



WA Country Health Service Human Research Ethics Committee Terms of Reference

1. Preamble

The WA Country Health Service (WACHS) Human Research Ethics Committee (HREC) is a WA Health Lead HREC and is registered with the National Health and Medical Research Council (NHMRC). The HREC ensures all human research undertaken within or involving WACHS by internal or external applicants meets the ethical and scientific standards established by the NHMRC [National Statement on Ethical Conduct in Human Research \(2007\)\(as updated\)](#) (National Statement) guidelines. The HREC lies within the Ethics Review Function of the WACHS Research Governance Framework.

1.1 The HREC must operate in accordance with:

- a. WACHS [HREC Procedures](#)
- b. WACHS [Human Research Ethics Committee Appointment Policy](#).
- c. [WA Health Research Governance Policy and Procedures \(2012\)](#)
- d. [WA Health Single Ethical Review Standard Operating Procedures \(2013\)](#)
- e. [National Statement \(2007\)\(as updated\)](#).

2. Functions

2.1 The main functions of the HREC are to:

- a. provide ethical approval and oversight of all human research (excluding clinical trials) undertaken within WACHS sites or accessing WACHS participants such as patients, their carers or staff (including their data and/or tissue), and ensure compliance with the ethical standards established by the NHMRC
- b. provide advice and guidance on the ethical considerations of proposed research
- c. facilitate participation in research within WACHS
- d. operate as a WA Health Lead HREC for multi-centre research projects.

Note: Within WA Health, research cannot commence until ethical approval and local governance approval has been granted.

3. Responsibilities

3.1 The primary responsibilities of the HREC are to:

- a. provide timely ethical review of low risk or more than low risk human research projects involving WACHS sites or accessing WACHS participants (including their data or tissue)
- b. for single ethical review of multi-centre research, operate as a WA Health Lead HREC by providing ethical review and oversight of multi-centre research projects involving WACHS and other WA Health sites; or recognise and accept the ethical review conducted by another WA Health Lead HREC for multi-centre research projects

- c. protect the welfare and the rights of participants in research
- d. monitor the progress of all approved research projects until completion to ensure they continue to conform to ethical standards, in accordance with Chapter 5.5 of the National Statement. This includes reviewing amendments, annual progress reports, final reports and safety reports relating to previously approved research projects
- e. act as a point of reference for information or assistance in relation to the ethical conduct of research
- f. maintain communication with the NHMRC, the Australian Health Ethics Committee (AHEC), and upon request, provide evidence of compliance with the National Statement
- g. provide advice to the WACHS Quality Improvement Ethical Assessment Panel regarding projects that have ethical considerations and/or that warrant clarification on the level of ethical review required.

4. Ethical Considerations

- 4.1 When reviewing an ethics application, the HREC is to satisfy itself that:
- a. the project conforms to the National Statement
 - b. the project complies with the WA Health Research Governance Policy and Procedures (2012) and with the WA Health Single Ethical Review Standard Operating Procedures (2013)
 - c. potential participants are to be provided with sufficient information, at their level of comprehension, to enable them to make informed decisions as to whether to participate in a study
 - d. appropriate procedures relating to obtaining informed consent are observed
 - e. the privacy of participants involving the collection, storage, security, disclosure or other use of personal information is protected
 - f. procedures are in place for the handling of complaints from research participants and monitoring serious adverse events that may occur during the research process.

5. Accountability

- 5.1 The HREC is accountable to the WACHS Chief Executive (CE), who reports to the Health Service Board.
- 5.2 Operational management of the HREC is the responsibility of the WACHS Executive Director Medical Services (EDMS).
- 5.3 The WACHS Clinical Research Manager oversees the WACHS Ethics Review Function and is accountable to the WACHS EDMS.
- 5.4 The WACHS Ethics and QI Coordinator (EQIC) supports the HREC and reports to the WACHS Clinical Research Manager.
- 5.5 WACHS and the HREC are both accountable to the NHMRC.

6. Conduct of the Committee

- 6.1 The HREC is to conduct itself at all times in good faith, according to the principles of equity and the rules of natural justice, without conflicts of interest or bias.

7. Coordination and Secretariat

- 7.1** Coordination of and secretariat for the HREC is to be provided by the EQIC as well as the Clinical Research Manager from the WACHS Research Governance Unit at WACHS Central Office. These duties may include:
- a. liaison with internal and external research applicants
 - b. coordination of all research applications, reporting and notification forms
 - c. organisation of meeting venue
 - d. initiation of members
 - e. agenda preparation and minute taking
 - f. other duties as requested.

8. General

8.1 Membership

- 8.1.1** The HREC membership composition is to be in accordance with the National Statement and institutional requirements. As such, it is to consist of the following member representatives:
- a. Chair: An individual with a high level of knowledge and expertise in research ethics, who is independent from the institution with no current salaried or contractual relationship.
 - b. Male and female layperson: At least two lay people, one man and one women, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work.
 - c. Researcher: At least two people with knowledge of and current experience in, the areas of research that are regularly considered by the HREC (e.g. health, medical, social, psychological, epidemiological).
 - d. Professional care: At least one member with knowledge of, and current experience in the clinical/professional care, counselling, or treatment of people (e.g. medical practitioner, nurse, allied health practitioner).
 - e. Pastoral care: At least one person who performs a pastoral care role in a community, for example, an Aboriginal Elder or a minister of religion.
 - f. Lawyer: At least one lawyer, where possible one who is not engaged to advise the institution;.
 - g. WACHS CE or nominee representative: The CE or a nominee from within WACHS.
 - h. WACHS Aboriginal representative: The WACHS Area Director of Aboriginal Health Strategy or proxy.
- 8.1.2** Given the wide geographical coverage of WACHS sites and regions across Western Australia and the uniqueness of each region; where possible, at least one member of the HREC must be representative of the north of WACHS, whereby they reside north of the 26 parallel south latitude.
- 8.1.3** As far as possible, members are to represent multiple regions within WACHS.
- 8.1.4** As far as possible, the HREC is to reflect the diversity of the Australian population.
- 8.1.5** As far a possible the membership of the HREC should be equal numbers of men and women.

- 8.1.6** At least one third of the members should be from outside WACHS. Where there is more than one member from within WACHS, the members, as far as possible, should each represent different WACHS regions.
- 8.1.7** No member may be appointed in more than one of the above listed categories.

8.2 Chair

- 8.2.1** The Chair is the authorised channel of communication of all decisions of the HREC.
- 8.2.2** The appointment term of the Chair is to be for the same duration as the other member terms, outlined in the WACHS [Human Research Ethics Committee Appointment Policy](#).
- 8.2.3** A Deputy Chair is to be elected by the Chair and is to act as Deputy Chair in the temporary absence of the Chair.
- 8.2.4** In the temporary absence of the Chair and Deputy Chair, the Chair or Deputy Chair is to elect an Acting Chair.

8.3 Appointment / Re-appointment / Terms of Appointment

- 8.3.1** Members of the HREC are to be appointed (or re-appointed) by the WACHS CE, in accordance with sections 5.1.34 to 5.1.36 of the National Statement and the WACHS [Human Research Ethics Committee Appointment Policy](#).
- 8.3.2** The terms of appointment are also outlined in the WACHS [Human Research Ethics Committee Appointment Policy](#).
- 8.3.3** Appointments may be extended or terminated at the discretion of the CE.

8.4 Invited Experts

- 8.4.1** As per paragraph 5.1.33 of the National Statement, the HREC is free to seek advice from others who can provide assistance with specific issues. Experts are to be invited to attend the HREC meeting by the Chair, either physically, by teleconference or videoconference, and their presence is to be noted in the meeting minutes.

8.5 Meetings

- 8.5.1** The HREC is to meet monthly (except for January when the HREC is in recess).
- 8.5.2** The HREC meetings are to take place at WACHS Central Office. HREC members may attend the meetings in person, via telephone or videoconference.
- 8.5.3** Meetings are to be conducted as per P4 (Conduct of Meetings).

8.6 Quorum

- 8.6.1** A quorum exists when at least six members are present, including one of each of the following categories: chair/deputy chair, researcher, lawyer, layperson, professional care and either pastoral care or Aboriginal representative.

8.6.2 If a meeting does not achieve a quorum, this is to be managed as per P4 (Conduct of Meetings).

8.7 Meeting Minutes

8.7.1 In accordance with sections 5.2.25, 5.2.26 and 5.2.28 of the National Statement and P 6 (Preparation of Minutes) the minutes of each meeting is to reflect decisions made at the meeting and, where possible, link decisions made about a research project to the relevant section of the National Statement.

8.7.2 Specific views and/or comments are not to be attributed to particular HREC members in the minutes, except in circumstances where a member seeks to have their opinion or objections recorded.

8.7.3 The minutes are to reflect any conflict of interest declared by a HREC member in relation to matters discussed at the meeting and whether the member withdrew from all related discussions and did not participate in any decision making associated with the conflict of interest.

8.7.4 The minutes of each meeting are to be recorded and distributed to each member of the Committee as part of the next meeting pack for certification as a correct record of the proceeding.

8.7.6 The minutes are permanently retained as per the WACHS [Records Management Policy](#).

8.8 Conditions of Appointment

8.8.1 Members agree to their name and profession being made available to the public; including being published on the WACHS HREC website.

8.8.2 Eligible members will be remunerated at the rate recommended by the Public Sector Commission.

8.8.3 Members will be required to sign:

- a. a confidentiality form undertaking upon appointment stating that all matters of which he/she becomes aware during the course of his/her work on the WACHS HREC will be kept confidential; and
- b. a members duties statement that includes a declaration 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 WACHS HREC member.

9. Declarations of Interest

9.1 The HREC is to operate in accordance with P5 (Declarations of Interest), whereby all members must declare any interests associated with any research projects tabled for review. If the interest is deemed a conflict, this is to be managed as per the [WA Health Managing Conflicts of Interest Policy and Guidelines \(2010\)](#) where no member of the HREC is to adjudicate on the research where there is a conflict. This includes conflicts of interest such as ethical or moral bias, involvement or participation within the research project, financial interest in the outcome or any involvement in competing research.

- 9.2** Declarations of interest **and** any conflicts of interest are to be recorded within the quarterly report provided to the WACHS Executive Committee.

10. Confidentiality

- 10.1** The proceedings of the HREC are to be confidential, or as required by law.

11. Record Keeping

- 11.1** WACHS is to maintain a record of all research projects received and reviewed, including:
- a. name of responsible institution to which the research approval is provided
 - b. project reference number
 - c. project title
 - d. name of principal investigator and other research personnel
 - e. correspondence between the HREC and the researcher about the review
 - f. formal advice of ethical approval, or non-approval, with date
 - g. the terms and conditions, if any, of approval of any project
 - h. duration of approval
 - i. proposed date of completion of the project
 - j. actions taken by the HREC to monitor the conduct of the research
 - k. whether a waiver of consent was granted under the National Statement
 - l. the relevance, if any, of the Guidelines under Section 95 and Section 95A of the *Privacy Act 1988*.
- 11.2** The application form, protocol, and any relevant supporting documentation (including information sheet, consent form, questionnaire or relevant correspondence) are to be preserved in the form that it was approved.

12. Education

- 12.1** As per section 5.2.3 of the National Statement, HREC members are to attend education or training programs at least every three years.
- 12.2** Where possible, WACHS is to facilitate training for members annually and meet reasonable costs for members to attend regular training.
- 12.3** HREC members are encouraged to attend all education and training sessions, where possible.

13. Reporting

13.1 Research Reports

- 13.1.1 Safety Reports:** Researchers are required to immediately report protocol deviations, violations or serious adverse events of approved projects to the HREC. The process for safety reporting is outlined in P16 (Researcher Safety Reporting).

13.1.2 Annual Progress Reports: Once a project is granted ethical approval, researchers are to provide a report annually to the HREC describing their project's progress to date and continued compliance with the approved protocol. Annual progress reports are managed according to P 15 (Researcher Annual/Final Reporting).

13.1.3 Final / Closure Reports: As a condition of ethical approval, researchers are to submit a final report to the HREC at the completion of their study to describe the outcome of the project and any issues encountered since the submission of an annual progress report. Refer to P 15 (Researcher Annual/Final Reporting).

13.2 HREC Reports

13.2.1 The EQIC and Clinical Research Manager in conjunction with the Chair is to provide annual reports (and any other reports as required) of the HREC to the NHRMC or any other regulatory agencies. These reports require endorsement by the WACHS EDMS prior to being released.

13.3 WACHS Reports

13.3.1 The EQIC and Clinical Research Manager are to provide quarterly reports to the WACHS EDMS to present to the WACHS Executive Committee, including the following information:

- number, type and description of research projects reviewed by the HREC
- number of declarations of interest and the number of conflicts of interest
- number of safety issues (including adverse events) reported to the HREC
- number of complaints made to the HREC
- any other information as requested by the WACHS Executive Committee.

13.3.2 The EQIC and Clinical Research Manager are to develop biannual reports of the most recently approved project's summaries to be made available on the HREC website.

13.3.3 The EQIC and Clinical Research Manager are to provide annual reports of the HREC activity to the WACHS CE via the EDMS, for tabling at the WACHS Executive Committee meetings and Health Service Board meetings. A summary of this report is to be made available to the public via the HREC website.

14. Complaints

14.1 Any concerns, breaches or complaints in relation to the conduct of a project are to be handled in accordance with P 18 (Breaches in the Conduct of a Project) and P19 (Complaints about the Conduct of a Project).

14.2 Any complaints about the review or rejection of an application by the HREC are to be managed in accordance with P 20 (Complaints about the Review or Rejection of an Application).

14.3 All complaints are to be reported to the WACHS Executive as per section 13.3.1d and to the NHMRC as per section 13.2.

15. Review and Amendment of Terms of Reference

15.1 WACHS is to review the HREC's effectiveness annually and the Terms of Reference every two years in conjunction with the Chair.

15.2 Changes to the Terms of Reference are to be endorsed by the WACHS CE or delegate.

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on request for a person with a disability**

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