



Government of **Western Australia**
Department of **Health**
South Metropolitan Health Service

Standard Operating Procedures for the ethical approval of research within SMHS

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Contents

Purpose.....	1
Introduction	2
1. Application for ethical review	3
2. Review Process	5
3. Human Research Ethics Committee	6
4. Approval	8
5. Amendments.....	10
6. Monitoring	10
7. Accountability and Reporting	12
8. Fees.....	12
9. Complaints.....	12
10. Record Keeping	13

Document history

Editor	Date	Version	Amendments
HREC Office	May 2017	4.0	Minor revisions made to update in line with revised processes
HREC Office	May 2018	5.0	SOPs underwent significant revision to reflect new procedures in line with the online Research Governance Service. Duplication with the WA Health Operational Directives relevant to research has been removed.

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 South Metropolitan Health Service (SMHS). These SOPs outline the responsibilities and functions of the various stakeholders involved in research.

Introduction

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

The [WA Health Research Policy Framework](#) aims to ensure that all human research conducted within WA Health meets the highest ethical, scientific, regulatory and professional governance standards; and complies with relevant national and State legislation, guidelines and codes of conduct. The policy outlines how research is reviewed, approved, conducted, and monitored within WA Health. In line with this policy, SMHS has a two tiered system of review which includes:

- ethical and scientific review
- site authorisation

All research conducted within WA Health must be submitted using the online [Research Governance Service](#) (RGS).

Ethical and scientific review

To assess the scientific and ethical integrity of proposed research, and monitor its ongoing conduct, SMHS 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 2018* and the terms set out by the NHMRC in the [National Statement on Ethical Conduct in Human Research 2007](#) (*National Statement*).

This committee is an NHMRC registered HREC (EC00265) and is an NHMRC certified 'Lead HREC' under the National Mutual Acceptance Scheme.

These SOPs should be read in conjunction with the HREC *Terms of Reference 2018* and the [WA Health Research Policy Framework](#).

Site Authorisation

The site specific assessment at SMHS 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 site Executive Director, or delegate, as to whether the research project should be authorised to commence at a specified SMHS site. 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 Director.

Submission

1. Application for ethical review

1.1 Obtaining a project reference number

1.1.1 The registration number is a unique number allocated to each research application.

1.1.2 Investigators are responsible for:

- creating a workspace in RGS which generates a Project Reference Number (PRN)
- quoting the PRN in all correspondence related to the project.

1.1.3 SMHS is responsible for:

- approving the project workspace
- quoting the registration number in all correspondence related to the project.

1.2 Submission to the SMHS HREC

1.2.1 Investigators are responsible for ensuring that applications are:

- submitted electronically via RGS
- complete and include all required documentation and signatures
- correct, with version and date of documents provided
- submitted by the submission deadline

1.2.2 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
- research protocol.

1.2.3 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 Clinical Trial Notification/Clinical Trial Exemption studies)
- other relevant HREC approvals
- radiation safety officer/Radiological Council report.

1.2.4 The HREC Office is responsible for:

- validating the application
- checking applications for completion
- indicating the date on which the application will be reviewed by the HREC.

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

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

1.2.7 Investigators' contact details will be added to the SMHS Research distribution list.

1.2.8 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](#)

1.2.9 In cases where a research project involves the collection, use or disclosure of health information held by a commonwealth agency and/or private organisations, consent should be obtained from those individuals who have provided the data.

In cases where consent is unable to be obtained from these individuals (as when a waiver of consent has also been requested) then the investigator must request a HREC consider this matter.

The [Guidelines Approved Under Section 95 of the Privacy Act \(1988\)](#) and the '[Guidelines Approved Under Section 95A of the Privacy Act \(1988\)](#)' explain what the HREC must consider when investigators wish to utilise such data or samples and what information investigators should provide when requesting the HREC grant permission to use or share this data.

Only a full sitting HREC can consider a request for this data to be collected, used or disclosed. A HREC will consider these matters at its meeting. The legal issues regarding consent and data release will require additional review and approval as part of the site authorisation process. A waiver of consent granted by an HREC does not constitute full site approval.

Review and approval

2. Review Process

2.1 Review Stream

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

2.1.2 The review streams include:

- standard ethical review
- low risk review.

2.2 Standard review

2.2.1 All research involving humans which is deemed to pose more than low risk to participants will be reviewed through the standard review stream. This includes single-site research as well as research for which the SMHS HREC will act as the lead HREC.

2.2.2 All low risk projects seeking approval under the National Mutual Acceptance Scheme will be reviewed through the standard review stream.

2.2.3 The HREC will assess the scientific and ethical integrity of each study submitted for standard review.

2.2.4 The National Mutual Acceptance Scheme allows a study being conducted at multiple sites across Australia to be reviewed only once. This review must be conducted by an approved lead HREC. Other sites may then accept the lead HRECs approval.

2.2.5 If ethics approval has been granted by an approved lead HREC, SMHS will accept this approval. However, the study will still need to undergo site authorisation.

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

2.3 Low risk review

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

2.3.2 The review of low risk projects will be conducted by a minimum of three individuals. These individuals can be members of the HREC or appropriately qualified staff from the Research Support & Development Unit.

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

2.3.4 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. The legal aspects of consent will require additional review and approval as part of the site authorisation process.

3. Human Research Ethics Committee

3.1 Secretariat

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

- maintain responsibility for all communication with investigators, unless otherwise agreed by the Chair. This communication will be face to face, via telephone or written (including email and RGS).
- 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.

3.2 HREC meetings

3.2.1 HREC meetings will be conducted in accordance with its Terms of Reference and will consider each proposal for scientific validity and ethical integrity.

3.2.2 The HREC shall meet on a regular basis, which will normally be at monthly intervals a minimum of 11 times a year. Meeting dates and agenda closing dates will be published online.

3.2.3 Meeting papers will be circulated to members at least seven days prior to the meeting.

3.2.4 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.

3.2.5 The HREC will comply with the membership requirements prescribed in the *National Statement* and the Terms of Reference. 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.

3.2.6 Investigators may be invited to attend the meeting at which their project is being reviewed. They will only be present during the review of their own project.

3.2.7 Observers may request or be invited to attend a HREC meeting at the discretion of the HREC Chairperson. An observer attending a HREC meeting shall be required to maintain the confidentiality of all matters discussed at the meeting, including the committee's deliberations on research applications. The observer is required to sign a Declaration of Confidentiality prior to attendance at the meeting.

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

3.2.9 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 noted in the minutes.

3.2.10 The HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by general agreement. Any significant minority view shall be noted in the minutes.

3.2.11 The decisions available to the committee include:

- Approval granted.
- Additional information required. These queries may be resolved out of session.
- Approval not granted.

3.2.12 Investigators will be notified of the outcome of the HREC meeting within 3 working days.

3.3 Minutes

3.3.1 The minutes of each meeting will be recorded by the secretariat and provided to the HREC members for ratification.

3.3.2 Minutes of the meeting will provide a record of:

- the studies considered and key issues raised
- any queries raised
- committee decisions
- whether a multi-centre review process was involved
- whether the Delegate of the Chair has been given responsibility to approve proposals out-of-session.

3.4 Delegate of the Chair

3.4.1 The Chair may appoint a Delegate of the Chair. The Delegate of the Chair should be a staff member within the Research Support & Development Unit. There may be more than one individual delegated in this role.

3.4.2 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.

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

4. Responding to the HREC

4.1 Additional Information Required

4.2 The HREC Office is responsible for:

- notifying the investigators within three working days of the HREC meeting if additional information is required
- providing the HREC queries to the investigators.

4.3 Investigators are responsible for:

- responding to all queries within a maximum of four months
- resubmitting all amended documents via RGS.

4.4 Resubmission

4.4.1 The HREC and subcommittees reserve the right to request the resubmission of an application if substantial queries arise during review.

4.4.2 The HREC Office is responsible for:

- notifying the investigator within three working days of the decision
- offering support and advice to the investigator in regards to the HREC queries.

4.4.3 Investigators are responsible for:

- responding to all queries within two months
- resubmitting all amended documentation via RGS.

4.4.4 Once resubmitted the proposal will be reviewed at the next available meeting.

5. Approval

5.1 Granting approval

5.1.1 For a project undergoing standard review, the maximum time to approval is 60 days from the application closing date. The timeline for approval is dependent on the time taken for investigators to respond to any queries posed by the HREC, or associated subcommittees.

5.1.2 When a study is approved an approval letter will be issued via RGS.

5.1.3 The approval letter may be from the HREC Chair or an approved delegate. As the approval letter is generated through RGS it may not include a traditional signature.

5.1.4 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.

5.2 Approval expiry

5.2.1 HREC approval is valid for five years.

5.2.2 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.

5.2.3 Extensions beyond this must be reviewed by the HREC.

5.3 Approval withdrawal

- 5.3.1 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.
- 5.3.2 The HREC and SMHS retain the power to withdraw or suspend approval for the study in accordance with Section 5.5.7 of the *National Statement*.
- 5.3.3 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.
- 5.3.4 If approval is withdrawn the HREC is responsible for notifying the relevant approved sites immediately.

Post-approval

6. Amendments

6.1.1 All amendments to must be submitted for review and approval to the lead HREC.

6.1.2 In line with [OD 0446/13 WA Health Research Governance and Single Ethical Review Standard Operating Procedures 2013](#) 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.

6.1.3 Investigators are responsible for:

- submitting amendments
- utilising the appropriate forms
- responding to queries in a timely manner.

6.1.4 The HREC Office is responsible for:

- processing amendments within 10 working days
- issuing approval notifications.

7. Monitoring

7.1 Safety monitoring and reporting – investigator led research

7.1.1 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.

7.1.2 The HREC Office is responsible for:

- reviewing all submitted SAEs
- determining an appropriate course of action
- acknowledging all SAEs within 10 working days of receipt.

7.2 Safety monitoring and reporting - sponsored research

7.2.1 Reporting of adverse events should be in line with the [NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods 2016](#).

7.2.2 The sponsor, through the trial coordinator or local investigator 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 relevant findings, 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.

7.2.3 The HREC Office is responsible for:

- acknowledging 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.

7.3 Annual reports

7.3.1 Annual reports must be provided to lead HREC for all approved research projects.

7.3.2 Failing to submit an annual report will lead to the suspension of approval for research. No amendments will be approved if annual reports are overdue.

7.3.3 Investigators are responsible for submitting:

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

7.3.4 The HREC Office is responsible for:

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

7.4 Final reports

7.4.1 A final report needs to be provided to the lead HREC once a research project is completed.

7.4.2 Investigators are responsible for:

- submitting a final report and project summary for all approved 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 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.

7.4.3 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.

Administration

8. Accountability and Reporting

- 8.1 The HREC is accountable to the SMHS Area Executive Group (AEG) in the conduct of its business.
- 8.2 The HRECs shall provide an annual report to:
- the SMHS AEG, and the SMHS Board (on request)
 - the NHMRC in accordance with certification requirements.
- 8.3 The HREC ToR, Standard Operating Procedures and membership will be available on the SMHS Research Support & Development Unit website.

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 current fees is outlined in Table 1. Please note these fees may change and the table will be updated on the internet and intranet sites as appropriate

Table 1: Schedule of fees

	Scientific & Ethical Review	Research Governance Review
Commercial sponsored new project (single site)	\$3,500	\$3,500
- Per additional Site-specific assessment form (SSA)	No additional charge	\$1000
Addition of sub-studies or extensions to approved projects	\$1,750	\$1,750
Amendments to approved projects (commercially sponsored)*	\$600	\$600

10. Complaints

- 10.1 Complaints regarding research misconduct will be managed in accordance with the [Australia code for responsible conduct in research](#). The Chief Executive has overall responsibility for the complaints handling process.
- 10.1.1 Complaints concerning the HREC review process should be forwarded to the Manager of the Research Support & Development Unit.
- 10.1.2 Complaints related to the conduct of research, including research misconduct, will be managed in line with SMHS policies.

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 SMHS HREC, including details of research and contact information is maintained 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 the form of an amendment.
- 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 All correspondence originating from the HREC will be provided electronically and will make use of electronic signatures.