



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

Human Research Ethics Committee

Terms of Reference

Version: 8 June 2011

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1. Preamble

The Department of Health WA Human Research Ethics Committee is a Human Research Ethics Committee with special responsibility for oversight of the use and disclosure of personal health information held in Department of Health WA¹ data collections.

2. Objectives

The objectives of the Department of Health WA Human Research Ethics Committee are to:

- Promote the ethical use of health information.
- Promote ethical standards of human research.
- Protect the welfare, rights and dignity of individuals.
- Facilitate ethical research through efficient and effective review processes.

3. Functions

The functions of Department of Health WA Human Research Ethics Committee are:

- 3.1. To provide independent, competent and timely ethical review of projects² involving use and disclosure of personal health information³ and other research projects with respect to their ethical acceptability.
- 3.2. To review projects involving personal health information and other research projects in accordance with the *National Statement on Ethical Conduct in Human Research* and the *Department of Health WA Practice Code for the Use of Personal Health Information*.
- 3.3. To review projects requiring the use or disclosure of personal health information without consent to ensure:
 - The public interest in the project outweighs the public interest in the protection of privacy;
 - The project cannot be conducted using non-identifiable information;
 - It is impracticable to seek consent from the people whose information is to be used or disclosed;
 - The information requested is the minimum necessary to accomplish the purpose; and
 - The project ensures the security of the information.

¹ In these Terms of Reference 'Department of Health WA' does not include the Area Health Services or other health service providers.

² In these Terms of Reference: 'Projects' means

- Activities for the purpose of conducting research, establishing infrastructure for research, or the compilation or analysis of statistics; and
- Activities related to funding, management, planning, monitoring, improvement or evaluation of health services.

It includes activities conducted by employees of the WA Department of Health and those conducted either in collaboration with or solely by persons who are not employed by the WA Department of Health.

It excludes reporting for National Minimum Data Sets or other mandated reporting requirements.

³ In these Terms of Reference:

'Personal health information' means all health information where the identity of a person is apparent or can reasonably be ascertained from the information.

- 3.4. To provide ethical oversight, monitoring and advice for projects involving personal health information and other research projects.
- 3.5. To advise the Department of Health WA on the principles, guidelines and procedures governing the use or disclosure of personal health information.
- 3.6. To monitor and report to the Minister for Health and the Director General of the Department of Health WA on the use and disclosure of personal health information.

4. Scope of Responsibility

- 4.1. The Department of Health WA Human Research Ethics Committee will review and provide oversight, monitoring and advice for:
 - 4.1.1. All research projects involving the use or disclosure of personal health information from the data collections held by the Department of Health WA.
 - 4.1.2. All projects for funding, management, planning, monitoring, improvement or evaluation of health services that involve the disclosure of personal health information from data collections held by the Department of Health WA.
 - 4.1.3. All projects involving the establishment of new linkages between:
 - Data collections held by the Department of Health WA; or
 - Data collections held by the Department of Health WA and any other data sources.
- 4.2. The Department of Health WA Human Research Ethics Committee will provide oversight, monitoring and advice and will review requests to extend approval for:
 - 4.2.1. All projects previously approved by the Confidentiality of Health Information Committee.
- 4.3. The Department of Health WA Human Research Ethics Committee may review and provide oversight, monitoring and advice for:
 - 4.3.1. Other research projects involving humans (not included in paragraph 4.1.1.- 4.1.3., 4.2.1.) conducted by employees of the Department of Health WA or involving participants for whom the Department of Health WA has a duty of care.
 - 4.3.2. Other research projects involving humans (not included in paragraph 4.1.1.- 4.1.3., 4.2.1.) conducted by external organisations and researchers, provided an agreement exists between the Department of Health WA and the external organisation that defines the role of the Department of Health WA Human Research Ethics Committee in providing ethical approval and ethical monitoring of the research and the role of the external organisation in giving approval for the research to take place within its organisation. The agreement must specify which party bears the legal responsibility for the liability that arises from the ethical review conducted by the Department of Health WA Human Research Ethics Committee, and must also specify that the organisation is responsible for liabilities arising from the conduct of the research.

- 4.4. Paragraph 4.3.1. and 4.3.2. do not prohibit the Department of Health WA from accepting an ethical approval given by another Human Research Ethics Committee as a sufficient ethical approval to allow the Department of Health WA to approve the commencement of the project for which it is responsible, provided that such other Human Research Ethics Committee is registered with the Australian Health Ethics Committee (AHEC).
- 4.5. The Department of Health WA Human Research Ethics Committee may provide advice to the Department of Health WA on the principles, guidelines and procedures governing the use and disclosure of personal health information by the Department of Health WA for the purposes of funding, management, planning, monitoring, improvement or evaluation of health services, and research or the compilation of statistics.
- 4.6. The Department of Health WA Human Research Ethics Committee may monitor and report to the Director General of Health on the use and disclosure of personal health information by the Department of Health WA for the purposes of funding, management, planning, monitoring, improvement or evaluation of health services, and research or the compilation of statistics.

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

- 5.1. The Department of Health WA Human Research Ethics Committee is an advisory committee of the Department of Health WA with responsibility for:
 - 5.1.1. Granting, withholding or withdrawing ethical approval for the conduct of projects specified in paragraph 3.
 - 5.1.2. Providing advice to the Department of Health WA on the use and disclosure of personal health information by the Department of Health WA for the purposes of research or the compilation or analysis of statistics; and funding, management, planning, monitoring, improvement or evaluation of health services.
 - 5.1.3. Monitoring the use and disclosure of personal health information by the Department of Health WA for the purposes of research or the compilation or analysis of statistics; and funding, management, planning, monitoring, improvement or evaluation of health services.
 - 5.1.4. Reporting to the Minister for Health and the Director General of Health on the use and disclosure of personal health information by the Department of Health WA for the purposes of research or the compilation or analysis of statistics; and funding, management, planning, monitoring, improvement or evaluation of health services.
- 5.2. The Director General of the Department of Health WA, or delegate, or a person authorised by statute, or delegate, is responsible for granting Department of Health WA institutional approval for:
 - 5.2.1. The use and disclosure of personal health information from data collections held by the Department of Health WA.

- 5.2.2. Research to be conducted by employees of Department of Health WA or involving participants for whom the Department of Health WA has a duty of care.
- 5.2.3. The establishment of new linkages between data collections held by the Department of Health WA and to other data sources.
- 5.3. The Director General of the Department of Health WA, or delegate, will give due consideration to the advice of Department of Health WA Human Research Ethics Committee and will not give approval for projects specified in paragraph 4.1.1.-4.1.3, 4.2.1., 4.3.1. unless ethical approval has been granted by Department of Health WA Human Research Ethics Committee.

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

- 6.1. The Department of Health WA Human Research Ethics Committee is accountable to the Director General of the Department of Health WA in the conduct of its business. The minutes of each Department of Health WA Human Research Ethics Committee meeting will be available to the Director General of the Department of Health WA.
- 6.2. The Department of Health WA Human Research Ethics Committee will provide an annual report for each calendar year to the Director General of the Department of Health WA, 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 Department of Health WA Human Research Ethics Committee's responsibilities. The report will be available on request to the general public and will be posted on the Department of Health WA website.
- 6.3. The Department of Health WA Human Research Ethics Committee may from time to time bring to the attention of the Director General of the Department of Health WA issues of significant concern within the scope of Department of Health WA Human Research Ethics Committee responsibilities.
- 6.4. The Department of Health WA Human Research Ethics Committee will provide reports:
 - To the AHEC in accordance with the requirement of the National Health and Medical Research Council (NH&MRC), and
 - In accordance with any other statutory reporting requirements in force at the time.
- 6.5. The Terms of Reference, Standard Operating Procedures and membership of the Department of Health WA Human Research Ethics Committee will be available on request to the general public and will be posted on the Department of Health WA website.

7. Membership

7.1. Composition

- 7.1.1. The composition of the Department of Health WA Human Research Ethics Committee shall comply with the *National Statement on Ethical Conduct in Human Research* and shall include at least:
- A chair who is from outside the Department of Health WA;
 - At least two members who are lay people, one man and one woman, who have no affiliation with the Department of Health WA, and are not currently involved 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 institution;
 - 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 a pool of further members;
 - 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 large health data collections who is employed by the Department of Health WA.
- 7.1.2. No member of the committee will 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 Department of Health WA Human Research Ethics Committee should be equal numbers of men and women and at least one half of the members should be from outside the Department of Health WA.
- 7.1.5. To ensure that the membership of the Department of Health WA Human Research Ethics Committee 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. The Director General of the Department of Health WA may appoint a Deputy Chair from amongst the membership of the Department of Health WA Human Research Ethics Committee who may exercise the powers of the Chair when the Chair is unavailable.

7.2. Appointment

- 7.2.1. The Director General of the Department of Health WA shall appoint the Chair and the members of the Department of Health WA Human Research Ethics Committee, in consultation with the Department of Health WA Human Research Ethics Committee and other senior Department of Health WA officials, as deemed appropriate.
- 7.2.2. Prospective members of the Department of Health WA Human Research Ethics Committee may be recruited by direct approach, nomination or by advertisement.
- 7.2.3. The Director General of the Department of Health may appoint a selection committee, which includes at least one representative of the Department of Health WA Human Research Ethics Committee, to interview prospective applicants, consult with Department of Health WA Human Research Ethics Committee members and make a recommendation to the Director General of the Department of Health WA.
- 7.2.4. Appointments will allow for continuity, the development of expertise within the Department of Health WA Human Research Ethics Committee, and the regular input of fresh ideas and approaches.

7.3. Terms of Appointment

- 7.3.1. The positions within the Department of Health WA Human Research Ethics Committee are fixed term 3 year appointments. Recruitment into these positions are staggered to ensure continuity and expertise of the Department of Health WA Human Research Ethics Committee.
- 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 the Director General of the Department of Health WA. The Director General may approve further terms, of varying duration, for members in order to ensure continuity and expertise of the Department of Health WA Human Research Ethics Committee.
- 7.3.3. Deputy members are appointed to the Department of Health WA Human Research Ethics Committee 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 the Director General of the Department of Health WA.
- 7.3.4. Membership will lapse if a member fails without reasonable excuse, or without notifying the Chair, to attend three consecutive meetings of the Department of Health WA Human Research Ethics Committee 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 from the Department of Health WA Human Research Ethics Committee 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. The Director General of the Department of Health WA may terminate the appointment of any member of the Department of Health WA Human Research Ethics Committee if the Director General of the Department of Health WA is of the opinion that:
- It is necessary for the proper and effective functioning of the Department of Health WA Human Research Ethics Committee;
 - The person is not a fit and proper person to serve on the Department of Health WA Human Research Ethics Committee;
 - The person has failed to carry out their duties as a member of the Department of Health WA Human Research Ethics Committee.
- 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 Department of Health WA Human Research Ethics Committee, Department of Health WA Human Research Ethics Committee meeting attendance responsibilities and general responsibilities as a Department of Health WA Human Research Ethics 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 Department of Health WA 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 Department of Health WA Human Research Ethics Committee will be kept confidential;
 - That any conflicts of interest which exist or may arise during his/her tenure on the Department of Health WA Human Research Ethics Committee 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 Department of Health WA Human Research Ethics Committee member.

7.5. Education for Department of Health WA Human Research Ethics Committee 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 attend conferences and workshops relevant to the work and responsibilities of the Department of Health WA Human Research Ethics Committee, at the expense of the Department of Health WA.

7.6. Sub-committees

The Department of Health WA Human Research Ethics Committee 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 Department of Health WA Human Research Ethics Committee. Members of the sub-committee need not be members of the Department of Health WA Human Research Ethics Committee subject to paragraph 8.7.6.

7.7. Liability Coverage

The Department of Health WA provides indemnity for members of the Department of Health WA Human Research Ethics Committee 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

The Department of Health WA Human Research Ethics Committee will perform its functions according to written Standard Operating Procedures. These procedures shall be reviewed at least every five years and amended and updated as necessary. All Department of Health WA Human Research Ethics Committee members shall have access to copies of the procedures and shall be consulted with regard to changes.

8.2. Executive Support

The Department of Health WA will provide administrative support for the Department of Health WA Human Research Ethics Committee by the provision of an Executive Officer. The Executive Officer will attend meetings of the Department of Health WA Human Research Ethics Committee 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

- 8.3.1. All applications for ethical approval must be submitted to the Executive Officer of the Department of Health WA Human Research Ethics Committee, by the relevant closing date, in writing in the format approved from time to time by the Department of Health WA Human Research Ethics Committee and shall include such documentation as the Department of Health WA Human Research Ethics Committee may specify.
- 8.3.2. Guidelines will be issued to assist applicants in their preparation of applications.
- 8.3.3. The Department of Health WA Human Research Ethics Committee may request the applicant to supply any further information in relation to an application and may request the applicant to attend a meeting of the Department of Health WA Human Research Ethics Committee at which the application will be considered for the purpose of providing information to and answering questions from the Department of Health WA Human Research Ethics Committee members.
- 8.3.4. The Department of Health WA Human Research Ethics Committee will consider every correctly completed application, which it receives, at its next available meeting following receipt, provided that the application is received by the

relevant closing date. The Executive Officer shall circulate the completed application and associated documents received with a meeting agenda to all members of the Department of Health WA Human Research Ethics Committee at least 7 days prior to the next meeting.

- 8.3.5. The Department of Health WA Human Research Ethics Committee may delegate consideration of certain scientific or technical matters to a Department of Health WA Human Research Ethics Committee member or sub-committee of members. The Department of Health WA Human Research Ethics Committee may also obtain expert scientific/technical advice from external sources, subject to paragraph 8.7.6.
- 8.3.6. The Department of Health WA Human Research Ethics Committee may request and consider a report on an application from the custodians of the relevant data collections.
- 8.3.7. The Department of Health WA Human Research Ethics Committee may take into account the views or opinion of another Human Research Ethics Committee in relation to a project.
- 8.3.8. The Department of Health WA Human Research Ethics Committee will promptly notify the applicant in writing, advising whether the application, which it has considered, has received ethical approval and any conditions of that approval.

8.4. Expedited Review

- 8.4.1. The Department of Health WA Human Research Ethics Committee may establish an Executive, consisting of at least the Chair/Deputy Chair and Executive Officer of the Department of Health WA Human Research Ethics Committee. The Executive may undertake expedited review of project proposals involving minimal risk to participants in accordance with the Standard Operating Procedures. The Executive may seek advice from other Department of Health WA Human Research Ethics Committee members before reaching a decision. The Executive will provide a report and recommendation on the project proposal for ratification at the next Department of Health WA Human Research Ethics Committee meeting.
- 8.4.2. The Executive may meet to consider and decide other items of business that are considered to be of minimal risk to participants such as project reports, minor amendments and the like. The Executive will provide a report on the decisions of any such meetings for ratification at the next Department of Health WA Human Research Ethics Committee meeting.

8.5. Multi-centre research

To facilitate multi-centre research the Department of Health WA Human Research Ethics Committee may:

- Communicate with any other Human Research Ethics Committee, and
- Accept a scientific, technical or ethical assessment of the research by another Human Research Ethics Committee.

8.6. Advocates and interpreters

- 8.6.1. The Department of Health WA Human Research Ethics Committee will consider whether an advocate for any participants or group of participants should be invited to the Department of Health WA Human Research Ethics Committee meeting to ensure informed decision-making.
- 8.6.2. Where research involves the participation of persons unfamiliar with the English language, the Department of Health WA Human Research Ethics Committee may require that any documents for participants are translated into the participant's language.

8.7. Meetings

- 8.7.1. The Department of Health WA Human Research Ethics Committee will meet on a regular basis, which will normally be at monthly intervals.
- 8.7.2. Meeting dates and agenda closing dates will be published.
- 8.7.3. A quorum for meetings of the Department of Health WA Human Research Ethics Committee 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 Department of Health WA Human Research Ethics Committee and at least one third of those present are from outside the Department of Health WA.
- 8.7.4. 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.
- 8.7.5. Any member of the Department of Health WA Human Research Ethics Committee who has any interest, financial or otherwise, in a proposal or other related matter considered by the Department of Health WA Human Research Ethics Committee, 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 Department of Health WA Human Research Ethics Committee 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.
- 8.7.6. The Department of Health WA Human Research Ethics Committee may consult with any person(s) considered by the Department of Health WA Human Research Ethics 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.
- 8.7.7. The Department of Health WA Human Research Ethics Committee 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 (ie 2 or more members) shall be noted in the minutes.

8.8. Fees

A fee will not be charged for applications submitted for assessment by the Department of Health WA Human Research Ethics Committee.

8.9. Records

- 8.9.1. The Executive Officer will prepare and maintain written records of the Department of Health WA Human Research Ethics Committee activities, including agendas and minutes of all meetings of the Department of Health WA Human Research Ethics Committee.
- 8.9.2. The Executive Officer will prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the Department of Health WA Human Research Ethics Committee.
- 8.9.3. Files will be kept securely and confidentially.
- 8.9.4. Records shall be held for sufficient time to allow for future reference and to comply with the General Disposal Authority for Administrative Records issued by the State Records Office and the Department of Health WA Records Retention and Disposal Schedule.
- 8.9.5. The Department of Health WA Human Research Ethics Committee will maintain a register of all the applications received and reviewed in accordance with the *National Statement on Ethical Conduct in Human Research*.

9. Post Approval Responsibilities

- 9.1. The Department of Health WA Human Research Ethics Committee will monitor the conduct of approved projects in terms of compliance with the Department of Health WA Human Research Ethics Committee ethical approval. The Department of Health WA Human Research Ethics Committee will require applicants to provide periodic reports at least annually and a final report on completion of the project. The Department of Health WA Human Research Ethics Committee may request additional information, conduct random checks or adopt any additional mechanisms to monitor approved projects.
- 9.2. The Department of Health WA Human Research Ethics Committee will require that investigators immediately report anything which might warrant review of ethical approval of the project, including:
 - Proposed changes in the research protocol or conduct;
 - Any breaches, complaints, adverse events or any other unforeseen events that might affect the ethical acceptability of the project;
 - The suspension or cessation of a project.

10. Complaints and Review

10.1. Breaches or complaints concerning the conduct of a project

- 10.1.1. Any reports of breaches, or concerns or complaints about the conduct of a project should be directed to the Executive Officer of the Department of Health WA Human Research Ethics Committee. The Executive Officer will notify the Chair of the Department of Health WA Human Research Ethics Committee and the Director of the area of the Department of Health WA responsible for the administration of the Department of Health WA Human Research Ethics Committee. The Director will convene an Incident Review Committee, which includes the Chair of the Department of Health WA Human Research Ethics Committee, or delegate, to investigate the complaint or breach and determine the consequences.
- 10.1.2. If a complainant is not satisfied with the outcome of the investigation, then he or she can refer the complaint to the Director General of the Department of Health WA who will review the decision.
- 10.1.3. If a complainant is not satisfied with the decision of the Director General of the Department of Health, then depending on the nature of the breach or complaint the matter can be referred for external review to the Ombudsman Western Australia, Office of Health Review or Federal Privacy Commissioner.

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

- 10.2.1. Any concern or complaint concerning the Department of Health WA Human Research Ethics Committee review process or the rejection of an application should be directed to the Executive Officer of the Department of Health WA Human Research Ethics Committee. The Executive Officer will notify the Chair of the Department of Health WA Human Research Ethics Committee and the Director of the area of the Department of Health WA responsible for the administration of the Department of Health WA Human Research Ethics Committee. The Director of the area of the Department of Health WA responsible will convene an Incident Review Committee, which includes the Chair of the Department of Health WA Human Research Ethics Committee or delegate, to investigate the complaint or breach and make a recommendation on the appropriate course of action. If a complainant is not satisfied with the outcome of the investigation, then he or she can refer the complaint to the Director General of the Department of Health WA.
- 10.2.2. The Director General of the Department of Health WA will determine whether there is to be a further investigation of the complaint. If there is to be a further investigation, then the Director General of the Department of Health WA will convene a suitable panel to review the complaint and will ensure that both the complainant and the Department of Health WA Human Research Ethics Committee are afforded the opportunity to make submissions.
- 10.2.3. The review panel will consider whether the Department of Health WA Human Research Ethics Committee has acted in accordance with its Terms of Reference, Standard Operating Procedures, the *National Statement on Ethical Conduct in Human Research* and otherwise acted in a fair and unbiased manner.

- 10.2.4. If the complainant is not satisfied with the outcome of the panel's investigation, then he/she can refer the complaint to the Ombudsman Western Australia. The Ombudsman may conduct a procedural review of the decision of the Department of Health WA Human Research Ethics Committee review panel.

11. Amendments to the Terms of Reference

These Terms of Reference may be amended by following the procedures specified below.

- 11.1. For those proposals made by a Department of Health WA Human Research Ethics Committee member:
- The proposal must be in writing and circulated to all Department of Health WA Human Research Ethics Committee members for their consideration.
 - The views of the members should be discussed at the next scheduled meeting of the Department of Health WA Human Research Ethics Committee, 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 Director General of the Department of Health WA for consideration and approval where appropriate.
- 11.2. For those proposals made by the Director General of the Department of Health WA:
- The Director General of the Department of Health WA will send the proposal to Department of Health WA Human Research Ethics Committee and seek the views of the members before making any amendment.

12. Acknowledgements

The Department of Health WA acknowledges the assistance derived from the Human Research Ethics Committees Operations Manual of NSW Health in the preparation of these Terms of Reference.



Delivering a **Healthy WA**