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

Submission guidelines for SMHS Human Research Ethics Committees

Southern Integrated Research Organisation (SIRO)
Telephone: (08) 6151 1180
Email: SMHS.REG@health.wa.gov.au
www.southmetropolitan.health.wa.gov.au

Contents

Introduction

The WA Health Research Governance Framework (policy and standard operating procedures) outlines how single and multi-centre research at WA Health sites is to be conducted. All human research conducted in WA Health must undergo ethical and scientific review, approval and monitoring by a human research ethics committee (HREC) registered with the National Health and Medical Research Council (NHMRC) and operating in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007 (National Statement).

HRECs are established to assist institutions in meeting their obligation for the effective governance of research involving humans by ensuring the quality, safety and ethical acceptability of research that they sponsor or permit to be carried out under their auspices. The role of an HREC is to provide an ethical review of the proposed research including consideration of:

- the scientific design and proposed conduct of the study
- how participants will be recruited, including the means of obtaining consent
- care and protection from harm of research participants
- protection of research participants' confidentiality

These guidelines have been prepared to assist individuals through the process of submitting a research project to a SMHS HREC for scientific and ethical review and should be read in conjunction with the WA Health Research Governance Framework documents.

1. Which HREC should I apply to?

SMHS has implemented an area wide approach to research ethics and governance and has established a centralised research ethics and governance unit (REGU) through the Southern Integrated Research Organisation (SIRO). The SIRO REGU provides support for the ethical review of research, conducts research governance reviews of proposed research and monitors approved research for all SMHS hospitals / Health Services.

WA Health has implemented a process, whereby, all research projects being conducted at sites under the control of WA Health or involving participants, their tissue or data accessed through WA Health must be ethically and scientifically reviewed only once, by a Lead WA Health HREC, unless approval is required from a specialised HREC (see section 3.4 below).

WA Health is not currently participating in the National Approach to Single Ethical Review of Multi-centre Research (National Approach). It is expected WA Health will join the National Approach in late 2016 at which time review by a NHMRC certified Lead HREC will be able to be used.

1.1. HRECs within SMHS

In SMHS there are two HRECs:

- SMHS HREC. This committee is a NHMRC certified Lead HREC under the National Approach to Single Ethical Review and meets at in the Perkins (South) building on the Fiona Stanley Hospital campus.
- Royal Perth Hospital HREC. This committee is registered with the NHMRC and meets at Royal Perth Hospital.

Investigators should submit an application for ethical review via the SIRO REGU email SMHS.REG@health.wa.gov.au. The application will be allocated for review at the next available and appropriate HREC meeting (either SMHS HREC or Royal Perth Hospital HREC) or to a non-HREC Low Risk Review Panel (LRP).

In addition to receiving ethical approval from a Lead WA Health HREC, all research in SMHS is also required to undergo a site governance review regardless of the risk. In order for a project to proceed at a SMHS site, site authorisation is required from the Chief Executive (or delegate). Site authorisation will not be granted until a project has received ethics approval and a site governance review completed (through the WA Health Site Specific Assessment form) by a SMHS Research Governance Officer (RGO). All SMHS RGOs are co-located in the SIRO REGU. Further information on site authorisation is provided on the SIRO REGU website.

2. Quality assurance activities versus Research

Prior to making a submission to the SIRO REGU, it is important to distinguish quality assurance (QA) activities from research as this will determine the avenue of review and approval required. If a project is classified as research it must be reviewed by a HREC, or alternative low-risk review process. If a project is QA it is reviewed by the hospital's Safety and Quality Office (or equivalent) where the project is undertaken.

To assistance in determining whether a project is research or QA the following documents may be of use:

- Quality Assurance Activities SMHS guidelines
- NHMRC's Ethical Considerations in Quality Assurance and Evaluation Activities

3. Review by a SMHS HREC

3.1. Ethics application forms

All ethics applications must be made to the SIRO REGU by the Coordinating Principle Investigator (CPI) using either the:

1. **National Ethics Application Form (NEAF)**
   Although WA Health is not currently participating in the National Approach, SMHS HRECs will accept the NEAF when used in conjunction with the WA-Specific Module. The NEAF (plus WA-Specific Module) can be used for ethical and scientific review irrespective of risk for both single-centre and multi-centre research projects involving humans. The NEAF is *mandatory for ethics applications utilising the National Approach and National Mutual Acceptance initiatives*.

   PLUS

   The WA-Specific Module
   This form must accompany ethics applications using the NEAF. This module addresses legal issues, relevant to ethical review that are specific to WA, that are not addressed in the NEAF and must be considered when conducting both single-centre and multi-centre research in WA.

   OR

2. **WA Health Ethics Application Form**
   This form is available for use by investigators who are conducting human research projects within WA Health or accessing WA Health participants, their tissue or data. This is an alternative to completing the NEAF plus WA-Specific Module.

The WA Health Research Governance Policy and Procedures provides further information about the forms. The forms are available to download from the WA Health Research Governance website.

3.1.1. Qualifying or waiver conditions for consent

There may be instances in research where the requirement for consent maybe qualified or justifiably waived as outlined in Chapter 2.3 of the National Statement. Examples include:

- Limited disclosure
- Opt-out approach
- Waiver of consent (includes research projects where the investigator wishes to access medical records without obtaining consent)

Research projects using qualifying or waiver conditions for consent must be reviewed by a HREC.

Investigators submitting applications with these conditions are advised to contact the SIRO REGU for assistance.

3.2. Protocols

It is a requirement of WA Health that a protocol is submitted with the ethics application.

WA Health has developed the WA Health Research Protocol Template for Clinical Trials and the WA Health Research Protocol Template for Non-Clinical Trials as a **guide** for investigators who do not already have a protocol for their research. These templates are based on the Therapeutic Goods Authority (TGA) Note for Guidance on Good Clinical Practice and the World Health Organization Recommended Format For a Research Protocol. Please refer to the WA Health Research Governance website for further details.

The templates are to be used as a guide to meet Good Clinical Practice and should as far as possible, contain, but not be restricted to, the information within these templates (as applicable to specific projects). Sections that are not relevant to the research should be deleted.

It is important that the protocol is given a version number/date and the pages numbered. This information should be included in the footer section of the document.

3.3. Participant Information Sheet and Consent Form (PICF)

Informed consent is required for all research unless qualifying or waiver conditions for consent have been approved by a HREC. Informed consent is an important part of the research process and the HREC review must scrutinise all PICF documents to ensure that they are in accordance with national and state requirements (e.g. National Statement, the TGA Note for Guidance on Good Clinical Practice and the Consent to Treatment Policy for the Western Australian Health System 2011).

The NHMRC has developed a suite of standardised PICFs which are available for downloading at: http://hrep.nhmrc.gov.au/toolbox/standardised-forms. These forms are provided as a guide and should be viewed as a **minimum starting point** for informed consent forms. As always, jurisdiction-specific and study-specific information should be added as necessary. Likewise, portions that are not applicable to the research project being proposed may be removed as required.

SIRO REGU has developed PICF templates that may also be of assistance to investigators. Templates are available for download from the SIRO REGU website.

SMHS HRECs place specific emphasis on the following issues:

- The language used in PICFs should be simple enough that it can be easily understood by the average lay person (Grade 8 reading level or below).
- It is important to check for spelling and typographical errors as well as ensuring that the grammar/punctuation is correct.
- The overall presentation of the PICF should be neat and easy to read. Fonts and headings should be consistent throughout the document.
- The opening paragraph should be written such that it:
    - invites the individual to participate in the research
    - makes clear the funding arrangements for the research (who is sponsoring the study or providing funding) if relevant
    - mention which HREC has approved the research

  For example: "*We invite you to participate in a multicentre clinical research study sponsored by (insert name of sponsoring company if relevant) comparing different ways of controlling diabetes in the setting of a suspected heart attack or unstable angina. The local sponsor at this site is ……... This study has been approved by the (insert name of HREC) Human Research Ethics Committee*."
- Inclusion of the contact details for the SIRO REGU, should the participant have any complaints or questions about their rights as a research subject. The contact details for the SIRO REGU are:
    - Phone – 6151 1180
    - Email – SMHS.REG@health.wa.gov.au
- Where appropriate PICFs should be on site-specific letterheads and include page numbering (e.g. page 1 of 4) and a version number/date in the footer.
    - For multi-centre research it is suggested that a Master PICF be submitted to the HREC. The text from the Master PICF can then be transferred (copy-paste) into templates with site specific letterheads and the version updated to, for example, "[site] PICF version 1.0, dated 1 January 2016 based on Master PICF version 1.0, dated 1 December 2015" when submitting for site approval/research governance.
    - SIRO has developed site specific PICF letterhead templates for Fremantle Hospital and Health Service, Fiona Stanley Hospital and Royal Perth Hospital that comply with WA Health guidelines. These templates are available on the SIRO REGU website as "PICF template for FHHS/FSH/RPH" under the heading "Documents".
- If the research involves collection of biological samples (e.g. blood, tissue) for other research purposes (e.g. a pharmacokinetic or genetic sub-study (or other similar purpose), information on this should be provided in the main study PICF, clearly stating the purpose of the investigations and whether it is an optional component. If the additional investigations are optional, participants should be informed that they do not need to agree to take part in the optional components to be part of the main study and the consent form should provide clear options for the participant to consent only to the main study or to the main study and the optional components.

3.4. Other specialist HREC approvals

As per the WA Health Research Governance Framework, certain research projects will require additional review by specialist HRECs regardless of whether or not they have been, or are to be, reviewed by a Lead WA Health HREC. These include:

- the Western Australian Aboriginal Health Ethics Committee (WAAHEC) for health and medical research projects where Aboriginality is a key determinant or explicitly directed at Aboriginal people
- the Coronial Ethics Committee WA for research projects that require access to coronial samples, data or information
- the Department of Health WA HREC for all research projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage

Contact details for these committees are available on the WA Health Research Governance website.

3.5. Ionising radiation

Research that involves exposing participants to radiation even if it is considered standard of care, should provide a report from the Radiation Safety Officer. For research that involves participant radiation exposure greater than 5mSv the Radiation Safety Officer will be required to submit an application to the Radiological Council for approval. The Radiation Safety Officer report and/or the Radiological Council report should be submitted as part of the submission to the HREC.

3.6. Submission of research for ethical review

3.6.1. Documents required for ethical review by a HREC

To submit an application for ethical review, the following documents are required:

1. Application form – either the NEAF with WA-Specific Module, or the WA Health Ethics Application Form (with all required signatures) (**mandatory**)
2. Protocol (**mandatory**)
3. Participant Information and Consent Form (PICF)
4. Other Information and Consent forms (e.g. Person Responsible, Parent etc) as required
5. Recruitment documents (e.g. letters, posters, advertisements)
6. Questionnaires, surveys, interview outlines etc
7. Other participant documents (e.g. identification card, diaries)
8. Investigator's Brochure (for CTN/CTX studies)
9. Other HREC approvals (refer section 3.4)
10. Radiation Safety Officer/Radiological Council report

In addition, the SIRO REGU asks investigators to provide a list of submitted documents (including version number and creation date) in the body of the submission email. For example:

- ABC Protocol version 1.0 dated 1 January 2016
- ABC Master PICF version 1.0 dated 1 January 2016
- Patient food diary version 1.0 dated 1 January 2016
- ABC Investigator Brochure version/addition 1.0 dated 1 January 2016

For commercially sponsored research it is recommended that investigators complete and submit the Sponsor Details form (see section 3.6.3 below).

Submission documents should be emailed to the SIRO REGU at SMHS.REG@health.wa.gov.au

3.6.2. SMHS HREC meeting dates and deadlines

Each HREC is each able to review 10 new applications per meeting. Applications are accepted on a first come basis, on receipt of a full submission to the SIRO REGU (including any questionnaires/assessment tools, etc). Researchers are not able to "reserve" a place on the agenda prior to submitting an application to the SIRO REGU.

The SMHS HREC meets on the second Tuesday of each month, except for January when there is no meeting.

The Royal Perth Hospital HREC meets on the fourth Wednesday of each month, except for January when there is no meeting.

Please check the list of meeting dates and submission deadlines (HREC 2016 Meeting Dates / Deadlines).

3.6.3. Schedule of administrative charges

As of 1 July 2015, SMHS levies a fee for the review of commercially sponsored research. Fees do not influence the decision of the HRECs and the same fee is charged regardless of the outcome of the submission. The fees cover the cost of reviewing the documents and the associated administrative responsibilities and are used to support the functions of the SIRO REGU.

Payment is invoiced directly to the external sponsor by the SIRO REGU, irrespective of whether the research project commences. It is recommended that investigators complete the Sponsor Details form.

The SMHS research ethics and governance schedule of administrative charges is available on SIRO REGU website.

Applications by individual SMHS investigators for non-commercially sponsored research or grant funded applications do not attract an application fee.

3.7. Pre-review of submitted applications

SMHS is committed to ensuring that high quality, ethical research is undertaken with fully informed participants and that the HREC provides quality oversight. To this end, our Ethics Coordinators undertake a thorough review of the research submission and provide feedback to the investigator before the submission goes to the HREC meeting.

The Ethics Coordinators have many years of experience and knowledge of the National Statement, State and WA Health requirements. They are well versed in assisting investigators to ensure their research is presented/described in a manner that enables HREC members to focus on the scientific merit and ethical considerations of the research.

Any issues identified by the Ethic Coordinators in their feedback should be addressed by the investigator and any modifications to the submission, or missing documentation provided, by the deadline specified by the Ethics Coordinator. Researchers are able to discuss any issues raised in the pre-review with the Ethics Coordinator prior to the ethics review.

Investigators are encouraged to contact an Ethics Coordinator for advice in developing their applications early on in the process rather than waiting until after the meeting submission deadline.

If the Ethics Coordinator determines that the research submission does not meet the national, State and WA Health requirements and that it is therefore highly likely that the HREC will reject the

application at the meeting, the Ethics Coordinator will inform the investigator and advise that the submission be held over to the next meeting.

4. The HREC meeting

The HREC's primary role is to protect the welfare and rights of individual participants in research and the primary responsibility of each committee member is to decide independently whether, in his/her opinion, the conduct of each research project submitted to the HREC will protect participants.

In doing so the HREC shall satisfy itself that:

- the project conforms to the National Statement
- the project complies with the WA Health Research Governance Policy and Procedures
- persons invited to participate will be provided with enough information, at their level of comprehension, to enable them to make an informed decision as to whether to participate in a study
- appropriate procedures relating to the obtaining of informed consent are observed
- the privacy of persons participating in research projects involving the collection, storage, disclosure or other use of personal information is protected
- the funding arrangements are sufficient to conduct and complete the project
- arrangements exist to ensure adequate compensation to participants for any injury suffered as a result of participation in a clinical research trial sponsored by a commercial organisation
- research projects involving the use/storage of human genetic material, or the use of Genetic Registers, conform to the guidelines set out in the National Statement and NHMRC Guidelines for Genetic Registers and Associated Genetic Material (2000)
- procedures are in place for the handling of complaints from research participants
- no member of the HREC adjudicates on research in which that member has any conflict of interest, including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research

At the HREC meeting members discuss the scientific and ethical merits of the research with reference to the National Statement.

4.1. Investigator attendance at the HREC meeting

The SMHS HREC has a long history of inviting investigators to attend the meeting to present new applications and to answer questions raised by the HREC members. Members of the SMHS HREC believe this assists in clarifying any concerns or issues that were unclear in the submission documents. It is not compulsory for investigators to attend the HREC meeting, however they are encouraged to attend if possible. Should the investigators decide to attend they will be allocated a time by the SIRO REGU.

In general, investigators will give a brief description of their proposed research at the meeting. The HREC members will then ask the investigator for clarification around the issues they found unclear. Areas that frequently require further clarification can include explanations of what is considered standard of care, justification of statistical calculations or approaches, appropriateness of control groups etc.

The Royal Perth Hospital HREC does not routinely invite investigators to its meeting, but investigators can be asked to attend.

4.2. HREC meeting outcomes

Decisions made by the HREC about whether a research project meets the requirements of the National Statement is informed by an exchange of opinions from the HREC membership, taking into consideration the requirements of the National Statement, as well as other state and national regulations/policies/procedures. The minutes of the meetings reflect decisions made and, where possible, include a link to the relevant section/chapter/paragraph of the National Statement.

Following the review process, the HREC will make one of the following recommendations:

- that the research be approved outright with no further amendments/clarification
- that further information being provided to the SIRO REGU for sign off by the HREC Chairperson out-of-session
- that further information be provided to a subsequent HREC meeting for further discussion
- that the research be rejected.

Investigators will be advised in writing of the outcome of the meeting within 7 working days of the meeting date. Correspondence to investigators will reflect the decisions made by the HREC and will where possible, provide a link to the relevant section/chapter/paragraph of the National Statement.

If further information is requested, the investigator will receive a letter outlining any amendments that are required to the study protocol and/or PICF document/s.

Depending on the scale of modifications required, investigator responses are considered by the HREC Chairperson out-of-session or are submitted to the HREC at the next HREC meeting. If the investigators have adequately addressed the issues raised by the HREC, they will receive an ethics approval letter from the HREC Chairperson.

If a research project is rejected by the HREC, it must be re-submitted as a new application.

5. Ethical review for low or negligible risk research

For low or negligible risk research, institutions may establish an alternative non-HREC level (e.g. sub-committee, delegate) ethical review process or exempt research from ethical review (National Statement Chapter 2.1).

SMHS HRECs have a pathway for the review of low or negligible risk research between scheduled HREC meetings. The HREC Chairperson may delegate the power of approval to the Delegate of the Chair (DoC). The DoC may undertake review of low risk research proposals with a scientific review provided by a panel of low risk review (LRP) members. Members of the LRP need not be members of the HREC. The DoC may also seek advice from other HREC members, as appropriate, before reaching a decision. If approval is granted, such approval shall be tabled at the next HREC meeting for noting.

The requirements for submission for LRP review are identical to those for submissions to a HREC. Research approved by the LRP is subject to the same general conditions of approval and monitoring processes as a HREC reviewed research, including the submission of annual reports on the anniversary of ethical approval.

As with HREC submissions, the Ethics Coordinator will complete a standard administrative pre-review of the research and contact the investigator if further information or clarifications are required.

6. Site authorisation

Before research commences at a SMHS hospital / Health Service, projects must undergo:

1. ethical and scientific review **AND**
2. research governance review

The two arms of the review process occur independently, but usually in parallel. Scientific and ethical approval must be obtained and **forms part** of the governance approval. However the SMHS hospital / Health Service retains the right not to authorise commencement of a research project, even if a HREC has recommended ethical approval. For information on achieving site authorisation within SMHS please refer to the WA Health Research Governance Framework.

7. Reporting requirements

The HRECs and Health Service are bound by NHMRC Guidelines to monitor the progress of all approved projects until completion, in accordance with Chapters 3.3 and 5.5 of the National Statement, to ensure that they continue to conform to approved ethical standards.

In addition, HRECs and Health Service are required to monitor all approved research in accordance with Sections 2.19 and 3.4 of the WA Health Research Governance Policy and Procedures and for multi-centre research projects approved in SMHS under one of the single ethical review processes, the WA Health Research Governance and Single Ethical Review Standard Operating Procedures.

Investigators are required to submit the following to the SIRO REGU:

- ***Progress Report*** - A progress report annually at the anniversary of approval, or more frequently if requested by the HREC. Investigators will receive a reminder that a report is due around the anniversary date of the ethics approval.
- ***Final Report -*** A final report on completion of the project, including the results, and submit a copy of any publications eventuating as a result of the research.
- ***Protocol Amendment*** – Any changes to the study documentation, including the Study Protocol and/or participant informed consent documents, if required.
- ***Protocol Deviation / Violation*** - Any deviation from, or violation of, the study protocol.
- ***Protocol Withdrawal / Termination / Suspension*** - If the research project is withdrawn, terminated or suspended before the expected date of completion, providing reasons for this.
- ***Reporting of Adverse / Serious Adverse Events*** - any reports of adverse / serious adverse events in accordance with the SMHS Reporting Guidelines.

Forms and further information is available on the WA Health Research Governance Framework.