Standard Operating Procedures

The process of ethical approval for research within the Sir Charles Gairdner and Osborne Park Health Care Group

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## Abbreviations List

<table>
<thead>
<tr>
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<tr>
<td>CTN</td>
<td>clinical trial notification</td>
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<td>CTX</td>
<td>clinical trial exemption</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>SAE</td>
<td>serious adverse event</td>
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<td>SCGOPHCG</td>
<td>Sir Charles Gairdner and Osborne Park Health Care Group</td>
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1. Purpose

The purpose of these Standard Operating Procedures (SOPs) is to serve as a guide to the process of ethical review for research involving human participants within the Sir Charles Gairdner and Osborne Park Health Care Group (SCGOPHC). These SOPs outline the responsibilities and functions of the various stakeholders involved in research.

2. Overview

To be properly governed, research must be conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation, regulations and institutional policy. Research governance also incorporates credentialing and training of researchers and managing institutional risk (Australian Clinical Trials; NHMRC).

The WA Health Research Governance Policy and Procedures 2012 (OD 0411/12) was implemented to ensure that all human research conducted within WA Health meets the highest ethical, scientific, regulatory and professional governance standards. It also aims to ensure that research complies with relevant national and State legislation, guidelines and codes of conduct. The policy articulates the framework through which research is reviewed, approved, conducted and monitored within WA Health. In line with this policy, SCGOPHC has a two tiered system of review which includes:

- scientific and ethical review
- site specific assessment.

Scientific and ethical review

To assess the scientific and ethical integrity of proposed research, and monitor its ongoing conduct, SCGOPHC has an established Human Research Ethics Committee (HREC) which is accredited by the National Health and Medical Research Council (NHMRC). The primary purpose of the HREC is to protect the welfare and rights of participants in research. The operation of the HREC is governed by its Terms of Reference 2016 and the terms set out by the NHMRC in the National Statement on Ethical Conduct in Human Research 2007 (National Statement).

These SOPs should be read in conjunction with the HREC Terms of Reference 2016 which provide detail on the operation, responsibilities and functions of the HREC.

Site specific assessment

The site specific assessment at SCGOPHC is designed to protect the interests of the institution and ensure that it is not exposed to any undue risk. This process is documented in its own standard operating procedures and runs in parallel to the ethical and scientific review process. The site specific review assesses aspects of proposed research which may have legal or financial implications for the institution, including resource utilisation, budgets, contracts, insurance policies and indemnities. Once the site specific assessment has been completed a recommendation is made to the SCGOPHC Executive Director, or delegate, as to whether the research project should be authorised to commence at SCGOPHC. The institution retains the right not to authorise the commencement of a research project, regardless of the outcome of the site specific or HREC review. Applicants have the right to appeal this decision directly with the Executive.
Section One

Submission
3. Application for ethical review

3.1 Obtaining a registration number

3.1.1 The registration number is a unique number allocated to each research application submitted to SCGOPCG for ethical review.

3.1.2 Investigators are responsible for:

- providing the title and contact person when registering an application via email to HREC.SCGH@health.wa.gov.au
- quoting the registration number in all correspondence related to the project.

3.1.3 The HREC Office is responsible for:

- issuing a registration number for each application
- ensuring that each application has been registered in the database with its associated title and contact person
- quoting the registration number in all correspondence related to the project.

3.2 Submission to the SCGOPHCGB HREC

3.2.1 Investigators are responsible for ensuring that applications are:

- submitted in electronic format via email to HREC.SCGH@health.wa.gov.au
- complete and include all required documentation and signatures
- received by the HREC Office prior to the submission deadline
- accompanied by a declaration of conflict of interest (if a conflict of interest exists).

3.2.2 The following documents are required for all studies and should be provided when submitting a research application for ethical review:

- application form – WA Health Ethics Application Form OR the Human Research Ethics Application and WA Specific Module
- protocol/research plan.

3.2.3 In addition to the above, the following documents should be provided as required:

- participant information sheet and consent form/s
- recruitment documents (letters, posters, advertisements)
- questionnaires, surveys, interview outlines
- other participant documents (identification card, diaries)
- investigator brochure (for CTN/CTX studies)
- other relevant HREC approvals
• radiation safety officer/Radiological Council report.

3.2.4 The HREC Office is responsible for:
  • checking applications for completion
  • providing a receipt to confirm that an application has been received
  • logging all complete applications in the database
  • indicating the date on which the application will be reviewed by the HREC.

3.2.5 All required forms necessary for the submission of a research application are available on the WA Health Research Governance website.

3.2.6 Late and/or incomplete applications will not be accepted.

3.2.7 If an investigator has an actual or perceived conflict of interest this must be declared to the HREC at the time of submission.

3.2.8 Investigators’ contact details will be added to the Department of Research distribution list.

3.2.9 Investigators must register studies with a public trials registry which must be:
  • accessible to the public at no charge
  • open to all prospective registrants
  • managed by a not-for-profit organisation
  • electronically searchable

Examples of appropriate trial registries include, but are not limited to:
  • Australian and New Zealand Clinical Trials Registry
  • Clinicaltrials.gov
  • International Standard Randomised Controlled Trial Number [ISRCTN] Register

3.3 Resubmission

3.3.1 The HREC and subcommittees reserve the right to request the resubmission of an application if substantial queries are raised during review.

3.3.2 The HREC Office is responsible for:
  • notifying the investigator within two working days of the decision
  • offering support and advice to the investigator in regards to the HREC queries.

3.3.3 Investigators are responsible for:
  • responding to all queries within two months
  • resubmitting all amended documentation.

3.3.4 Once resubmitted the proposal will be reviewed at the next available meeting.
Section Two

Review and approval
4. Review Process

4.1 Review Stream

4.1.1 The type of review each application undergoes is dependent on the nature of the research.

4.1.2 The review streams include:

- standard ethical review
- low risk review.

4.1.3 A flow chart of the submission and approval process is provided at Appendix A.

4.2 Standard review

4.2.1 Studies undergoing a standard review will be assessed for their scientific and ethical integrity by the full HREC and any associated subcommittee.

4.2.2 All research involving humans which is deemed to pose more than low risk to participants will be reviewed through the standard review stream.

4.2.3 This includes single-site research as well as research for which the SCGOPHCG HREC will act as the lead HREC.

4.2.4 WA Single Ethical Review of multi-centre research allows a study being conducted at multiple sites within WA Health to be reviewed only once. This review must be conducted by an approved lead HREC. Other WA Health sites may then accept the lead HRECs approval.

4.2.5 If ethics approval has been granted by an approved lead HREC, SCGOPHCG will accept this approval. However, the study will still need to undergo site specific assessment.

4.2.6 For SCGOPHCG to be an accepting institution all approved study material, including the letter granting ethics approval, should be forwarded to the Research Governance Office for site authorisation.

4.2.7 This should be read in conjunction with WA Health Research Governance Policy and Procedures 2012 (OD 0411/12).

4.3 Low risk review

4.3.1 In addition to the points included under Section 4.2, the following applies to studies deemed to be low risk.

4.3.2 Research which is deemed to pose low or negligible risk to participants may be reviewed through a low risk review process.

4.3.3 There are no submission deadlines for low risk research and applications may be submitted at any time.

4.3.4 Low risk research will be reviewed by a low risk committee which will contain a minimum of three individuals from the HREC, Department of Research and any associated subcommittees.
4.3.5 Low risk research requesting an opt-out approach or a waiver of consent must address all aspects of Section 2.3.6 or Section 2.6.10 respectively of the National Statement in the application. The request for an opt-out approach or a waiver of consent must be reviewed by the full HREC and will be reviewed at the next available meeting following submission. An opt-out approach is considered as an alternative form of a waiver of consent where participants are formally offered the opportunity to refuse to participate, or withdraw, from being involved in the research project.

5. Committees

5.1 Secretariat

5.1.1 The Department of Research will provide secretariat support to the HREC. The secretariat will:

- maintain responsibility for all communication with investigators, unless otherwise agreed by the Chair
- organise meetings of the HREC
- maintain up-to-date membership details and distribution lists
- attend to all meeting documentation
- arrange training opportunities for HREC members
- record the minutes of HREC meetings
- provide timely updates and communication with committee members
- provide reports in line with governance requirements
- maintain records in line with institutional, state and federal requirements.

5.2 Subcommittees

5.2.1 Subcommittee meetings will be conducted in accordance with their associated terms of reference.

5.2.2 The decisions available to the committee include:

- Approval granted. These proposals may proceed to the HREC for review.
- Approval granted with queries. These proposals may proceed to the HREC for review, however approval will not be granted until the issues are resolved.
- Approval not granted. These applications must be revised and resubmitted to the subcommittee for review.

5.2.3 If the subcommittee has raised any queries regarding the proposal, or if the proposal requires resubmission, the investigator will be notified within two working days of the meeting.

5.3 HREC meetings

5.3.1 HREC meetings will be conducted in accordance with its Terms of Reference 2016.
5.3.2 Following the review of a proposal by a subcommittee, the HREC will consider each proposal for ethical integrity.

5.3.3 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.

5.3.4 The decisions available to the committee include:

- Approval granted.
- Approval granted with queries. These queries may be resolved out of session.
- Approval not granted. These applications must be revised and resubmitted to the HREC for review.

5.3.5 If the HREC has raised any queries regarding the proposal, or if the proposal requires resubmission, the investigator will be notified within two working days of the meeting.

5.4 Minutes

5.4.1 Minutes of each meeting will be recorded by the secretariat and provided to the committee for ratification.

5.4.2 Minutes of the meeting will provide a record of:

- the studies considered
- any queries raised
- committee decisions
- whether the Delegate of the Chair has been given responsibility to approve proposals out-of-session.

5.4.3 Following ratification by the committee, an abridged version of the minutes will be made available online.

5.5 Delegate of the Chair

5.5.1 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.

5.5.2 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
- provide timely communication and advice to investigators
- approve studies, with clearance from the HREC
• monitor approved research through reviewing and acknowledging amendments and reports.

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

6. Approval

6.1 Granting approval

6.1.1 For a project undergoing standard review, the minimum time to approval is one month from the submission deadline. The timeline for approval is dependent on the time taken for investigators to respond to any queries posed by the HREC, or associated subcommittees.

6.1.2 When a study is approved an approval letter will be issued which contains the following information:
  • approval date
  • a list of approved study documents
  • a list of sites for which approval is granted.

6.1.3 The approval letter may be signed by the HREC Chair or an approved delegate.

6.1.4 This letter provides ethical approval only. Site authorisation is required from each site that the study will be conducted prior to the commencement of the study at that site. Site authorisation is provided by the Research Governance Office.

6.2 Approval expiry

6.2.1 HREC approval is valid for five years.

6.2.2 An extension of up to three additional years may be granted out-of-session. Any extension is conditional on the performance and monitoring of the project.

6.2.3 Extensions beyond this must be reviewed by the HREC.

6.3 Approval withdrawal

6.3.1 All approved research must continue to meet the standards outlined in the National Statement as well as the terms of approval stipulated by the HREC.

6.3.2 The HREC and SCGOPHCG retain the power to withdraw or suspend approval for the study in accordance with Section 5.5.7 of the National Statement.

6.3.3 If approval is withdrawn the investigator is responsible for:
  • immediately suspending research
  • informing participants of any impact this will have on their care
  • modifying research to ensure sufficient protection of participants
  • resuming research only after ethical approval of any modifications.
Section Three

Post-approval
7. Amendments

7.1.1 All amendments to research projects must be submitted for review and approval to the lead HREC.

7.1.2 The HREC Office reserves the right to assess whether an amendment needs to be reviewed by the HREC or whether the amendment can be reviewed out-of-session.

7.1.3 Amendments which do not require review by the HREC may be approved by the Delegate of the Chair and can include, but are not limited to:

- typographical and grammatical corrections to project documentation
- minor changes to project documentation which do not impact on the participant experience
- protocol changes which do not have associated changes to the participant information sheet.

7.1.4 Amendments which have an impact on the participant experience or the management of their data must be reviewed by the HREC. This includes:

- significant changes to recruitment strategies
- significant changes to analysis strategies
- project extensions beyond eight years from original approval.

7.1.5 Investigators are responsible for:

- submitting amendments via email to HREC.SCGH@health.wa.gov.au
- utilising the appropriate forms
- responding to HREC Office queries in a timely manner.

7.1.6 The HREC Office is responsible for:

- processing amendments within 10 working days
- issuing approval letters
- recording all amendments in the appropriate database and/or record keeping system.

8. Monitoring

8.1 Safety monitoring and reporting – investigator led research

8.1.1 Investigators are responsible for:

- reporting all serious adverse events (SAE) that are suspected to be related to the study within 5 working days or 24 hours (if the participant has died)
- indicating whether any action will be taken as a result of the event or report.
8.1.2 The HREC Office is responsible for:

- reviewing all submitted SAEs
- liaising with the HREC to determine an appropriate course of action
- acknowledging all SAEs within 10 working days of receipt.

8.1.3 The HREC Office reserves the right to acknowledge multiple SAE reports for the same participant relating to the same event in a single letter.

8.2 Safety monitoring and reporting - sponsored research

8.2.1 Reporting of adverse events should be in line with the *NHMRC Australian Health Ethics Committee Position Statement 2016*.

8.2.2 The sponsor is responsible for:

- proactively monitoring the ongoing-risk-benefit ratio of the study
- providing the HREC with an annual safety report written in lay language which includes a description of new and relevant finding, a discussion of the implications of the safety data, any measures taken to minimise risk and confirmation that the study is being adequately monitored
- reporting to the HREC within seven days of being made aware of the breach, all serious breaches of the Protocol or Good Clinical Practice, that are likely to affect participant safety and/or the reliability of the data
- providing the HREC with an annual update of the investigator brochure
- reporting to the HREC within 72 hours all significant safety issues that adversely affect the safety of the participant.

8.2.3 The HREC Office is responsible for:

- acknowledge all safety reports and investigator brochure updates within 10 working days of receipt
- satisfying itself that the sponsor’s ongoing safety monitoring arrangements are adequate
- assessing whether changes to the risk-benefit ratio that are reported by the sponsor are compatible with continued ethical approval
- assessing any reports of serious breaches, including any corrective and preventative actions taken by the sponsor and take any action deemed necessary.

8.2.4 The HREC Office reserves the right to acknowledge multiple safety reports for the same study in a single letter.
8.3 **Annual reports**

8.3.1 Annual reports should include information pertaining to:

- adverse events and any changes arising from these events
- publications
- staffing changes
- current findings
- issues with recruitment or results
- whether the project is progressing as expected.

8.3.2 Failing to submit an annual report will lead to the suspension of approval for research.

8.3.3 Investigators are responsible for submitting:

- an annual report to the lead HREC covering all approved WA Health sites (multi-centre trials)
- a site specific annual report at each site the study is being conducted
- annual reports on, or prior to, the anniversary of study approval.

8.3.4 The HREC Office is responsible for:

- reviewing all annual reports
- providing acknowledgment of annual reports within 10 working days of receipt.

8.4 **Final reports**

8.4.1 Final reports should include information pertaining to:

- adverse events and any changes arising from these events
- publications
- staffing changes
- current findings
- issues with recruitment or results
- whether the project progressed as expected
- whether the aims of the research have been met.

8.4.2 Investigators are responsible for:

- submitting a final report and project summary for all approved WA Health sites to the lead HREC
• submitting all reports in a timely manner
• circulating the final report to all sites at which the study was conducted
• providing the reasons for a decision to discontinue or suspend a study prior to expected completion
• provide evidence on how the safety of participants will be managed if a study has been discontinued or suspended
• notifying the HREC if a suspended study is to be recommenced.

8.4.3 The HREC Office is responsible for:
• reviewing all final reports
• providing acknowledgment of final reports within 10 working days of receipt
• archiving all documents pertaining to the study held within the HREC Office.
Section Four
Administration
9. Fees

9.1 Studies which are fully sponsored or funded by commercial entities, such as pharmaceutical sponsors, attract a submission fee. Fees are payable on submission.

9.2 Additional fees may be charged for amendments made throughout the life of the study, if they require review by the HREC or associated subcommittee.

9.3 A schedule of fees is outlined in Table 1.

Table 1

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<tr>
<td>New application</td>
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<tr>
<td>Amendment (if reviewed by a committee)</td>
<td>$440</td>
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These fees are inclusive of GST.

10. Complaints

10.1 All complaints regarding the conduct of research or HREC processes should be managed through the Ethics Coordinator within the HREC Office.

10.2 The HREC Office is responsible for:

- recording all complaints in writing
- informing the HREC Chair of any complaints immediately
- sending a letter of acknowledgment to the complainant within five working days
- notifying the investigator within five working days of the complaint
- investigate the complaint and recommend an appropriate course of action within 30 days of receipt of the complaint
- informing the complainant of the outcome of the investigation.

10.3 If the complainant is not satisfied with the outcome of the Chairperson’s investigation, then they can refer the complaint to the Executive Director.

10.4 The Executive Director will determine whether there is to be a further investigation of the complaint. Where no further investigation is to occur, the Executive Director will inform the complainant and the Chairperson of this.

10.5 All complaints will be managed in line with the HREC Office’s complaints policy.
11. Record Keeping

11.1 Research records

11.1.1 All records are maintained electronically and disposed of in accordance with Section 5.2.24 of the National Statement, the State Records Act 2000 and WA Department of Health Retention and Disposal Schedule for Administrative and Functional Records 2007.

11.1.2 Investigators are responsible for maintaining comprehensive records of all study material and procedures in line with the State Records Act 2000 and WA Department of Health Retention and Disposal Schedule for Administrative and Functional Records 2007.

11.1.3 All Freedom of Information requests should be lodged with the Freedom of Information Office.

11.2 Confidentiality

11.2.1 All data provided to the SCGOPHC G HREC and its subcommittees, including details of research and contact information is kept private and confidential.

11.2.2 Only those staff members involved in the study may access the HREC records. Investigators adding additional staff members to the research team are required to submit notification of this to the HREC in a letter.

11.2.3 Any investigators wishing to give individuals who are not involved in their research access to details of their application are required to confirm these intentions in a letter to the HREC.

11.3 Signatures

11.3.1 The HREC Office accepts electronic signatures on all signed documents. While scanned signatures will be accepted, electronic signatures are preferred.

11.3.2 All correspondence originating from the HREC Office will be provided electronically and will make use of electronic signatures which record the date and time of signing.