
2. Objectives	2
3. Functions	2
4. Scope of Responsibility	3
5. Status of the Department of Health WA Human Research Ethics Committee within the Department of Health	4
6. Accountability of Department of Health WA Human Research Ethics Committee	4
7. Membership	5
7.1. Composition	5
7.2. Appointment	5
7.3. Terms of Appointment	6
7.4. Conditions of Appointment	7
7.5. Education for members	7
7.6. Sub-committees	7
7.7. Liability Coverage	7
8. Conduct of Business	7
8.1. Procedures	7
8.2. Executive Support	8
8.3. Submissions, notifications and approvals	8
8.4. Exemption or Expedited Review	8
8.5. Advocates and interpreters	8
8.6. Meetings	8
8.7. Fees	9
8.8. Records	9
9. Monitoring of Approved Projects	9
10. Complaints and Review	9
10.1. Breaches or complaints concerning the conduct of a project	9
10.2. Complaints concerning review processes or the rejection of an application	9
11. Amendments to the Terms of Reference	10
12. Glossary	11

1. Preamble

The Department of Health Human Research Ethics Committee (DOH HREC) is a Human Research Ethics Committee that is registered with the National Health and Medical Research Council's (NHMRC's) Australian Health Ethics Committee (AHEC) to provide ethical review and advice to the Department of Health. It has special responsibility for the oversight of the use and linkage of information held by the Department.¹

2. Objectives

The objectives of the DOH HREC are to:

- review projects in accordance with the National Statement on the Ethical Conduct in Human Research (2007) incorporating all updates (National Statement)
- promote the ethical use of health information
- promote ethical and scientific standards of human research
- protect the welfare, rights and dignity of individuals, as well as the privacy and confidentiality of their information (including health information)
- facilitate ethical research through efficient and effective review processes.

3. Functions

The functions of the DOH HREC are:

- 3.1. To provide independent, competent and timely advice and ethical and scientific review of projects involving data collections held or linked by the Department and other research projects with respect to their ethical and scientific acceptability.
- 3.2. To review projects involving data collections held or linked by the Department and other research projects in accordance with the National Statement and Department policies.
- 3.3. To ensure projects reviewed by the DOH HREC that involve the use of information without the consent of the individual, take into consideration the following before granting approval:
 - the public interest in the project outweighs the public interest in the protection of privacy
 - if the project is requesting personal information, that the research cannot be conducted using non-personal information
 - whether the participant group would support the research
 - it is impracticable to seek consent from the people whose information is to be used or disclosed
 - the privacy of individuals is maximised
 - the project ensures the security of the information.
- 3.4. To provide ethical oversight and advice for projects approved by the DOH HREC.

¹ In this Terms of Reference the Department of Health and Health Service Providers are considered separate entities and therefore only data, including statutory data collections, held or linked by the Department must be reviewed by the DOH HREC.

- 3.5.** To monitor and report to the Minister for Health and the Director General (DG) of Health on projects involving data collections held or linked by the Department and other research projects.
- 3.6.** To advise the Department on the principles, guidelines and procedures governing the use of its information (including health information).

4. Scope of Responsibility

- 4.1.** The DOH HREC will review and provide monitoring and advice for:
- 4.1.1. All research projects involving personal and non-personal, record-level information from the data collections held by the Department. Research projects requesting aggregate level information from the data collections held by the Department of Health may also be reviewed by the DOH HREC at the discretion of the Data Custodian or Data Steward.
 - 4.1.2. The establishment of new linkages to the WA Data Linkage System infrastructure.
 - 4.1.3. All research, quality assurance and evaluation projects where:
 - A written agreement with a custodian external to WA Health requires approval from the DOH HREC, or
 - A Data Steward or delegate requests approval from the DOH HREC.
- 4.2.** The DOH HREC may review and provide ethical review, monitoring and advice for:
- 4.2.1. Quality assurance or evaluation projects referred by the Data Steward(s) or their delegate(s).
 - 4.2.2. Other research projects (not included in paragraphs 4.1.1., 4.1.2., 4.1.3) conducted by employees of, or entities contracted by, the Department, or involving participants for whom the Department has a duty of care (e.g. employees of the Department).
- 4.3.** The DOH HREC may provide advice to the Department on the principles, guidelines and procedures governing the use of data collections held by the Department and the linkage of these and other data collections, for the purposes of research, quality assurance or evaluation.
- 4.4.** The DOH HREC may monitor and report to the Minister for Health and the DG on the use of data collections maintained by the Department and the linkage of these and other data collections for the purposes of research, quality assurance or evaluation.
- 4.5.** The DOH HREC may from time to time bring to the attention of the DG issues of significant concern within the scope of the Committee's responsibilities.

5. Status of the Department of Health WA Human Research Ethics Committee within the Department of Health

- 5.1.** The DOH HREC is an advisory committee of the Department.
- 5.2.** The DG or his/her delegate is responsible for granting Departmental approval for:
 - 5.2.1. The use of personal or non-personal (record-level) information from data collections held or linked by the Department.
 - 5.2.2. Research to be conducted by employees of the Department or involving participants for whom the Department has a duty of care (e.g. employees of the Department).
 - 5.2.3. The establishment of new linkages with data collections held by the Department and other data sources as specified in paragraph 4.1.3.
- 5.3.** The DG or delegate will give due consideration to the advice of the DOH HREC and will only give approval for projects reviewed by the Committee where ethical and scientific approval has been granted by DOH HREC.

6. Accountability of Department of Health WA Human Research Ethics Committee

- 6.1.** The DOH HREC is accountable to the DG in the conduct of its business. The minutes of each meeting will be available to the DG.
- 6.2.** The DOH HREC will provide an annual report for each calendar year to the DG, which will include information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcome, and any general issues within the scope of the Committee's responsibilities. The report will be available on request to the general public and will be posted on the DOH HREC website.
- 6.3.** The DOH HREC will provide reports:
 - to the AHEC in accordance with the requirement of NHMRC, and
 - in accordance with any other statutory reporting requirements in force at the time.
- 6.4.** The Terms of Reference (TOR), Standard Operating Procedures (SOP) and membership details will be available on request to the general public and will be posted on the DOH HREC website.

7. Membership

7.1. Composition

- 7.1.1. The composition of the DOH HREC shall comply with the National Statement and shall include at least:
- a Chair, with suitable experience, who is from outside the WA health system
 - at least two members who are lay people, one man and one woman, who have no affiliation with the WA health system, and do not currently engage in medical, scientific, legal or academic work
 - a member with knowledge of, and current experience in, the professional care, counselling, or treatment of people, for example a medical practitioner, nurse or allied health practitioner
 - a member who performs a pastoral care role in the community for example, a minister of religion or an Aboriginal elder
 - a member who is a lawyer, but not a lawyer engaged to advise the WA health system
 - at least two members with knowledge of and current experience in research relevant to research proposals considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant experience
 - at least one member with knowledge of and current experience in information security
 - at least one member with knowledge of and current experience in the management and uses of statewide health data collections who is employed by the WA health system.
- 7.1.2. Members of the DOH HREC will not be appointed to more than one of the categories in paragraph 7.1.1.
- 7.1.3. Members will be appointed for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.
- 7.1.4. As far as possible the membership of the DOH HREC should be equal numbers of men and women and at least one half of the members should be from outside the WA health system.
- 7.1.5. To ensure that the membership of the DOH HREC is equipped to address all the relevant considerations arising from the projects likely to be submitted, additional members in any category may be appointed and deputy or alternating members may be appointed.
- 7.1.6. Cabinet may appoint a Deputy Chair from amongst the membership of the DOH HREC who may exercise the powers of the Chair when the Chair is unavailable.

7.2. Appointment

- 7.2.1. Cabinet shall appoint the Chair and the members of the DOH HREC, in consultation with the other senior officials within the Department, as deemed appropriate.
- 7.2.2. Prospective members of the DOH HREC may be recruited by direct approach, nomination or by advertisement for Expressions of Interest.

- 7.2.3. Cabinet may appoint a selection committee, which includes at least one representative of the DOH HREC, to interview prospective applicants and make a recommendation to Cabinet.
- 7.2.4. Appointments will allow for continuity and the development of expertise within the DOH HREC.

7.3. Terms of Appointment

- 7.3.1. The positions within the DOH HREC are fixed term three year appointments. Recruitment into these positions is staggered to ensure continuity of expertise and knowledge.
- 7.3.2. Members are recruited and appointed to these fixed term positions as they become vacant. Members may serve one term only unless otherwise approved by Cabinet. Cabinet may approve further terms, of varying duration, for members in order to ensure continuity of expertise and knowledge.
- 7.3.3. Deputy members are appointed to the DOH HREC to provide category representation when the relevant member is unable to attend meeting(s). Deputy members are appointed to fixed term deputy positions as they become vacant. Deputy members may only serve two consecutive terms unless otherwise approved by Cabinet.
- 7.3.4. Membership will lapse if a member fails without reasonable excuse, or without notifying the Chair, to attend three consecutive meetings or if the member fails to attend in full at least two thirds of all scheduled meetings in each year, unless there are exceptional circumstances. The Chair will notify the member, in writing, of such lapse of membership. The Chair will initiate the process to appoint a new member to fill the vacancy of the lapsed member.
- 7.3.5. A member may resign at any time by giving notice in writing to the Chair. The Chair will initiate the process to appoint a new member to fill the vacancy of the former member. Where a member resigns, the appointment of the new member will be for the remaining term of the fixed term position.
- 7.3.6. Cabinet may terminate the appointment of any member if Cabinet is of the opinion that:
 - it is necessary for the proper and effective functioning of the DOH HREC
 - the person is not a fit and proper person to serve on the DOH HREC
 - the person has failed to carry out their duties as a member of the DOH HREC.
- 7.3.7. Members will be provided with a letter of appointment which will include the 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 member of the DOH HREC, meeting attendance responsibilities and general responsibilities as a Committee member.

7.4. Conditions of Appointment

- 7.4.1. Members must agree to their name and profession being made available to the public, including being published on the DOH HREC website.
- 7.4.2. The Chair and members will be remunerated at the rate recommended by the Department of Premier and Cabinet for advisory committees.
- 7.4.3. Members will be required to sign a statement undertaking:
 - that all matters of which he/she becomes aware during the course of his/her work on the DOH HREC will be kept confidential
 - that any conflicts of interest which exist or may arise during his/her tenure on the DOH HREC will be declared, and
 - that he/she has not been subject to any criminal conviction or disciplinary action, and there is no other matter which may prejudice his/her standing as a DOH HREC member.

7.5. Education for members

- 7.5.1. Newly appointed members shall be provided with adequate orientation.
- 7.5.2. Throughout their tenure, members shall be given the opportunity to participate in on-line training and attend workshops relevant to the work and responsibilities of the DOH HREC.
- 7.5.3. Expenses for these activities will be covered by the Department at the discretion of the DG or delegate.

7.6. Sub-committees

The DOH HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of project proposals, or ethical review of minimal risk projects, submitted to the DOH HREC. Members of the sub-committee need not be members of the DOH HREC subject to paragraph 8.7.6.

7.7. Liability Coverage

The Department provides indemnity for members of the DOH HREC for any legal liabilities that arise as a result of decisions and advice by the member exercising his or her duties as a member in good faith.

8. Conduct of Business

8.1. Procedures

- 8.1.1. The DOH HREC will perform its functions according to the TOR and SOP. These procedures shall be reviewed at least every five years and amended and updated as necessary. All members shall have access to copies of the procedures and shall be consulted with regard to changes.
- 8.1.2. The DOH HREC will also operate in accordance with the requirements of the [Research Policy Framework](#).

8.2. Executive Support

The Department will provide executive support for the DOH HREC by the provision of an Ethics Executive Officer (EEO). The EEO will attend meetings of the DOH HREC to provide executive support to the committee but will not be a member of the committee with voting rights.

8.3. Submissions, notifications and approvals

Project submissions notifications and approvals must comply and be managed in accordance with the SOP.

8.4. Exemption or Expedited Review

The DOH HREC may exempt projects from ethical and scientific review in accordance with the National Statement and SOP.

The DOH HREC will provide an expedited review process for projects in accordance with the SOP.

8.5. Advocates and interpreters

8.5.1. The DOH HREC will consider whether an advocate for any participants or group of participants should be invited to the meeting to ensure informed decision-making.

8.5.2. Where research involves the participation of persons unfamiliar with the English language, the DOH HREC may require that any documents for participants are translated into the participant's language.

8.6. Meetings

8.6.1. The DOH HREC will meet on a regular basis, which will normally be at monthly intervals.

8.6.2. Meeting dates and agenda closing dates will be published on the DOH HREC website.

8.6.3. A quorum for meetings shall exist when at least 5 members are physically present including one of each of the following categories: Chair/Deputy Chair, lay person, researcher who has knowledge of and current experience in the areas of research that are regularly considered by the DOH HREC and at least one third of those present are from outside the WA health system.

8.6.4. Where there is less than full attendance at a meeting, the Chair must be satisfied, before a decision is reached, that the minimum membership listed in sub paragraph 7.1.1. have received all the papers and have had an opportunity to contribute their views in writing and that those views have been recorded and considered at the meeting.

- 8.6.5. Any member who has any interest, financial or otherwise, in a proposal or other related matter considered by the DOH HREC, should as soon as practicable declare such interest. If the member is present at the meeting at which the project is the subject of consideration, the member will withdraw from the meeting until the DOH HREC 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 concerned will be minuted.
- 8.6.6. The DOH HREC may consult with any person(s) considered by the Committee to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.
- 8.6.7. The DOH HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Where a unanimous decision is not reached, the decision will be carried by a majority of two-thirds of members present at the meeting, provided that the majority includes at least one layperson. Any significant minority view (i.e. 2 or more members) shall be noted in the minutes.

8.7. Fees

A fee will not be charged for non-commercial applications submitted for assessment by the DOH HREC. Fees for reviewing commercial applications may apply.

8.8. Records

The EEO will prepare, manage and retain records of the DOH HREC in accordance with the SOP.

9. Monitoring of Approved Projects

The DOH HREC will monitor the conduct of approved projects in accordance with the SOP.

10. Complaints and Review

10.1. Breaches or complaints concerning the conduct of a project

- 10.1.1. Any reports of breaches or concerns and complaints about the conduct of a project must be recorded and managed in accordance with the complaints management process detailed in the SOP.

10.2. Complaints concerning review processes or the rejection of an application

- 10.2.1. Any concern or complaint concerning the DOH HREC review process or the rejection of an application must be recorded and managed in accordance with the complaint management process detailed in the SOP.

11. Amendments to the Terms of Reference

These TOR may be amended by following the procedures specified below.

- 11.1.1. Minor amendments to the TOR can be actioned by the EEO. A minor amendment means a correction or change which is administrative in nature and does not significantly change the specific meaning, purpose or intent of the TOR.
- 11.1.2. For major amendments, including changes in meaning, purpose or intent, that are proposed by a DOH HREC member:
 - the proposal must be in writing and circulated to all members for their consideration
 - the views of the members should be discussed at the next scheduled meeting and a vote taken at that meeting. Any member unable to attend the meeting may register his or her views in writing
 - the proposal shall be ratified if two thirds of the members agree to the amendment
 - the Chair shall send the amendment to the DG for consideration and approval where appropriate.
- 11.1.3. For those proposals made by the DG or delegate:
 - The DG or delegate will send the proposal to DOH HREC and seek the views of the members before making any amendment.

12. Glossary

Term	Definition
Australian Health Ethics Committee (AHEC)	The committee that advises the National Health and Medical Research Council on ethical issues related to health.
Confidentiality	The obligation of people not to use or disclose information for any purpose other than which is was given to them, without consent.
Consent	Consent means voluntary agreement to some act, practice or purpose.
Data Collection	A systematic gathering or organised collection of data, in any format, for a particular purpose, including manual entry into an application system, questionnaires, interviews, observation, existing records and electronic devices. This includes, but is not limited to, statewide and statutory data collections managed by the Department of Health (e.g. Emergency Department Data Collection, Hospital Morbidity Data Collection, Midwives Notification System, Western Australian Cancer Registry).
Data Custodian	The person(s) responsible for the day-to-day management of a data collection, as nominated by the Data Steward. Data Custodians assist the Data Steward to protect the privacy, security and confidentiality of information within data collections. Data Custodians also aim to improve the accuracy, usability and accessibility of data within the data collection.
Data Linkage	A complex technique connecting data records within and between thought to relate to the same person, place, family or event. Data linkage typically uses demographic data (for example: name, date of birth, address, sex, medical record number) and facilitates analysis of linked information in a way that protects individual privacy.
Data Steward	A position with delegated responsibility from the Director General of the Department to manage a data collection. The Data Steward's primary responsibility is to protect the privacy, security and confidentiality of information within data collections. Data Stewards also approve the conditions for appropriate use and disclosure of information for clearly defined purposes that comply with Department of Health's statutory obligations and Information Management Policy Framework.
De-identified Information	Refer to 'non-personal information'. (Privacy Manual for Health Information . Reproduced by permission, NSW Ministry of Health © 2016)
Duty of Confidentiality	The legal duty of confidentiality obliges health care practitioners to protect their patients against inappropriate use or disclosure of personal health information.
Ethics	As defined in the National Statement (Section 1).

Term	Definition
Evaluation	<p>Is a term that generally encompasses the systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and or appropriateness of an activity.</p> <p>(Australasian Evaluation Society Incorporated Guidelines for the Ethical Conduct of Evaluations, July 2013.)</p>
Health Information	<p>Means – (a) information, or an opinion, that is also personal information, about:</p> <ul style="list-style-type: none"> (i) the health (at any time) of an individual; or (ii) a disability (at any time) of an individual; or (iii) an individual’s expressed wishes about the future provision of health services to the individual; or (iv) a health service provided, or to be provided, to an individual; or <p>(b) other personal information collected to provide, or in providing, a health service.</p> <p>(Refer to section 213 of the <i>Health Services Act 2016</i>).</p>
Health Service Provider	<p>Means a health service provider established under section 32 of the <i>Health Services Act 2016</i> and may include North Metropolitan Health Service (NMHS), South Metropolitan Health Service (SMHS), Child and Adolescent Health Service (CAHS), WA Country Health Service (WACHS), East Metropolitan Health Service (EMHS), Quadriplegic Centre and Health Support Services (HSS).</p>
Human Research Ethics Committee (HREC)	<p>A human research ethics committee constituted in accordance with, and acting in compliance with, the National Statement to review and where appropriate approve and monitor the ethical and scientific aspects of human research.</p>
Information	<p>The term ‘information’ generally refers to data that has been processed in such a way as to be meaningful to the person who receives it. Information can be personal or non-personal in nature. The terms ‘data’ and ‘information’ are often used interchangeably and should be taken to mean both data and information in this document.</p>
National Health and Medical Research Council (NHMRC)	<p>Consolidates within a single national organisation the often independent functions of research funding and development of advice.</p>
Multi-centre Research	<p>Research that is conducted at more than one site within the authority of more than one Human Research Ethics Committee.</p>
National Statement	<p>Means the <i>National Statement on Ethical Conduct in Research Involving Humans</i>, as in force from time to time, issued under the <i>National Health and Medical Research Act 1992</i> (Cwlth) clause 7(1) (a).</p>

Term	Definition
Non-personal Information	Is synonymous with the term 'de-identifiable information' and refers to information or opinion about a person whose identity is not apparent and cannot be reasonably ascertained from the information or opinion.
Personal Information	<p>Has the meaning given in the <i>Freedom of Information Act 1992</i> in the Glossary clause 1:</p> <p>Means information or an opinion, whether true or not, and whether recorded in a material form or not, about an individual, whether living or dead -</p> <p>(a) whose identity is apparent or can reasonably be ascertained from the information or opinion; or</p> <p>(b) who can be identified by reference to an identification number or other identifying particular such as a fingerprint, retina print or body sample.</p>
Principal Investigator (PI)	The individual responsible for the overall conduct, management conduct monitoring and reporting of research conducted at a site.
Privacy	The individual's right or expectation that health information and other identifying information will not be disclosed.
Quality Assurance	<p>An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation with the aim of improving that service. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably. In this document the term quality assurance is used to include all of these terms.</p> <p>(National Health and Medical Research Council - Ethical Considerations in Quality Assurance and Evaluation Activities. Canberra)</p>
Research	Original investigation undertaken to gain knowledge, understanding and insight as described in the National Health and Medical Research Council - Australian Code for the Responsible Conduct for Research 2007 .
Research Governance	The framework through which the Department of Health implements the principles, requirements and standards of research. It addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements and promotes good research culture and practice. The governance of research will ensure that its delivery meets its objectives and conforms to relevant institutional, jurisdictional and national ethical, scientific, regulatory and professional standards and applicable laws.
Standard Operating Procedures (SOPs)	The documented procedures and processes supporting the Department of Health Research Ethics Committee.

Term	Definition
Statutory Data Collections	The information must be collected by law. Hence, there is a mandatory legal requirement for health professionals to report the medical events, conditions and diseases to the Department of Health.
Use	Refers to the communication or handling of personal and non-personal information by individual(s) internal or external to the WA health system.
WA health system	The WA health system is comprised of the Department of Health, Health Service Providers (NMHS, SMHS, CAHS, WACHS, EMHS, Quadriplegic Centre and HSS) and to the extent that contracted health entities provide health services to the State, the contracted health entities.
Western Australian Data Linkage System (WADLS)	The Western Australian system used to connect available health and other related information for the population of Western Australia. This incorporates database tables holding demographic data and linkage keys, and the bespoke tools used by linkage staff to process, create, store and retrieve them.

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