

**Sir Charles Gairdner Group (SCGG)
HUMAN RESEARCH ETHICS COMMITTEE (HREC)
TERMS of REFERENCE**

Preamble

These Terms of Reference (ToR) are intended to serve as a guide to the functions and status of the HREC established to provide ethics advice to the SCGG. The NHMRC National Statement on Ethical Conduct in Human Research does not prescribe how any ToR are written for HRECs nor is there any statutory authority invested in any such ToR developed by HRECs. However, The Therapeutic Goods Act 1989 requires that HRECs follow the guidelines laid out in the NS for the purposes of studies involving access to unapproved therapeutic goods and the NHMRC requires compliance with the NS for studies funded by the NHMRC. It is therefore important to provide a clear description of the functions, responsibilities and management of the HREC within the SCGG for the purposes of complying with the NS and TGA Act in a transparent manner.

The SCGG HREC is acting as an advisory committee to the SCGG, and gives advice to both the investigators and to the Executive Director of the SCGG. However, the decision to approve (or not approve) any research conducted within the SCGG rests with the Executive Director or delegate as described in these ToR.

1. OBJECTIVES

The HREC objectives are to:

- 1.1. protect the mental and physical welfare, rights, dignity and safety of participants of research.
- 1.2. review and monitor research in accordance with the requirements set out in the National Statement on Ethical Conduct in Human Research 2007.
- 1.3. facilitate ethical research through efficient and effective review processes.
- 1.4. promote ethical standards of human research.

2. FUNCTIONS

The HREC functions are to:

- 2.1. provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.
- 2.2. provide ethical oversight, monitoring and advice for research projects involving humans.
- 2.3. prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.

3. SCOPE OF RESPONSIBILITY

- 3.1. Research proposals involving humans will be reviewed by the SCGG HREC where the research involves health services at the following sites:
 - o Sir Charles Gairdner Hospital (including all “institutes” and other health services on the QEII site)
 - o Osborne Park Hospital
 - o Swan Districts and Kalamunda Hospitals (by agreement as not part of SCGG)
 - o Other institutions/individuals on an ad hoc basis
- 3.2. Term of reference 3.1 does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the

institution to approve the commencement of the project, provided that such other HREC is registered with the Australian Health Ethics Committee.

- 3.3. Research 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.

4. STATUS OF THE HREC WITHIN THE HEALTH SERVICE

- 4.1. The HREC is an advisory committee of the SCGG with responsibility for:

- recommending ethical approval;
- recommending that ethical approval be withheld; and
- recommending the withdrawal of ethical approval

for research to be carried out within the institutions noted in paragraph 3.1.

- 4.2. The Executive Director or delegate is responsible for granting the SCGG institutional approval for research to be conducted within its institutions giving due consideration to the advice of the HREC.

- 4.3. The Executive Director requires the HREC provide advice on whether to:

- give approval on behalf of the SCGG to the conduct of ethically approved research in the institutions referred to in paragraph 3.1 of these Terms of Reference;
- approve amendments on behalf of the SCGG to research conducted at those institutions;
- suspend approval on behalf of the SCGG for the conduct of research at those institutions;
- withdraw approval on behalf of the SCGG for the conduct of research at those institutions.

- 4.4. The Executive Director may allow the SCGG HREC Office to accept the scientific and ethical review of another duly constituted HREC without requiring review by the full SCGG HREC, in accordance with the National Statement. Such approvals are still subject to Research Governance Review and approval will be tabled at the SCGG HREC meeting for ratification.

5. ACCOUNTABILITY OF THE HREC

- 5.1. The HREC is accountable to the Executive Director in the conduct of its business. The minutes of each HREC meeting shall be forwarded to the Executive Director, following confirmation.

- 5.2. 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, a description of any complaints received and their outcome, and general issues raised.

- 5.3. The HREC may from time to time bring to the attention of the Executive Director issues of significant concern.

- 5.4. The HREC will provide reports:

- to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NHMRC);
- to the Federal Privacy Commissioner in accordance with the requirements of the Privacy Act 1988 (Cwth);

5.5. The HREC Terms of Reference, Operating Procedures and membership will be available upon request to the general public and will be posted on the SCGH website (See also 18)

6. MEMBERSHIP OF SCGG HREC

6.1. Composition

6.1.1. The composition of the HREC shall be in accordance with the NS, including additional members relevant to SCGG research as prescribed within the NS

6.1.2. 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 institution for which the HREC is reviewing research. The minimum membership shall be:

- a chairperson;
- at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work.
- at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people, for example, a nurse or social worker;
- at least one member who performs a pastoral care role in a community, for example, a minister of religion or an Aboriginal elder;
- at least one member who is a lawyer, but not a lawyer engaged to advise the institution;
- at least two medical qualified members with current research experience relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from a pool of further members. (section 4.1.7 of NS)
- Person with knowledge of medical research ethics
- Member of the SCGG Executive

6.1.3. No member may be appointed in more than one of the foregoing categories, but in each category proxy members may be appointed to ensure all categories required by the NS are present or available to provide comment for all meetings.

6.1.4. The HREC will ensure that the membership includes a member or members with experience in the application of the National Statement.

6.1.5. Where required, the HREC may seek advice and assistance from appropriate experts to assist with the review of a project. However, the HREC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

6.1.6. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted to it for consideration. If

additional members are appointed the composition of the HREC shall continue to reflect the diversity and balance of its members, including gender and the relative proportion of institutional and non-institutional members.

6.2. Appointment Of Members

- 6.2.1. Members are appointed as individuals rather than in a representative capacity.
- 6.2.2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the Sir Charles Gairdner Hospital website.
- 6.2.3. A selection committee, consisting of the Chairperson, Executive Officer and at least one other HREC member shall interview the prospective applicant, consult with the HREC members and make a recommendation to the Deputy Executive Director, SCGG (DED). Prospective members may be invited to attend a meeting of the HREC as an observer.
- 6.2.4. Members are appointed by the Executive Director and will receive a formal notice of appointment.
- 6.2.5. The Chairperson will be appointed by the Executive Director on recommendation of the HREC. In the absence of the Chairperson at a meeting, a proxy Chairperson elected by the HREC members at the meeting will perform the role and duties of the Chairperson.
- 6.2.6. The Executive Director will appoint a Delegate of the Chair who will be responsible for signing correspondence on behalf of the HREC and the review of HREC requested changes to applications, administrative amendments, annual reports and SAE/SUSAR reports.

6.3. Terms Of Appointment

- 6.3.1. The letter of appointment shall 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 HREC member, the circumstances whereby membership may be terminated and the conditions of their appointment.
- 6.3.2. Members will be required to sign a confidentiality undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.
- 6.3.3. Upon appointment, members shall be provided with the following documentation:
 - HREC Terms of Reference;
 - HREC Operating Procedures;
 - up-to-date list of members' names and contact information including that of the Executive Officer;
 - NHMRC National Statement on Ethical Conduct in Human Research;
 - The Australian Code for the Responsible Conduct of Research
 - any previous reports on the HREC's activities; and

- any other relevant information about the HREC's processes, procedures and protocols.

6.3.4. Members are appointed for a period of three years and may serve two consecutive terms only unless otherwise approved by the Executive Director. Members will be advised when his/her term has expired. Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Executive Director.

6.3.5. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

6.3.6. New members are expected to attend WA Health and NHMRC education and training sessions as soon as practicable after their appointment. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met by the SCGG HREC.

6.4. Conditions Of Appointment

6.4.1. 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 travelling and parking expenses by application to the Research Ethics and Governance Office.

6.4.2. Members may seek a leave of absence from the HREC for up to 6 months. Steps shall be taken to fill the vacancy.

6.4.3. Membership will lapse if a member fails to attend three consecutive meetings of the HREC without reasonable excuse/apology, unless exceptional circumstances exist. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy, which may arise.

6.4.4. Membership will lapse if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

6.4.5. Members will be expected to participate in relevant specialised working groups as required. The Chairperson will be expected to be available between meetings to participate in Executive meetings where required.

6.4.6. A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.

6.5. Orientation Of New Members

6.5.1. New HREC members will be provided with adequate orientation.

6.5.2. Orientation will involve all of the following:

- Informal meeting with Chair and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures.
- An opportunity to sit in on HREC meetings before their appointment takes effect.
- 'Partnering' with another HREC member in the same category.

6.6. Subcommittees:

6.6.1. The HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of minimal risk research, submitted to the HREC. The Chair of any such subcommittee will be appointed by the HREC. Members of the subcommittee need not be members of the HREC. Sub-committees report to and are responsible to the HREC.

6.7. Liability Coverage

6.7.1. The SCGG 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 WA Risk Cover.

7. CONDUCT OF BUSINESS

7.1. Procedures

7.1.1. The HREC will perform its functions by adopting Operating Procedures that fulfill the requirements laid out in the AHEC/NHMRC National Statement. These procedures will be made available on the SCGG HREC website or in hard copy on request.

7.2. Submissions, notifications and approvals

7.2.1. All applications for ethical approval must be submitted via the SCGG Research Governance and Ethics Office, by the relevant closing date, in writing in the format approved by the HREC and shall include such documentation as the HREC may specify.

7.2.2. Guidelines will be issued to assist applicants in their preparation of applications.

7.2.3. The HREC may request the applicant to supply any further information in relation to an application and/or request the applicant to attend a meeting of the HREC at which the application will be considered for the purpose of providing information to and answering questions from the HREC members.

7.2.4. The HREC will consider every correctly completed application that it receives at its next available meeting following receipt, provided that the application is received by the relevant closing date. The Research Governance and Ethics Office shall circulate the completed application and associated documents received with a meeting agenda to all members of the HREC at least 7 days prior to the next meeting.

7.2.5. The HREC delegates consideration of scientific/technical matters to its expert sub-committees. The RGU will make arrangements separately to forward papers to these Sub-committees. The HREC may also obtain expert scientific/technical advice, subject to paragraph 6.6.1.

7.2.6. The HREC may take into account the views or opinions of another HREC in relation to a research protocol.

7.2.7. The HREC 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.

7.3. Low risk review

7.3.1. The HREC may establish an Executive, consisting of at least the Chairperson and Executive Officer. Where provided by the Operating Procedures, the Executive may undertake review of low risk research proposals between scheduled meetings at the discretion of the Chairperson. The Executive may seek advice from other HREC members, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the next HREC meeting.

7.3.2. The Executive may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, protocol reports, minor amendments and the like. The minutes of any such meetings will be tabled for ratification at the next HREC meeting.

7.4. Recognised prior review

7.4.1. The SCGG will establish operating procedures to fulfill the directions of the National Statement on reducing duplication of review for multicentre trials. This allows the SCGG HREC Office to recommend approval of a study to the Executive Director based on the approval of another HREC without requiring a review by the SCGG HREC.

7.5. Advocates and interpreters

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

7.5.2. Where research involves the participation of persons unfamiliar with the English language, the HREC will ensure that the participant information sheet is translated into the participant's language and that an interpreter is present during the discussion on the project.

7.6. Meetings

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

Consistent with the NS a quorum will be deemed to have been reached where all of the members described in 11.1 have been provided with meeting papers and given an opportunity to provide comment in time for the meeting .

7.6.2. Meeting dates and agenda closing dates will be published.

7.6.3. Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is the subject of consideration, 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. All declarations of interest and absence of the member concerned will be minuted.

7.6.4. The HREC will endeavor to reach a decision concerning the ethical acceptability of a proposal by unanimous consensus. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, 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.

7.7. Fees

7.7.1. A fee will be charged for applications submitted for assessment by the HREC.

7.8. Records

7.8.1. The SCGG HREC Office will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.

7.8.2. The SCGG HREC Office 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 HREC.

7.8.3. Files shall be kept securely and confidentially in accordance with the requirements of the Health Services (Conciliation and Review) Act 1995 (WA), The State Records Act (2000) and the Privacy Act-Cwth (1988)

7.8.4. Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least 5 years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply.

7.8.5. The SCGG HREC Office will maintain a register of all the applications received and reviewed in accordance with the National Statement.

8. POST APPROVAL RESPONSIBILITIES

8.1. The HREC will, as a condition of approval of each project, 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;
- unforeseen events that might affect continued ethical acceptability of the project; -eg serious or unexpected adverse events that independent review by the investigator, TGA or sponsor, if any has determined materially affect the safety of the study and require a change to the Protocol or the consent documentation ; and
- if the project is abandoned for any reason.

9. COMPLAINTS AND REVIEW

Complaints concerning the conduct of a project

Complaints concerning the HREC's review process

9.1. Any concern or complaint about the HREC's review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing. The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Executive Director, or his/her nominee, or request the Chairperson to do so. The Chairperson will provide to the Executive Director all relevant information about the complaint/concern. The Executive Director will determine whether there is to be a further investigation of the complaint. If it is decided there is to be a further

investigation, then the Executive Director will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.

- 9.2. In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference, the Operating Procedures, or otherwise acted in an unfair or unbiased manner.

10. AMENDMENT TO THE TERMS OF REFERENCE

10.1. These Terms of Reference may be amended by following the procedure below:

10.1.1. For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a 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 Chairperson shall send the amendment to the Area Chief Executive for review and approval if appropriate.

10.1.2. For those proposals made by the Area Chief Executive:

- The Area Chief Executive will send the proposal to the HREC and seek the views of any relevant person.

Chairperson

Date