



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

Terms of Reference

**Sir Charles Gairdner and Osborne Park Health Care Group
Human Research Ethics Committee**

Version 1.2

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Contents

1. Purpose	2
2. Overview	2
3. Role of the HREC	2
4. Functions	2
5. Scope of responsibility	3
6. Accountability of the HREC	3
7. Membership	4
8. Delegate of the Chair	6
9. Meetings	6
10. Secretariat	7
11. Subcommittees	7
12. Communication	7
13. Amendment to the ToR	8

Document history

Editor	Date	Version	Amendments
HREC Office	April 2016	-	Terms of reference drafted and circulated to members.
HREC Office	May 2016	1.0	Terms of reference scheduled for discussion at 19 May 2016 HREC meeting.
HREC Office	May 2016	1.0	Discussed at HREC meeting with no additional comment. To be distributed to members for final comment before the Terms of Reference are agreed at the 16 June 2016 meeting.
HREC Office	July 2016	1.1	Updated in line with comments from 16 June 2016 HREC meeting.
HREC Office	August 2016	1.2	Updated in line with the comments from the 21 July 2016 HREC meeting

1. Purpose

The purpose of these Terms of Reference (ToR) is to serve as a guide to the responsibilities, functions and status of the Human Research Ethics Committee (HREC) established by the Sir Charles Gairdner and Osborne Park Health Care Group (SCGOPHCG), also referred to as the Sir Charles Gairdner Group HREC.

2. Overview

The HREC was established to provide advice to the SCGOPHCG, and investigators, regarding the ethical conduct of research. While the HREC provides a recommendation that proposed research meets the requirements of the National Statement and is ethically acceptable, the Executive Director of the SCGOPHCG retains the final decision regarding approval of any research to be conducted within the SCGOPHCG.

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 2015 (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, and
- by other grant providers and publishers.

These ToR should be read in conjunction with the *Standard Operating Procedures* which provide a detailed outline of the processes and procedures for reviewing, approving and monitoring research within the SCGOPHCG.

3. Role of the HREC

The role of the HREC is to:

- protect the mental and physical welfare, rights, dignity and safety of participants of research
- review and monitor research in accordance with the requirements set out in the *National Statement*
- facilitate ethical research through efficient and effective review processes, and
- promote ethical standards of human research.

4. Functions

The HREC, in line with the *Standard Operating Procedures*, will perform the following functions:

- provide independent, competent and timely review of research proposals involving humans in respect of their ethical acceptability and scientific rigour
- provide ethical oversight, monitoring and advice for research proposals involving humans, and

- prescribe the principles and procedures to govern research projects involving humans, human tissue and/or personal records within the SCGOPHCG.

5. Scope of responsibility

- 5.1 The HREC is responsible for reviewing the ethical and scientific rigour of all research involving human participants at the following sites:
 - Sir Charles Gairdner Hospital
 - Osborne Park Hospital, and
 - other institutions/individuals at the discretion of the Executive Director.
- 5.2 Research involving humans includes, but is not limited to, research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records, as well as epidemiological, social, and psychological investigations.
- 5.3 For research being conducted within the institutes or organisations noted in 5.1, the HREC is responsible for providing:
 - ethical approval
 - withholding ethical approval
 - the withdrawal of ethical approval, and
 - ongoing monitoring of approved research.
- 5.4 The Executive Director, or approved delegate, is responsible for granting the SCGOPHCG institutional approval for research, giving due consideration to the advice of the HREC and the Research Governance Office.

6. Accountability of the HREC

- 6.1 The HREC is accountable to the Executive Director in the conduct of its business.
- 6.2 The HREC shall provide an annual report to the Executive Director at the end of each calendar year, which will include information on membership, the number of proposals reviewed, status of proposals, as well as a description of any complaints received and their outcome.
- 6.3 In addition, the HREC will provide reports to the:
 - NHMRC, and
 - Australian Health Ethics Committee.
- 6.4 The HREC ToR, *Standard Operating Procedures* and membership list will be available online, including names of all committee members.

7. Membership

7.1 Committee composition

- 7.1.1 The composition of the HREC shall be in accordance with the *National Statement*, including additional members relevant to SCGOPHCG.
- 7.1.2 Minimum membership shall comprise of ten members, being as far as possible an equal number of men and women, and at least one third of the members should be from outside the SCGOPHCG. The minimum membership shall include a(n):
- Chair
 - laywoman
 - layman
 - professional care provider (eg. nurse or social worker)
 - pastoral care provider (eg minister of religion, Aboriginal elder)
 - lawyer
 - member of the SCGOPHCG Executive, and
 - two individuals with experience in conducting human research.
- 7.1.3 No member may be appointed in more than one of the foregoing categories.
- 7.1.4 At least one of the above members should have experience in medical ethics.
- 7.1.5 At least one member at every meeting must be a nurse.
- 7.1.6 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.
- 7.1.7 The HREC may co-opt expertise as required for review of specific proposals or issues, with support of the Chair. Where this is the case, unless otherwise agreed by the HREC, the secretariat will coordinate obtaining such expertise.

7.2 Appointment of members

- 7.2.1 Members are appointed as individuals for their own knowledge and experience, rather than as representatives of an organisation, group or opinion. This is with the exception of the Executive member.
- 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 Recommendations for appointment will take into account diversity of views and skills that representatives can bring to support the purpose and objectives of the HREC.
- 7.2.4 The Chairperson and an Executive sponsor will endorse the appointment of all members.
- 7.2.5 An Executive sponsor will appoint the Chair.

7.3 Terms of appointment

- 7.3.1 Members shall receive a letter of appointment which 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 by the secretariat. This will include the provision of the following information:
- these ToR
 - HREC Standard Operating Procedures
 - up-to-date list of members' names and contact information
 - the *National Statement*
 - The Australian Code for the Responsible Conduct of Research, and
 - any other relevant information about the HREC's processes, procedures and protocols.
- 7.3.3 Members are appointed for a period of three years. An additional term may be negotiated with the approval of the Executive Director. Reappointment is by application to the Chair who, with advice from the secretariat, will make a recommendation to the Executive Director.

7.4 Responsibilities of HREC members

- 7.4.1 HREC members will:
- attend meetings regularly or provide sufficient notification if unable to attend. If unable to attend members should provide written feedback on the proposals under review, unless otherwise arranged.
 - come to 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
 - sign a declaration of confidentiality upon appointment, and
 - notify the Chair 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.
- 7.4.3 Should a member wish to resign from their position, the member is to notify the Chair, in writing, copied to the secretariat. The Chair, with input from the secretariat, is responsible for appointing a replacement.

7.4.4 The Chair or Executive Director may terminate the appointment of any HREC member for reasons, including:

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

7.4.5 The SCGOPHCG 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 WA Risk Cover.

8. Delegate of the Chair

8.1 The Executive Director, with support of the Chair, will appoint a Delegate of the Chair. The Delegate of the Chair should be a staff member within the Department of Research. There may be more than one individual delegated in this role.

8.2 The Delegate of the Chair will:

- sign correspondence on behalf of the Chair
- assist in the review of low risk applications
- review responses to HREC queries
- approve studies with clearance from the HREC, and
- monitor approved research through reviewing and acknowledging amendments and reports.

8.2.1 The Delegate of the Chair is not a full member of the HREC and does not have the right to vote on its deliberations.

9. Meetings

9.1 The HREC shall meet on a monthly basis, a minimum of 11 times in a calendar year. Meeting dates will be agreed in advance by the HREC and will be published online, along with associated submission dates.

9.2 In the absence of the Chair, a proxy Chair will be appointed for the duration of the meeting and will perform the role and duties of the Chair.

9.3 Consistent with the *National Statement*, if at a meeting of the HREC there is less than full attendance of the minimum membership, the Chair 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 or verbal comments.

9.4 The HREC will consider every correctly completed application that it receives at its next available meeting.

9.5 The secretariat shall circulate the completed application material to all members at least seven days prior to the meeting.

- 9.6 Any member of the HREC who has any interest, financial or otherwise, in a research proposal or other related matter(s) considered by the HREC should declare such interest to the Chair. The member will withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. The member will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter. The departure of any member who declares a conflict of interest will be noted in the minutes of the meeting.
- 9.7 The HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by general agreement. Any significant minority opinions will be minuted.
- 9.8 The secretariat may, on behalf of the Chair, invite investigators to attend an HREC meeting in order to provide clarification on a research proposal.

10. Secretariat

- 10.1 The Department of Research will provide secretariat support to the HREC including:
- maintaining responsibility for all communication with investigators, unless otherwise agreed by the Chair
 - organising meetings of the HREC
 - maintaining up-to-date membership details and distribution lists
 - attending to all meeting documentation
 - arranging training opportunities for HREC members
 - recording the minutes of HREC meetings
 - providing timely updates and communication with committee members
 - providing timely communication and advice to investigators
 - providing reports in line with governance requirements, and
 - maintaining records in line with institutional, state and federal requirements.

11. Subcommittees

- 11.1 The HREC may convene, and disband, subcommittees to review the scientific rigour of research proposals, or perform other functions as agreed by the Chair.
- 11.2 Subcommittees will develop, and be governed by, their own ToR which will be approved by the HREC.
- 11.3 The Subcommittees will report to the HREC, and must provide it with a copy of any meeting minutes, including all decisions reached.

12. Communication

- 12.1 The HREC will accept all communication, including signatures, in an electronic format.

12.2 The HREC will utilise both formal and informal methods of communication, placing importance on face-to-face meetings, especially if any issues regarding proposed research have not been resolved by written or telephone communication.

12.3 Following the meeting of the HREC, investigators will be notified within two working days of the outcome of the meeting.

13. Amendment to the ToR

13.1 These ToR may be amended following a formal written proposal to the HREC. For any change to be ratified the proposal must be:

- circulated to all members
- discussed and voted upon at a meeting of the HREC. Any member unable to attend such a meeting may register his or her views in writing, and
- supported by at least two thirds of the members of the HREC.

13.2 The revised ToR will be presented to the Executive Director for review and approval if appropriate.

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