



Terms of Reference

South Metropolitan Health Service Human Research Ethics Committee

1. Preamble

The South Metropolitan Health Service (SHMS) Human Research Ethics Committee (HREC) was established to provide advice regarding the ethical conduct of research. While the HREC provides a recommendation that proposed research is ethically and scientifically sound, the Chief Executive (or delegate) of each proposed research site retains the final decision regarding approval of any research to be conducted at that site.

The HREC is bound by state and national policy and legislation. The operation of the HREC is governed by the terms set out by the National Health and Medical Research Council (NHMRC) in the [National Statement on Ethical Conduct in Human Research 2023](#) (National Statement).

Compliance with the National Statement, while not statutory, is required for research:

- involving unapproved therapeutic goods as outlined in the Therapeutic Goods Act 1989
- conducted in WA Health or requesting information from WA Health data collections funded by the NHMRC
- by other grant providers and publishers.

These Terms of Reference (ToR) serve as a guide to the functions and status of the SMHS HREC (EC00265), which is a certified 'Lead HREC' under the [National Mutual Acceptance Scheme \(NMA\)](#).

These ToR should be read in conjunction with the SMHS Research Governance and Integrity Policy and the SMHS Ethical Review of Research Projects Procedure, which are published on the internal Research Support & Development Unit SharePoint site and provide a detailed outline of the processes and procedures for reviewing, approving and monitoring research within SMHS, and the [National Clinical Trials Governance Framework \(NCTGF\) 2022](#).

2. Objectives

2.1. The HREC objectives are to:

- protect the mental and physical welfare, rights, dignity and safety of participants of research projects
- review and monitor research projects in accordance with the National Statement
- facilitate ethically acceptable and scientifically sound research projects through efficient and effective review processes
- promote ethical standards of human research.

3. Functions

- 3.1. The HREC functions are to ensure that all research projects comply with the National Statement by:
- providing independent, competent and timely review of research projects involving humans in respect of their ethical acceptability
 - providing ethical oversight, monitoring and advice for research projects involving humans
 - prescribing the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.

4. Scope of responsibility

- 4.1. The HREC is responsible for reviewing the ethical and scientific rigour of research projects involving human participants:
- to be undertaken within SMHS
 - received as part of the WA Single Ethical Review scheme
 - received as part of the National Mutual Acceptance (NMA) Scheme.
- 4.2. SMHS may accept the ethical approval provided by another HREC, provided that the alternative HREC is:
- a certified lead HREC under the NMA Scheme, or
 - an approved lead HREC under the WA Single Ethical Review scheme.
- 4.3. Research projects 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. A research project may be classified as a clinical trial.
- 4.4. For research projects being conducted within the institutions or organisations noted in clause 4.1, the HREC is responsible for:
- providing ethical approval
 - withholding ethical approval
 - withdrawal of ethical approval
 - ongoing monitoring of approved research projects.
- 4.5. The Chief Executive of each site, or approved delegate, is responsible for granting the site authorisation for research projects, giving due consideration to the advice of the HREC and the Research Governance Officers.

5. Accountability of the SMHS HREC

- 5.1. The HREC is accountable to the SMHS Director Research in the conduct of its business.
- 5.2. The HREC shall provide an annual report to:
- the Director Research
 - the NHMRC in accordance with certification requirements.
- 5.3. The HREC ToR and membership will be publicly available on the [SMHS Research Support & Development Unit \(RSDU\)](#) website.

6. Confidentiality

- 6.1. All data provided to the SMHS HREC, including details of the research project and contact information, is maintained as private and confidential.
- 6.2. Only those researchers involved in the research project may access the HREC records. Researchers adding additional personnel to the research project team are required to submit notification of this to the HREC in the form of an amendment.
- 6.3. Any researchers wishing to give individuals who are not involved in their research project access to details of their application are required to confirm these intentions in a letter to the HREC.

7. Membership

7.1. Composition

- 7.1.1. The composition of the HREC shall be in accordance with the National Statement (5.1.30 - 5.1.32), including additional members relevant to SMHS research.
- 7.1.2. Minimum membership shall comprise of eight members, with 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 shall be:
 - a chairperson (or proxy)
 - a male community representative
 - a female community representative
 - a professional care representative (e.g. Doctor, nurse or allied health worker)
 - a pastoral care representative (e.g. Minister of religion, Aboriginal elder, community leader)
 - a lawyer
 - two individuals with current experience conducting human research.
- 7.1.3. No member may be appointed in more than one of the foregoing categories.
- 7.1.4. The HREC will ensure that the membership includes at least one member with experience in reflecting on and analysing ethical decision-making.
- 7.1.5. The HREC may utilise a pool of inducted members in each category to ensure that the minimum membership requirements are met for each HREC meeting.
- 7.1.6. Full attendance of the minimum membership is required to achieve quorum. If at a meeting of the HREC there is less than full attendance of the minimum membership, the Chairperson should be satisfied that the views of those absent have been considered before a decision is reached. This may be through the provision of written comments prior to the meeting.
- 7.1.7. The HREC may co-opt expertise as required for review of specific proposals or issues, with support of the Chairperson. These individuals should have no conflict of interest in relation to the research projects they review.

7.2. Appointment of members

- 7.2.1. Members are appointed as individuals rather than in a representative capacity.
- 7.2.2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. Members will be appointed using an open and transparent process.
- 7.2.3. A selection committee shall interview the prospective applicant and make a recommendation to the SMHS Director Research. Prospective members may be invited to attend a meeting of the HREC as an observer.
- 7.2.4. Members, including the Chairperson, are appointed by the SMHS Director Research and will receive a formal notice of appointment.

7.3. Terms of appointment

- 7.3.1. Members shall receive a letter of appointment that includes 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 HREC member, the circumstances whereby membership may be terminated and the conditions of their appointment.
- 7.3.2. Upon appointment, members will be provided with a comprehensive induction and shall be provided with the following documentation:
 - current ToR
 - SMHS Ethical Review of Research Projects Procedure
 - SMHS Review of Low and Negligible Risk Research Procedure
 - up-to-date list of HREC members' names and contact information including that of the Ethics Coordinator and Administrative Officer
 - NHMRC National Statement on Ethical Conduct in Human Research 2023
 - The Australian Code for the Responsible Conduct of Research 2018
 - WA Health Research Governance Framework policies
 - Health Services Act 2016
 - SMHS Research Governance & Integrity Policy
 - Access to and training for the online Research Governance Service (RGS).
- 7.3.3. Members are appointed for a period of three years. An additional term of two years may be negotiated with the approval of the SMHS Director Research.
- 7.3.4. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches. New members may be appointed to the committee prior to the expiry of outgoing individual's memberships to allow for continuity. The committee should endeavour to add new members to the membership pool each year.

7.4. Conditions of appointment

- 7.4.1. HREC members will:
 - comply with SMHS policies and procedures regarding recruitment of volunteers, such as criminal record screening

- attend meetings regularly or as rostered and provide sufficient notification if unable to attend. If unable to attend members should provide out of session written feedback to the Secretariat via email on the proposals under review prior to the meeting, unless otherwise arranged. A proxy member from the same category may attend if comments cannot be provided
- attend meetings prepared for the relevant discussion
- attend ongoing training and education throughout their tenure on the HREC
- participate in relevant specialised working groups as required, including low risk review
- agree to their name being made available to the public, including being published on the SMHS Research Support & Development Unit website
- sign a declaration of confidentiality upon appointment
- notify the Chairperson of any actual or perceived conflicts of interest that exist or arise during their tenure on the HREC.

7.4.2. Members shall not be paid a sitting fee for attendance at the meeting. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as parking expenses (as per SMHS policies).

7.4.3. A member may resign from the HREC at any time upon giving 4 weeks' notice in writing to the Chairperson, or SMHS Director Research in the case of the Chairperson resigning. Recruitment will occur to fill the vacancy of the former member.

7.4.4. The SMHS Director Research may terminate the appointment of any HREC member for reasons, including:

- failure to disclose a conflict of interest
- failure to fulfil his/her obligations as a HREC member.

7.5. Liability coverage

7.5.1. SMHS provides indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith. Such indemnity is provided through the Insurance Commission of Western Australia agreement with SMHS.

8. Secretariat

8.1. SMHS will provide secretariat support to the SMHS HREC. The secretariat will:

- maintain responsibility for all communication with researchers, unless otherwise agreed by the Chairperson. This communication will be in person, via telephone or written (including email and via the RGS system)
- organise meetings of the HREC including venue, agenda and dates in RGS
- maintain up-to-date membership details and distribution lists
- arrange training opportunities for HREC members
- document the minutes of HREC meetings
- provide timely updates and communication with committee members
- provide reports in line with internal and external governance requirements
- maintain records in line with institutional, state and federal requirements.

9. Chairperson

- 9.1. The Chairperson is appointed in a voluntary capacity by the SMHS Director Research.
- 9.2. The Chairperson is responsible for managing the discussions associated with each agenda item and ensuring the views of all members have been considered before a decision is reached.
- 9.3. The Chairperson may delegate the power of approval to the Delegate of the Chair. The Delegate of the Chair will be responsible for signing correspondence on behalf of the HREC and the review of HREC requested changes to applications, administrative amendments, annual reports, safety reports and other duties as appropriate.
- 9.4. In the absence of the Chairperson, a proxy Chairperson will be appointed for the duration of the meeting and will perform the role and duties of the Chairperson.

10. Delegate of the Chair

- 10.1. The Chairperson may appoint a Delegate of the Chair. The Delegate of the Chair should be a staff member within the SMHS Research Support & Development Unit. There may be more than one individual delegated in this role.
- 10.2. The Delegate of the Chair will:
 - sign correspondence on behalf of the Chairperson
 - assist in the review of low and negligible risk applications
 - review responses to HREC queries
 - provide timely communication and advice to researchers
 - provide ethical approval of research projects, following recommendations of the HREC
 - monitor approved research projects through reviewing and providing approval for amendment applications and reports.
- 10.3. The Delegate of the Chair is not a full member of the HREC and does not have the right to vote on its deliberations.

11. Subcommittees

- 11.1. The HREC may convene, and disband, subcommittees to review the scientific rigour of research proposals, low risk proposals, or perform other functions as agreed by the Chairperson.

12. Fees

- 12.1. Research projects which are fully sponsored or funded by commercial entities, such as commercial sponsors, attract a submission fee for the ethical review of the project. Fees are payable following the review of the research project regardless of the outcome or whether the research project is approved or withdrawn.
- 12.2. Additional fees may be charged for amendments made throughout the life of the research project if they require review by the HREC or associated low risk review panel.
- 12.3. All fees are charged in line with the SMHS Administrative Fees Procedure.

13. Complaints and review

- 13.1. Complaints concerning the HREC review process should be forwarded to the Manager of the SMHS Research Support and Development Unit (RSDU).
- 13.2. Complaints related to the conduct of research, including research misconduct, will be managed in line with the SMHS Managing Research Complaints and Investigating Misconduct Procedure.

14. Amendments to the ToR

- 14.1. These ToR will be reviewed annually.
- 14.2. These ToR may be amended by submitting a written proposal to the SMHS Director Research. Any proposal will be discussed by the full HREC.
- 14.3. The ToR will be endorsed by the SMHS Director Research.



MELANIE WRIGHT

SMHS Director Research

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