Government of **Western Australia**
East Metropolitan Health Service

Standard Operating Procedures for the approval of research within EMHS

EMHS Research Ethics and Governance

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1. Table of Contents

2. Introduction

Research governance refers to the processes used by institutions to ensure that they are accountable for the research conducted under their auspices. To be properly governed, research must be conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy. Research governance is also about credentialing and training of researchers and managing institutional risk (National Health and Medical Research Council; 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; and complies with relevant national and State legislation, guidelines and codes of conduct. The policy establishes the framework through which research is reviewed, approved, conducted and monitored in an effective and efficient manner. As such, the East Metropolitan Health Service (EMHS) has a two-tiered system of approval for research made up of:

- Ethical and scientific review and
- Research governance review.

EMHS has a centralised research ethics and governance unit (REGU) which provides support for the ethical review of research, conducts research governance reviews of proposed research and monitors approved research for each of the EMHS hospitals and health services.

Ethical and scientific review

The primary role of Human Research Ethics Committees (HRECs) is to protect the welfare and the rights of participants in research. HRECs assess submissions against the NHMRC "National Statement on Ethical Conduct in Human Research" (National Statement).

In EMHS there is the Royal Perth Hospital (RPH) HREC. This committee is registered with the NHMRC and meets at Royal Perth Hospital.

The RPH HREC operate under terms of reference based on the National Statement. The HREC Chairperson and members of the HREC are appointed by the Director of Research Development for a three year term.

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 website

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Research governance review

The research governance review at health services involves a Site Specific Assessment (SSA) by a Research Governance Officer (RGO). The RGO makes a recommendation to the Executive Director or Delegate of the health service as to whether the research project should be authorised to commence at that specific health service. The health service retains the right not to authorise commencement of a research project, even if a HREC has recommended ethics approval.

3. Registration of clinical trials

The International Committee of Medical Journal Editors (ICMJE) member journals require registration in a public trials registry as a condition of consideration for publication. The ICMJE does not advocate one particular registry but its member journals will require authors to register their trial in a registry that meets several criteria:

- must be accessible to the public at no charge
- must be open to all prospective registrants
- must be managed by a not-for-profit organisation
- must be a mechanism to ensure the validity of the registration data
- should be electronically searchable.

An acceptable registry must include the following information as a minimum:

- a unique identifying number
- a statement of the intervention and comparison studied
- a statement of the study hypothesis
- definitions of the primary and secondary outcome measures
- eligibility criteria
- key trial dates(registration date, anticipated or actual start date, anticipated or actual date of last follow-up, planned or actual date of closure to data entry, and date trial data considered complete)
- target number of subjects
- funding source
- contact information for the principal investigator.

Clinical trials must be registered at or before the onset of participant enrolment to be eligible for publication. This applies to any clinical trial commencing enrolment after 1 July 2005. For trials that began enrolment before this date, the ICMJE member journals require registration to have occurred by 13 September 2005, before considering the trial for publication.

Registries recognised by ICMJE include:

- Australian New Zealand Clinical Trials Registry
- Clinicaltrials.gov
- International Standard Randomised Controlled Trial Number [ISRCTN] Register
- Netherlands Trial Register
- UMIN [Japanese] Clinical Trials Registry

4. Contacts

The EMHS HREC Chair, Ethics Coordinator and RGOs are contactable through the EMHS Research Ethics and Governance website.

Location: Perkins (South) building, Fiona Stanley Hospital Campus, 11 Robin Warren Drive, MURDOCH WA 6150

Postal address: Locked Bag 100, PALMYRA DC WA 6961, Australia

Tel: +61 (08) 6151 1180

Email: EMHS.REG@health.wa.gov.au

Web (internet):
http://southmetropolitan.health.wa.gov.au/services/about.aspx?SiteID=13&ServiceID=529

Web (intranet):
http://EMHS.hdwa.health.wa.gov.au/ServicesFacilitiesLocator/sa/ethics/aboutus.asp?v=0

5. Reference documents

Investigators should be familiar with the following key documents before preparing a submission:

- WA Health Research Governance Policy and Procedures
- WA Health Research Governance and Single Ethical Review Standard Operating Procedures
- National Statement on Ethical Conduct in Human Research
- Australian Code for the Responsible Conduct of Research
- Australian Clinical Trial Handbook
- Note for guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments

For further information related to specific issues within WA Health some recommended reading includes the following Operational Directives/Information Circulars:

- Guidelines for human biobanks, genetic research databases and associated data
- Information Access and Disclosure Policy
- Information Use Policy
- Data Stewardship and Custodianship Policy
- Practice Code for the Use of Personal Health Information Provided by the Department of Health
- Patient Information Retention and Disposal Schedule Version 4, 2014

6. Standard Operating Procedures

SOP001: Overview of research approval at EMHS sites

Function: To provide an outline of the process of research approval

Applicable to: All investigators wishing to undertake research

Version: 2.0 dated July 2016

Due for Review: July 2019

001.1 The Standard Operating Procedures (SOPs) outline the process and procedures involved in the review and approval of research within EMHS hospitals and health services.

001.2 All research involving humans to be carried out within EMHS requires institutional approval and must undergo ethical (including scientific) and governance review. Such research may involve patients, staff, data, samples or information. See Diagram 001.1 for schematic representation of approval process.

001.3 Institutional approval for research will be granted only after the outcome of the ethical and governance reviews are received by the authorised member(s) of the EMHS Executive.

001.4 Research that involves no more than negligible risk does not require ethical or governance review (refer to Section 2 of the National Statement for definition of negligible risk).

001.5 Quality Assurance (QA) or Audit projects do not require ethical or governance review. Such projects should be registered with the institution's Safety and Quality Office (or equivalent). For assistance in determining whether a project fits the criteria for QA please refer to the EMHS QA versus Research document available on the EMHS Research Ethics and Governance website.

001.6 Research that requires ethical approval can be submitted under one of the following submission streams:

- Standard ethical review
- Low risk review
- Single site review of multicentre research within WA Health

Please refer to SOP101 for further information regarding submission streams. All applications must obtain a Registration Number (see SOP102) at the time that the application is submitted.

001.7 The review pathway for multicentre research applications is determined by whether or not the application has been approved by another WA Health HREC.

Where the application has not been reviewed by another WA Health HREC and review by a EMHS HREC is required, the process outlined for standard applications will be followed. Please also refer to SOP103.

Where the application has been reviewed by another WA Health HREC, no further ethical review is required. Please refer to SOP105.

001.8 Research submitted as Low Risk must meet the criteria set out in National Statement. The review process for Low Risk applications is included in SOP104. It should be noted that where a waiver of consent is sought for low risk research, such a request is reviewed by the HREC (SOP103).

001.9 Research undertaken at EMHS sites will also undergo governance review prior to institutional approval being granted. This review can occur concurrently with the ethical and scientific review, provided all documentation has been submitted. Please refer to SOP201-208 for information regarding the governance review process and the documentation requirements for submissions.

001.10 EMHS will grant institutional approval to research that has received ethical (including scientific) approval from a WA Health HREC and undergone a satisfactory governance review at site. Please refer to SOP401-402 for further information.

001.11 HREC approval is valid for a period of three years (SOP401) - this can be extended to a maximum of five years if justified. Continued HREC endorsement is conditional on adherence to the terms of approval. The HREC can suspend HREC approval or recommend termination of the project to the Institution where necessary.

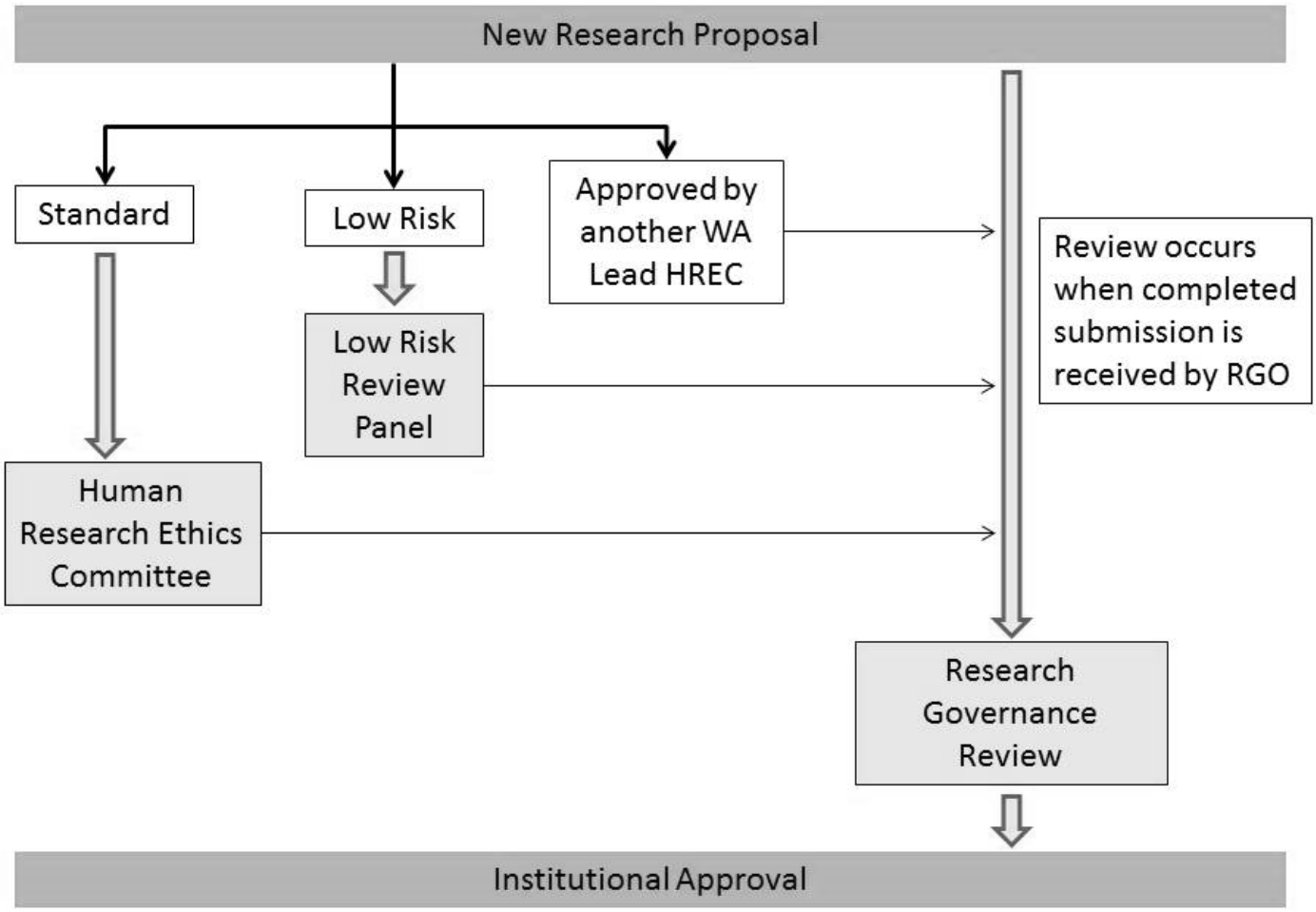
An extension to the approval period can be given once, for a period of three years. Any further extension requests will require a resubmission and be considered at the discretion of the HREC.

The HREC has the capacity to set a specific approval period depending on the level of risk and complexity of the project.

Related Websites

WA Health Research Governance Framework
EMHS Research Ethics and Governance website
Quality Assurance or Research

Diagram 001.1: Schematic representation of approval process



SECTION 1: APPLICATIONS FOR ETHICAL REVIEW

SOP101: Types of ethical review of submitted applications

Function: To describe the different ways research maybe submitted to a EMHS HREC and the criteria for each review stream

Applicable to: All investigators submitting research applications to a EMHS HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

101.1 The type of ethical review each application undergoes is dependent on the nature of the research and what review, if any, it has previously undergone.

101.2 The types of review are as follows:

- Standard ethical review
- Low Risk review
- Single site review of multicentre research within WA Health

Quality Assurance (QA) or Audit projects should be registered with the institution's Safety and Quality Office (or equivalent) (see SOP001)

101.3 **Standard ethical review**

An application for standard ethical review includes research that:

- has not been previously approved, and is not going to be conducted outside EMHS
- has not been previously approved, and is going to be conducted across multiple sites within WA Health
- has been previously approved by a non-WA Health HREC (until such time as WA Health participates in the National Approach)

Applications submitted under this stream are reviewed by a EMHS HREC. Further information regarding submission requirements for standard applications can be found in SOP102-105.

101.4 **Low Risk review**

Low risk research is a review stream in which applications may be submitted at any time and the application documentation is reviewed by the Low Risk Review Panel (LRP). To qualify for submission as low risk research an application must meet the criteria described in the National Statement sections 5.1.18 to 5.1.23. This can be summarised as "research in which the only foreseeable risk is one of discomfort". Detailed criteria and information for low risk research review can be found in SOP104.

101.5 **Single site review of multicentre research within WA Health**

Research which has been granted ethical approval by one WA Health HREC, may be conducted at any other WA Health institution based on this ethical review and approval. The HREC providing the approval will be designated the WA 'lead' HREC and all amendments, additional documentation and reports generated by the ongoing research must be submitted to this WA lead HREC for approval.

A research governance review (SOP201-208), which is site specific, must still be conducted and approval granted by each individual institution before the research can be

undertaken at that site. In order for the governance review to be completed proof of ethical approval and original submission documents are still required.

Further information on multicentre research within WA Health can be found on the Department of Health Research Governance website.

Related Standard Operating Procedures

SOP102: Obtaining a Registration Number (RN)
SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP104: Submission of research deemed to be Low Risk for ethical review
SOP105: Single site review of multicentre research within WA Health

Related Websites

Department of Health Research Governance website
EMHS Research Ethics and Governance website

SOP102: Obtaining a Registration Number (RN)

Function: To describe the process for the application and receipt of a research application registration number from the REGU

Applicable to: All investigators wishing to conduct research within EMHS or have a research application reviewed by a EMHS HREC

Version: 2.0 dated JJuly 2016

Due for Review: July 2019

102.1 The Registration Number (RN) is a unique number allocated to all research applications submitted to the REGU for either ethical and/or governance review. The number is used as a reference for the project and is included in all correspondence and information related to the project.

102.2 Every research application associated with EMHS is required to apply for a RN, regardless of the type of research or whether approval has been granted by another WA Health HREC/site.

102.3 The RN is assigned to an application upon receipt of either a submission for ethical review or research governance review. Only one RN is assigned to an application.

If prior approval has been granted, the ethics reference number from the lead HREC must also be included.

102.4 Submissions must be sent as an email to EMHS.REG@health.wa.gov.au

102.5 Upon receipt of a submission (either ethics or governance) a RN will be allocated to the application and a response sent to the investigator.

102.6 This number must be included in all correspondence to the REGU and EMHS sites regarding this research and will be quoted on all correspondence from the REGU.

Related Standard Operating Procedures

SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP104: Submission of research deemed to be Low Risk for ethical review
SOP105: Single site review of multicentre research within WA Health
SOP201: Research governance review process

SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review

Function: To describe the requirements when submitting a research application to a EMHS HREC

Applicable to: All investigators submitting research applications to a EMHS HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

103.1 Applications submitted for ethical review are required in electronic format and should be emailed to EMHS.REG@health.wa.gov.au by 4:30pm on the submission date of the appropriate month.

A calendar containing all the relevant dates for submissions is available on the EMHS Research Ethics and Governance website.

103.2 The following documents (where applicable) are to be submitted as an application for ethical review:

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

103.3 All of the required forms necessary for the complete submission of a research application are available on the Department of Health Research Governance website.

The EMHS Research Ethics and Governance website provides additional resources/guidelines to assist with the process.

103.4 Late and/or incomplete applications will not be accepted under any circumstances.

103.5 Projects that can be submitted to a EMHS HREC for standard ethical review (see SOP103.1) include research that:

- has not been previously approved, and is not going to be conducted outside the EMHS.
- has not been previously approved, and is going to be conducted across multisites within WA Health.
- has previously been approved by a non-WA Health HREC (until such time as WA Health participates in the National Approach)

103.6 Ethical approval granted by a EMHS HREC will be accepted by all other WA Health institutions, however this ethical endorsement may not be valid on a national basis.

Related Standard Operating Procedures

SOP101: Types of ethical review of submitted applications
SOP102: Obtaining a Registration Number (RN)
SOP104: Submission of research deemed to be Low Risk for ethical review
SOP105: Submission of multicentre research within WA Health for reciprocal approval
SOP106: Conflict of Interest – Investigator
SOP107: Research involving an application for a Waiver of Consent
SOP301: Submission and meeting schedule
SOP304: The Human Research Ethics Committee (HREC) meetings and review process
SOP306: Resubmission of a research application that was not approved

SOP104: Submission of research deemed to be Low Risk for ethical review

Function: To describe the correct process for the submission of a low risk research application

Applicable to: Any investigator who wishes to submit their research application as low risk and has met the criteria to qualify for low risk

Version: 2.0 dated July 2016

Due for Review: July 2019

104.1 The National Statement defines low risk research as "research in which the only foreseeable risk is one of discomfort". Further information about low risk research can be found in Sections 2.1 and 5.1 of the National Statement.

Investigators seeking to determine whether their project is eligible for low risk review should read the 'Guidelines for Negligible and Low Risk Review Processes' which is part of the 'Guidelines' section of the WA Health Ethics Application Form.

104.2 Those investigators whose project qualifies for review under the low risk review stream should indicate this on their application form.

104.3 Low risk review is not available for proposals involving:

- Interventions and therapies, including clinical and non-clinical trials, and innovations
- Human genetics
- Human stem cells
- Women who are pregnant and the human foetus
- People highly dependent on medical care who may be unable to give consent
- People with a cognitive impairment, an intellectual disability, or a mental illness
- Aboriginal and Torres Strait Islander Peoples
- People who may be involved in illegal activities
- Sensitive personal or cultural issues; or
- Vulnerable people, including, but not limited to, children, non-English speaking participants,
- Persons under a legal or other disability, persons who are not competent to provide informed consent and persons over the age of 65

104.4 Low risk review is not available for any research proposal in which any member of the Committee is involved in any capacity.

104.5 If the research involves the requirement for consent to be qualified or justifiably waived as outlined in Chapter 2.3 of the National Statement (e.g. access to patient records or samples without the consent of the participant) submissions are required to be reviewed by the complete HREC and as such should be submitted as per the description in SOP103.

104.6 The investigator can request this submission stream however, the REGU has the final decision as to whether the research will be accepted into this submission stream.

104.7 The requirements for document submission for Low Risk review are identical to those for submissions to a HREC (see SOP103.2).
An electronic copy of the submission documents should be emailed to:
EMHS.REG@health.wa.gov.au

104.8 Submissions meeting the requirements for Low Risk review will be allocated by the REGU to the Low Risk Review Panel (LRP).

104.9 Projects approved by the LRP are reported to the HREC for noting.

Related Standard Operating Procedures

SOP101: Types of ethical review of submitted applications
SOP102: Obtaining a Registration Number (RN)
SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP106: Conflict of Interest - Investigator
SOP107: Research involving an application for a Waiver of Consent
SOP304: The Human Research Ethics Committee (HREC) meetings and review process
SOP306: Resubmission of a research application that was not approved.

Related Websites

National Statement
EMHS Research Ethics and Governance website

SOP105: Single site review of multicentre research within WA Health

Function: To describe the procedure for the submission of multicentre research application that has been reviewed and approved by another WA Health HREC

Applicable to: All investigators submitting multicentre research applications to EMHS that have received approval from another WA Health HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

105.1 Where a submission has been submitted for review and approved by a WA Health HREC outside of EMHS, then EMHS will accept this prior ethical review.

105.2 A RN must be sought and received in accordance with SOP102, at the time of submitting research governance documentation (see SOP201).

105.3 A copy of the ethically approved application and all necessary site specific documentation (including a conflict of interest form from each site investigator and WA Health Site Specific Assessment Form) must be submitted at the time of submitting documentation for research governance review.

The research cannot proceed at site until institutional authorisation is given (dependent on both ethical and governance endorsement).

105.4 All correspondence from the REGU will be sent to the site investigator who will be responsible for forwarding it to the Coordinating Principle Investigator.

Related Standard Operating Procedures

SOP101: Types of ethical review of submitted applications
SOP102: Obtaining a Registration Number (RN)

Related Websites

National Statement
Department of Health Research Governance website

SOP106: Conflict of Interest - Investigator

Function: To describe the process of managing a conflict of interest identified within a research project reviewed by a EMHS Human Research Ethics Committee (HREC)

Applicable to: The RPH HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

106.1 This SOP is written in accordance with chapter 5.4 of the National Statement.

106.2 All site investigators are required to complete the Conflict of Interest (CoI) form to be submitted with the application to REGU. The CoI form is available on the WA Health website.

106.3 Where an investigator has indicated a CoI the process undertaken to address this conflict will be reviewed by Research Governance. If the REGU determines the process is inadequate a letter will be sent to the investigator outlining their concerns and asking for these to be addressed in writing and/or attend a HREC meeting.

106.4 Where a CoI of an investigator in a research application under review (i.e. a conflict not already identified in the CoI form) is identified by the RPH HREC the subject of that conflict will be notified in writing by the REGU.

106.5 The letter will state the nature of the conflict. The investigator will be given the opportunity to respond and amend the planned research to remove the conflict if necessary.

106.6 The HREC or its Delegate will review the investigator's response and evaluate whether the investigator has adequately addressed its concerns.

106.7 If the HREC still feels that a conflict exists the investigator may be asked to attend a meeting to discuss these issues.

106.8 The research will not be given approval until this conflict is addressed to the satisfaction of the HREC.

Related Standard Operating Procedures

SOP101: Types of ethical review of submitted applications
SOP105: Submission of multicentre research within WA Health for reciprocal approval

Related Websites

Department of Health Research Governance website
National Statement

SOP107: Research involving an application for a Waiver of Consent

Function: To describe the process for the application of a Waiver of Consent

Applicable to: All investigators whose research does not involve obtaining consent from individuals for the use of their information/data or samples for research

Version: 2.0 dated July 2016

Due for Review: July 2019

107.1 Only a HREC may grant approval of research where the requirement for consent maybe qualified or justifiably waived (Chapter 2.3 of the National Statement).

107.2 Investigators wishing to apply for qualified or a waiver of consent must first ensure that their research meets the criteria set out in section 2.3.6 of the National Statement. The investigator needs to address all points (a-i) under this section within their submission when applying for a waiver of consent.

107.3 Investigators should also be aware that the National Statement recommends under Section 4.4.14 that, where applicable, participants should be informed of the research as soon as reasonably practicable and given the option to withdraw from it without any reduction in quality of care.

107.4 The HREC reviewing the submission will decide on granting a waiver of consent at its meeting.

107.5 Investigators applying for a waiver of consent that is granted by the HREC will receive notification of this with their approval documentation.

107.6 Investigators who are not successful in applying for a waiver of consent will be notified in writing of the HREC's decision and be provided with the reasons. The investigator can request that they be able to attend the next HREC meeting to discuss the matter.

Related Standard Operating Procedures

SOP101: Types of ethical review of submitted applications
SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP108: Addressing Section 95A of the Privacy Act (1988)

SOP108: Addressing Section 95A of the Privacy Act (1988)

Function: To describe the process taken by the HREC when considering Section 95A of the Privacy Act

Applicable to: Investigators whose research involves the collection, use or disclosure of health information held by private organisations without the consent of those individuals the data relates to

Version: 2.0 dated July 2016

Due for Review: July 2019

108.1 In cases where a research project involves the collection, use or disclosure of health information held by 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.

108.2 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 so what information investigators should provide when requesting the HREC grant permission to use or share this data.

108.3 Only a full sitting HREC can grant permission for this data to collected, used or disclosed. A HREC will consider these matters at its meeting.

108.4 Investigators who have not successfully addressed Section 95A will be notified in writing of the HREC's decision and be provided with the reasons. The investigator can resubmit an amended submission and/or request that they be able to attend the next HREC meeting to discuss the matter.

Related Standard Operating Procedures

SOP101: Types of ethical review of submitted applications
SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP107: Research involving an application for a Waiver of Consent

Related Website

NHMRC Guidelines approved under Section 95A of the Privacy Act 1988

SECTION 2: APPLICATION FOR RESEARCH GOVERNANCE REVIEW

SOP201: Research governance review process

Function: Outlines the process of the assessment of a research project by research governance staff

Applicable to: Investigators and study coordinators

Version: 2.0 dated July 2016

Due for Review: July 2019

201.1 In addition to obtaining ethical approval, all research projects intending to be undertaken within the EMHS must obtain site authorisation following a review by a Research Governance Officer (RGO) before proceeding.

Research Governance documents should be to emailed to the REGU at EMHS.REG@health.wa.gov.au. Hardcopies of finalised documents are also required and should be delivered to the REGU.

Received Research Governance documents will be checked by a REGU staff member to ensure that all the required documents have been completed and submitted. If the submission is found to be incomplete the application will be returned to the investigator – it can be submitted again to the REGU once all documentation is complete. Please note that research studies should not be submitted to Research Governance until all documents are completed, including all required signatures.

201.2 In order to complete a full assessment of the research application, the RGO will review and assess the following documentation and complete a Research Governance Review Report to send to the Principal Investigator (PI) and contact person:

- WA Health Site Specific Assessment form (SSA) / Access Request form
- NEAF or WA Health Ethics Application form
- Research protocol
- Participant Information and Consent Form (site specific) (PICF)

And where applicable:

- Clinical Trial Research Agreement (CTRA)
- Indemnity form
- Clinical Trial Notification (CTN) form
- Insurance certificate (and policy wording if necessary)
- Questionnaires, pamphlets, advertising material.

201.3 Ongoing communications between the RGO and the study team will usually occur via email. Investigators are, however, encouraged to contact the RGO via telephone or come to the REGU at any stage to discuss the application process or particular issues with their research study to facilitate communication. Once all the issues have been resolved or addressed, the RGO's assessment is completed. The RGO aims to maintain regular communications with investigators through the submission process until approval.

201.4 **Site Specific Assessment form (SSA)**. An integral part of the research governance review is to conduct a site specific assessment. This important risk management activity ensures

that all the resources required to conduct the study (financial, human, equipment and infrastructure) are considered to be appropriate and available. Those Departments and individuals on site who are requested or required to be involved in the project must agree by signing the SSA. Please refer to SOP202: Site Specific Assessment Form.

201.5 Projects that require support from EMHS in the form of access to participants, tissue or data, but do not involve the conduct of research at a EMHS (sites) require completion of an **Access Request form** (in place of the SSA). Please refer to SOP203: Access Request Form.

201.6 **The NEAF/WA Health Ethics Application form** requires the investigators to give information regarding the study pertaining to staff involvement, finances, other sites' involvement etc. The study team is required to outline their intention to comply with matters pertaining to patient privacy and confidentiality, gaining informed consent, professional safety, data transfer and storage and other matters of significance for a research study. RGO is required to ensure that investigators are aware of and compliant with relevant laws, policies and codes of conduct namely

- Good Clinical Practice (GCP) Guidelines
- National Statement on Ethical Conduct in Human Research
- Australian Code for the Responsible Conduct of Research
- WA Health and Institutional policies

201.7 **Research protocol**: As well as scientific and ethical review by a EMHS HREC, the research protocol is also reviewed by the RGO in detail. This is to ensure that the research activities described in the protocol are adequately communicated in the other study documents. For example, if patients are to undergo CT scans or X-rays, then RGO needs to check that the participants have been told in the PICF and that the Departments who provide those services have signed off the SSA.

201.8 **Clinical Trial Research Agreements (CTRAs)**. The CTRA is a legally binding contract between two or more parties that establishes the respective responsibilities and obligations of the parties conducting a research study. Most clinical trials and other research studies at site will require a CTRA. Investigators who are unsure if their research project will require a CTRA or other form of legal Agreement should contact the REGU. The RGO will review the submitted CTRA to ensure that the interests of WA public hospitals and funds are adequately represented and managed.

WA Health has developed standard, system-wide approach to the agreements applying to research projects conducted in WA Health.

Please refer to SOP204: Clinical Trial Research Agreements (CTRA) for more information. Intellectual Property provisions should be outlined in the CTRA. Please refer to SOP207: Intellectual Property and research projects for more information.

201.9 **Indemnity**. For commercially sponsored trials, indemnification of the HREC and EMHS staff must be provided by the study sponsor. Evidence of this indemnity is through use of the Medicines Australia Indemnity Form. Please refer to SOP205: Medicines Australia Form of Indemnity for Clinical Trials for further information regarding the provision and review of Indemnity Forms.

201.10 **Insurance**. The RGO must assess insurance provisions provided by a Collaborative Group or commercial entity to ensure that they comply with WA Government Insurer, Riskcover's, requirements. These requirements are the 13 points listed in the WA Health CTRA's (Forms A, B and D). Refer to SOP206: Insurance and research projects for further information regarding insurance requirements for research applications.

201.11 **Clinical Trial Notifications (CTN)**. For research studies involving the use of pharmaceuticals or medical devices that are not registered with the Therapeutic Goods Administration (TGA) or for registered pharmaceuticals or medical devices being used outside their registration approvals, a CTN is to be completed and submitted to the TGA. Prior to being submitted to the TGA, the CTN is to be submitted with the research study submission for institutional signing. The RGO will review the CTN and any errors or discrepancies will be identified and reported to the Principal Investigator.

Please refer to SOP208: Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) Schemes regarding completion and submission of a CTN. More detailed information can also be obtained from the TGA website.

201.12 When the HREC has given approval for the study and the RGO's assessment is complete, institutional approval can then be sought. Please refer to SOP402: Site authorisation for further information.

Related Standard Operating Procedures

SOP204: Clinical Trial Research Agreements (CTRA)
SOP205: Medicines Australia Form of Indemnity for Clinical Trials
SOP207: Intellectual Property and research projects
SOP206: Insurance and research projects
SOP208: Clinical Trials Notification (CTN) and Clinical Trials Exemption (CTX) Schemes
SOP202: Site Specific Assessment Form
SOP203: Access Request Form
SOP402: Site authorisation

Related Websites

Note for guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with TGA comments
National Statement
Australian Code for the Responsible Conduct of Research
Department of Health Research Governance website

SOP202: Site Specific Assessment form

Function: Outlines the functions and review process of the Site Specific Assessment Form by Research Governance

Applicable to: Investigators and Study Coordinators

Version: 2.0 dated July 2016

Due for Review: July 2019

202.1 The WA Health Site Specific Assessment (SSA) Form is a document that has been developed by WA Health for Research Governance to ensure that all human research conducted within WA Health complies with professional, legal and financial accountability and transparency and is consistent with the NHMRC's "Australian Code for the Responsible Conduct of Research" 2007 (**the Code**). This includes the requirement that all EMHS hospitals and health service departments who are asked to provide a service for a research study have been informed of the protocol requirements and agree to participate. The SSA form is written confirmation of this approval.

202.2 For low risk projects the SSA Form for Low and Negligible Risk Research should be used.

202.3 Investigators should provide a copy of the research proposal, together with the SSA form, to the relevant Departments. Please indicate the sections or pages of the protocol that are relevant to each Department as this will facilitate the process. Investigators must give the signatories of the relevant Departments sufficient time to read through the study information, determine the impact on their Department and confirm their ability to participate by completing section 15.3 and signing section 17.2 of the SSA form (or sections 8.3 and 10.2 for the low risk SSA form). This process should commence at least two weeks prior to the intended submission date. More time will be required where multiple Departments need to complete and sign the form and where the study involves radiation exposure, possible dosimetry assessment and Radiological Council approval may be needed.

202.4 The SSA form must be present and complete (with all required signatures) on submission to the REGU to accept the application and commence review of the project. If this form is not completed satisfactorily, it has not been determined if all the resources required for conduct of the study have been secured and review/approval may be delayed.

202.5 The SSA form consists of several sections:

1. Project Details
2. Research personnel details
3. Training requirements
4. Project Participants – identification, recruitment etc
5. Other approvals required (where applicable)
6. Regulatory documents – CTN, indemnity, insurance, CTRA
7. Intellectual Property
8. Safety issues
9. Resource & Budget information.
10. Funds Management details
11. EMHS Investigator Responsibilities – the EMHS Investigator is to read the declaration and sign.

12. Signatures of Support Departments. These Departments include those most commonly called on to provide resources for research such as Medical Records, Clinical Coding, Pharmacy, Diagnostic Radiology.
    - Head of Research Department – read the declaration and sign.
    - Business Manager – read the declaration and sign.
    - Divisional Co-Director – read the declaration and sign.

    The SSA form ensures that the EMHS Investigator, Head of Department, Business Manager and Divisional Co-Director of the Department under whose auspices the research is taking place have all signed to show they understand the financial, human resource, logistical and other resource implications a particular research study will have upon their Departments. The Divisional Co-Director should not sign until all other signatures have been obtained.

202.6 The REGU Staff and RGO will review all the required documents in the research application and determine if all the required documentation has been submitted. It will also ensure that each Department that is required to be involved in the project has been identified, approached and given approval for the use of their resources by way of completing and signing the relevant sections of the SSA form. If a research application utilises the services of a Department, even if it is considered 'standard of care' by the investigator, the investigator should still contact the Head of Department to discuss the research requirements and obtain sign-off.

202.7 It should be noted that all research applications that involve the use of a pharmaceutical must obtain sign off from Pharmacy, even those studies where Pharmacy will not be directly involved.

202.8 If there is uncertainty as to whether a Department needs to sign off for a particular research study, please contact the signatory of that Department or a RGO to discuss.

202.9 The REGU is to receive the original, completed SSA form on submission with the other research study documents.

Related Standard Operating Procedures

SOP201: Research governance review process

Related Website

WA Health Research Governance Framework

SOP203: Access Request form

Function: Outlines the functions and review process of the Access Request Form by Research Governance

Applicable to: Investigators and Study Coordinators

Version: 2.0 dated July 2016

Due for Review: July 2019

203.1 The WA Health Access Request Form is a document that has been developed for the governance review of single-centre and multi-centre research projects, irrespective of risk, that require support from an Area Health Service in the form of access to participants, tissue or data, but does not involve the conduct of research at the site under the control of that Area Health Service. An Access Request form must be completed for all the sites (single or multiple) requiring access for the research within the jurisdiction of an Area Health Service.

Examples of such projects are:

- Participant recruitment through posters, leaflets, handouts and letter of invitation (but not recruitment through direct contact with potential participants or enrolment)
- Distribution of surveys and questionnaires through staff of EMHS (but not collation and analysis of responses at a EMHS site)
- Access to data or tissue held at a EMHS site (but not processing or analysis at a EMHS site).

203.2 Documents to be submitted with the Access Request form:

- Evidence of approval from a recognised WA Health HREC
- A copy of the WA Health Ethics Application form or NEAF
- A copy of all documents to be distributed through EMHS sites (eg. posters, recruitment letter (on research site letterhead) or surveys)
- Written confirmation of support from EMHS staff, in the form of a letter or email, through which investigators are seeking access to participants, tissue or data
- A copy of a conflict of interest form for the Coordinating Principal Investigator.

203.3 The Access Request form should be complete on submission to REGU to commence review of the application. If this form is not completed satisfactorily or is not accompanied by the required documentation the application will be returned to the investigator for completion.

203.4 The Access Request form consists of several sections

- Project Details
- Research personnel details
- Details of requested access (including confirmation of support)
- Declaration by Coordinating Principal Investigator

203.5 REGU staff and Research Governance Officer (RGO) will review the application and determine if all the required documentation has been submitted. It will also ensure that each EMHS Department that has been asked to provide access to participants, data or tissue has been identified, approached and agreed (as evidenced by written confirmation).

203.6 If there is uncertainty as to whether a Department needs to provide confirmation for access, the investigator should contact the Department or RGO to discuss.

203.7 Once the RGO review is complete and all requirements are met, a recommendation will be made to the EMHS Executive to approve the access requested.

Related Standard Operating Procedures

SOP201: Research governance review process

Related Website

Department of Health Research Governance website

SOP204: Clinical Trial Research Agreements (CTRA)

Function: Outlines the process for administrative review of the CTRA

Applicable to: Investigators and Study Coordinators

Version: 2.0 dated July 2016

Due for Review: July 2019

204.1 The Clinical Trial Research Agreement (CTRA) is a legally binding contract between two or more parties that establishes the respective responsibilities and obligations of the parties conducting the study. Research Governance review of the CTRA is essential to ensure the interests of WA public hospitals and funds are preserved and adequately managed. It is particularly important for commercially sponsored studies that the CTRA adequately addresses issues including insurance, indemnity and intellectual property.

204.2 Public Hospitals in WA, including Royal Perth Hospital, are required to use CTRAs approved by the Legal & Legislative Services (LLS) branch of the WA Department of Health. The template agreements are:

1. CTRA - Medicines Australia Standard Form – Sponsor only (Form A)
2. WA CTRA Standard – involving a Sponsor and a Contract Research Organisation (Form B)
3. CTRA - Medicines Australia Form - Contract Research Organisation (CRO) acting as the Local Sponsor (Form D)
4. Clinical Trial Agreement - Collaborative or Cooperative Research Group (CRG) Studies (Form C)

[CTRAs 1, 2 & 3 contain specific amendments required by WA Health in Schedule 7]

Template agreements are available for download from the Department of Health Research Governance website.

204.3 Prior to submitting a research application for approval, a Commercial Sponsor, CRO or CRG should be sent the appropriate CTRA. These forms are available from the Department of Health Research Governance website. The Research Governance Officer (RGO) can advise investigators on the most appropriate CTRA form for a particular research study. Note that a number of sponsors and CRGs have negotiated specific CTRA's for use with WA Health and the RGO can advise whether such an agreement is available for use.

204.4 The RGO will examine the CTRA and determine that the correct details are included in the document and that these details correspond with information contained in the application. This includes:

- the institution's legal name (as a party to the CTRA)
- the title of the trial
- the sponsor entity corresponds with the entity name on the indemnity, CTN and other vital documents.

The RGO will review the submitted CTRA to ensure consistency with WA Health approved agreements. If changes have been made, the RGO will consult with LLS and advise the Sponsor/CRG whether the proposed amendments are acceptable.

204.5 Where a Sponsor or CRG submits, without amendment, the current version of an approved CTRA, that document will be accepted by the RGO.

204.6 If a Sponsor or CRG submits a CTRA containing material changes, the RGO will need to assess the effect of those changes on the integrity of the CTRA. This may involve requesting advice from LLS. In such instances the Sponsor/CRG will be expected to provide an electronic version of the CTRA to facilitate editing and tracking changes.

204.7 Amendments to the CTRAs must be set out in a schedule to the agreement and not in the actual body of the CTRA. Schedule 7 in the Medicines Australia CTRA (Forms A, B & D) and Schedule 4 of the CRG CTRA (Form C) are used specifically for this purpose. Sponsors, CROs and CRGs are strongly encouraged to accept the WA Health approved versions without change. Where changes are requested by those parties, they should not seek to substantially amend the CTRA or introduce provisions that contradict or undermine the intent of the CTRA.

204.8 For Investigator-initiated clinical trials where funding or other support is provided by an external party, the RGO should be contacted regarding the type of contract to be used.

204.9 By virtue of his or her employment status, the Principal Investigator (PI) cannot be a party to a CTRA. The CTRA is a legal document between the institution and the sponsor/CRG. The PI can acknowledge, by way of signing, their obligations as set out in the terms and conditions of the CTRA.

204.10 Once a CTRA has been reviewed and approved by the RGO, the Sponsor/CRG should send 3-4 complete and signed copies to the REGU for signing (usually one original for the Research Governance file, one for study team and one for Sponsor and CRO if required). REGU staff will arrange for sign-off of the CTRA with the other documents once RGO requirements have been met and HREC approval of the trial has been obtained.

204.11 Once signed (with other approval documentation) the CTRA will be given to the site study personnel for distribution to the Sponsor/CRG as relevant.

204.12 The CTRA has now been approved and any subsequent changes will be required to be submitted as an amendment.

Operating Procedure developed in conjunction with Don Black, Principal Policy Officer, WA Health Department of Legal and Legislative Services.

Related Standard Operating Procedures

SOP205: Medicines Australia Form of Indemnity for Clinical Trials
SOP206: Insurance and research projects
SOP207: Intellectual Property and research projects

Related Website

Department of Health Research Governance website

SOP205: Medicines Australia Form of Indemnity for Clinical Trials

Function: Outlines the process for administrative review of the Indemnity Form

Applicable to: Investigators and Study Coordinators

Version: 2.0 dated July 2016

Due for Review: July 2019

205.1 In all studies where the following Clinical Trial Research Agreements (CTRA), including amended versions, are used, the sponsor and/or the Contract Research Organisation (CRO) must provide indemnity to the institution and members of the responsible HREC against claims arising from the study on the terms and conditions set out in the relevant Medicines Australia Form of Indemnity for Clinical Trials:

- CTRA - Medicines Australia Standard Form (Form A)
- CTRA - Medicines Australia Form - Contract Research Organisation acting as the Local Sponsor (Form D)
- WA CTRA Standard Form B – involving a Sponsor and a Contract Research Organisation.

Studies conducted under the Clinical Trial Agreement - Collaborative or Cooperative Research Group (CRG) Studies – Standard Form (Form C) do not require the CRG to provide the institution and HREC with an indemnity. If a CRG offers to provide an indemnity it should be in the form of the Medicines Australia version.

205.2 There are two versions of Medicines Australia Form of Indemnity for Clinical Trials:

- Standard Form of Indemnity (for use where the Indemnified Party is providing premises for the conduct of the Study and HREC Review, or is providing premises only)
- HREC review only (for use where the Indemnified Party is providing HREC review ONLY of the study)

For the majority of studies, the Standard Form of Indemnity will be submitted. The most recent version has the file name Indemnity Form version 160104B 16 January 2004 in the footer, and can be downloaded from the Medicines Australia website.

205.3 As the Form of Indemnity is a legal document, the indemnifying party (e.g. the Sponsor) must ensure that the correct legal name appears for both ‘the Indemnified Party” and “the Sponsor”.

For EMHS institutions, the correct legal names are:

- The Minister for Health is incorporated as the board of Royal Perth Hospital under s7 of the Hospitals and Health Services Act 1927 (WA) and has delegated all the powers and duties as such to the Director General of Health ABN 13 993 250 709, Royal Perth Hospital, Wellington Street, PERTH, WA 6000 ("the Indemnified Party")

Note that the ABN [Australian Business Number] and address are included as part of the legal name. Investigators are advised to check the Australian Business Register for the correct entity names and ABN.

Prior to submitting these documents to REGU, research staff are to ensure that all study details, including the Study number and study title are consistent with the study title and number on the Protocol.

Other details that are to be confirmed on page 1 include identification of the “the Subjects” and “the Investigator” in paragraph 1.

Depending on the type of CTRA, a signed Form of Indemnity should be provided to each of the parties to the Agreement, including one for the Principal Investigator.

205.4 Following submission to REGU, the Form of Indemnity will be checked to verify that the details for each party are correct, that “the Subjects” and “the Principal Investigator” have been identified in paragraph 1, and that none of the wording has been altered, deleted or inadvertently omitted when completing the document details.

205.5 Any proposed changes to the ***wording*** of the Form of Indemnity by any party to the study, aside from those required above, must be made separate to this document. Generally this is done in **Schedule 3** of the respective CTRA.

If the indemnifying party makes any changes to the text of the Form of Indemnity, Research Governance will need to have these reviewed by Legal & Legislative Services (LLS) at the Department of Health.

205.6 Once the Form of Indemnity has been reviewed and approved by the RGO, the Sponsor/CRG should send 3-4 complete and signed copies to the REGU for signing (usually one original for the Research Governance file, one for study team and one for Sponsor and CRO if required). REGU staff will arrange for sign-off of the Form of Indemnity by a member of the Executive, acting as a delegate of the Minister for Health, with the other documents once RGO requirements have been met and HREC approval of the trial has been obtained.

205.7 REGU retains an original MA Form of Indemnity provided by the Sponsor. The other original forms are returned to the investigator for distribution to the relevant sponsor /CRO. Depending on the number of originals provided, the Principal Investigator may receive a photocopy of the Form for their own file.

Operating Procedure developed in conjunction with Don Black, Principal Policy Officer, WA Health Department of Legal and Legislative Services.

Related Websites

Medicines Australia
Australian Business Register
Department of Health Research Governance website

SOP206: Insurance and research projects

Function: Outlines the process of review of insurance provisions provided for a research project by Research Governance

Applicable to: Investigators submitting an application for governance review

Version: 2.0 dated July 2016

Due for Review: July 2019

206.1 Reviewing other parties' insurance is a risk management strategy which seeks to ensure that research activities are adequately covered by robust insurance provisions. This not only protects the interests of WA public hospitals but importantly also protects the interests of research subjects, as well as sponsors and supporting Clinical Research Organisations (CROs).

206.2 RiskCover manages the Western Australian Government's self insurance arrangements, which incorporate the WA Health system including research activities. RiskCover protects public institutions under the legal liability cover and also provides insurance and risk management advice to its public clients. Where a hospital-employed investigator initiates a research study, the study proposal must pass certain scrutinies through Research Governance, including examination of the external parties' insurances. RiskCover provides a support service in scrutiny and advice regarding these insurances, for consideration by the RGO.

206.3 The Clinical Trial Research Agreement (CTRA) stipulates what insurance requirements must be met.

206.4 Where insurance is required, an insurance certificate at the very least should be provided with the submission paperwork. A full copy of the insurance policy wording is preferable and research staff are encouraged to request this document from the sponsor. The RGO will assess the insurance information provided against the 13 points of insurance that have been outlined by RiskCover as the minimum amount of information that needs to be provided. These are listed in the WA CTRA's in Schedule 4 and are as follows:

1. Name and address of the insurer, including its Internet website address
2. Name and address of the insured. If the insurance extends to other parties relevant to the agreement, details should be provided. The Institution needs to be satisfied that the Sponsor is actually an insured under the policy.
3. Policy number
4. Period of insurance
5. Class of insurance
6. Sum insured per event including any sub limits
7. Aggregate sum insured
8. If applicable, any excess of loss/umbrella policy information
9. Deductibles/excesses
10. Whether the policy is constructed on an "occurrence" or "claims made" wording
11. Scope of cover. For example, "Legal liability of the insured for death and bodily injury arising from clinical trials, including products liability risks". There may be a need to quote the operative clause of the policy to capture the correct interpretation.
12. Territorial limits of the policy. It is essential that the policy respond to claims lodged and processed in an Australian jurisdiction. Notwithstanding that the cover may apply anywhere in the World, if there are any restrictions on claims in an Australian

jurisdiction, these must be detailed (If an overseas sponsor is providing insurance, it needs to be clarified that if a claim were to be made that it would not be required to be heard in a court overseas).

13. Relevant policy exclusions and conditions should be listed and detailed if appropriate. Exclusions relating to contractual liabilities, specific drugs and implements may be important (this is important as instances often occur where the very product being trialed is listed as an exclusion on the insurance policy, rendering the insurance policy provided for that research study as useless, leaving WA Health open to a claim).

206.5 The institution will review insurance limits with reference to the risks of the study however the minimum requirements for a sponsor and/or CRO are:

- public liability insurance for the minimum sum insured of AUD $5,000,000; and
- liability insurance covering:
    - clinical trial / product liability (or equivalent) and professional indemnity; and
    - the contractual obligations of the Sponsor contained in this Agreement

without limiting the indemnity obligations of the Sponsor set out in Schedule 3 of this Agreement;

for minimum sum insured of AUD $10,000,000 any one claim and also in the aggregate and which does not contain an excess/deductible or self-insured retention amount greater than AUD $25,000 for each and every claim or series of claims arising out of one originating cause.

206.6 Where the 13 points of insurance information have not been provided, the study team will be sent a request by the RGO for the balance of information that is to be obtained from the sponsor/CRO. Once this information is received by the RGO and deemed to be in order, then the insurance review is complete.

206.7 When the RGO receives information regarding insurance that does not comply with RiskCover's recommendations or is difficult to understand or analyse, RiskCover will be contacted for further advice.

206.8 If a policy has been provided that does not comply with requirements or not enough information has been received to undertake a thorough review of the insurance, then the RGO will take the information to the EMHS Executive to decide if the trial can proceed based on the insurance provisions provided.

Related Standard Operating Procedures

SOP201: Research governance review process
SOP204: Clinical Trial Research Agreements (CTRA)

SOP207: Intellectual Property (IP) and research projects

Function: Outlines the process for the protection and management of Intellectual Property in research studies

Applicable to: All staff involved in research at EMHS

Version: 2.0 dated Julyy 2016

Due for Review: July 2019

207.1 **Intellectual Property (IP)** is the tangible representation of intellect and creativity, which has value and is protectable by law. There is wide diversity in the types of IP that are generated in WA Health. These include new drugs, medical devices, data, software, teaching and training materials, reports or business processes. In some cases these products can have actual or potential commercial value, and may require some form of protection. In WA Health this is generally through Copyright and Patenting.

Copyright refers to a series of rights granted to the author or creator of an original work, including the right to copy, distribute and adapt the work. Copyright does not protect ideas, only their expression or fixation. Under the Copyright Act (Commonwealth 1968) copyright arises upon fixation and does not need to be formally registered.

Patents are applicable to inventions or innovations that potentially lead to new and improved products or processes. They provide a time-limited monopoly over commercialisation, and require formal registration procedures, that are complex, costly and require specialist advice. Care must be taken with respect to documentation, prior use or public disclosure, and the establishment of 'first to invent' status may apply.

The following reference documents provide further guidance in this area:

- Intellectual Property Management in the WA Department of Health
- WA Government Intellectual Property Policy and Best Practice Guidelines
- National Principles of Intellectual Property Management for Publicly Funded Research

207.2 **IP Management and Ownership**

The WA Health Code of Conduct states that staff will *"Protect and responsibly manage the intellectual property developed in, or used by, WA Health. The intellectual property we create in the course of our employment may remain the property of WA Health*".

When a EMHS employee is involved in a research study that has been approved by the institution, the institution supports this project by providing indemnity and insurance. If there are reasonable grounds to anticipate that significant IP could be developed in the study, the employee will be requested to acknowledge the ownership of this IP by the State of Western Australia, represented by WA Health/EMHS. The appropriate form can be sourced (under Research Governance forms) from the WA Health Research Development website.

Third Party IP - WA Health staff must make every effort to identify and acknowledge any third-party IP that they might use, and avoid any infringement of the IP rights of the other party(ies). This also applies to material that carries no evident ownership disclaimers, such as can be downloaded from the internet.

207.3 **IP in Collaborative Research Studies**

The ownership and use of both Background (pre-existing) IP and newly developed (Project) IP in collaborative research should be specified in written contractual agreements between the participating parties. These agreements should be approved by the RGO, which may consult with the Department of Health IP Coordinator. Background and Project IP can, in some circumstances, be assigned to another party, but only upon specific approval by the RGO, in consultation with the Department of Health IP Coordinator.

207.4 Patent protection or commercialisation of WA Health IP should not be undertaken without prior authorisation and guidance from Research Governance, which may consult with the IP Coordinator, Research Development Unit, Office of the Chief Medical Officer, Department of Health (DoH IP Coordinator).

207.5 **Publications**

Authorship of scientific publications resulting from research studies should be governed by the guidelines of the International Committee of Medical Journal Editors (the Vancouver Convention: Uniform Requirements for Manuscripts Submitted to Biomedical Journals).

Most scientific, technical and medical publications require that the IP rights to published articles be assigned to the Journal, although some open-access publications do not require this.

Unless IP assignment is required by the publisher, any publication, whether in print or electronic form, arising from WA Health activities should carry the copyright disclaimer available on the Department of Health IP Management website.

207.6 Any queries in relation to IP matters in WA Health/EMHS should be directed in the first instance to a RGO. If required these may be then referred to the IP Coordinator, Research Development Unit, Office of the Chief Medical Officer, Department of Health.

Related Standard Operating Procedures

SOP204: Clinical Trial Research Agreements (CTRA)

SOP208: Clinical Trials Notification (CTN) and Clinical Trials Exemption (CTX) Schemes

Function: Outlines the requirements for conducting clinical trials under the CTN/CTX Scheme

Applicable to: Investigators and Study Coordinators

Version: 2.0 dated July 2016

Due for Review: July 2019

208.1 The Therapeutic Goods Administration (TGA) is the organisation in Australia that is responsible for the regulation of therapeutic goods (medications and devices). The TGA administers two schemes under which clinical trials involving therapeutic goods may be conducted - The **Clinical Trial Notification (CTN)** Scheme and the **Clinical Trial Exemption (CTX)** Scheme.

A notification or application to the TGA is required for all clinical investigational use of a product in Australia, where that use involves:

- a product not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or
- use of a registered or listed product outside the conditions of its marketing approval.

In 2015 the TGA introduced an online system for the submission of CTN/CTX. Further information is available on the TGA's website and the REGU has developed a CTN Online Guide to assist researchers

The CTN scheme – for clinical trials being conducted under this scheme, all material relating to the proposed trial is submitted directly to the TGA using their online portal. A trial being conducted under the CTN scheme cannot commence until the trial has been notified to the TGA and the appropriated fee paid.

The CTX scheme is an approval process. A submission is made directly to the TGA for evaluation, along with a fee. A CTX trial cannot be commenced until written approval for the use of the investigational product has been received from the TGA.

This SOP will refer to the CTN scheme only as this is the most appropriate scheme for most research studies conducted at this site.

208.2 For commercially sponsored or Collaborative Research Group (CRG) projects where the commercial company or CRG is the sponsor, the sponsor is responsible for drafting the CTN, submitting the CTN to the TGA and paying the fee.

Investigators who are unsure if they require a CTN or for information about completing the form and the costs associated with lodging a CTN can contact the TGA directly 1800 020 653 for medicines and1800 141 144 for devices.

208.3 For investigator initiated and CRG projects where EMHS is the sponsor the Principal Investigator (PI) is responsible for contacting the Research Governance Officer (RGO) to

request a user ID, drafting the CTN and paying the fee. The EMHS RGO is responsible for requesting access for the PI, submitting the CTN to the TGA and forwarding the invoice to the PI for payment.

208.4 In all scenarios, at the time the CTN online form is submitted with the TGA an email confirmation should be provided to the REGU via the email EMHS.REG@health.wa.gov.au

208.5 To complete the CTN online form, it is necessary to provide information for each site regarding the local PI, approving HREC and approving Authority details. These details are available in 's CTN Online Guide.

208.6 Conducting a clinical trial under the CTN scheme requires the approval of a HREC. The Sponsor of the clinical trial must be an Australian entity i.e. they must have a registered ABN.

208.7 The CTN will be reviewed by RGO as part of the research application. The RGO will ensure that the details on the CTN are correct including:

- The Sponsor name on the CTN corresponds with the Sponsor name on all the other vital documents – in cases where the sponsor is an overseas entity the CRO may be named as the sponsor on the CTN (it is a TGA requirement that the sponsor on the form is an Australian entity). For commercially sponsored trials, the commercial sponsor is usually the last to sign.
- The title of the study and protocol numbers are correct.
- The medicine details correspond with those in the protocol and all medicines and placebo have been included and dosages printed correctly.
- Any unregistered devices being utilised in the study are included in Device details.
- Official HREC name and address and other pertinent details.
- Approving authority name and address are correct.

208.8 The online CTN can be submitted once proof of HREC approval and site authorisation are provided.

208.9 A copy of the electronic submission should be printed out and provided to the RGO to keep in the Research Governance file.

208.10 The CTN Scheme is a notification scheme and, as such, no TGA approval is given. A clinical trial is deemed to have been notified as soon as the CTN form has been completed and the relevant fee is sent to the TGA. Thus, legally, a sponsor or investigator does not have to wait for the TGA's acknowledgment letter before commencing the trial. However, it may be advisable for sponsors to wait for the TGA's acknowledgment in case there is anything, such as incomplete information on the CTN form, that might invalidate the notification. Please refer to the TGA website for more information.

208.11 A new CTN is required in the following circumstances where an existing CTN for the trial has been sent:

- There is a significant change in the protocol that resulted in a change in the HREC approval or conditions of the approval. The new notification should indicate to the TGA that the HREC at each site has approved the amended protocol.

- There are any additional new unapproved therapeutic products being added to the trial. The HREC approval should indicate that each institution at which the trial is being conducted has approved the additional investigational therapy.

If there is any doubt as to whether a new notification is required then advice should be sought from the TGA.

Related Standard Operating Procedures

SOP201: Research governance review process

Related Websites

TGA CTN forms
Access to unapproved therapeutic goods
CTN guide

SECTION 3: HUMAN RESEARCH ETHICS COMMITTEE (HREC) MEETINGS

SOP301: Submission and meeting schedule

Function: The schedule of submission and meeting dates for the HREC

Applicable to: All investigators submitting research applications (other than those classified low risk) or substantive amendments

Version: 2.0 dated July 2016

Due for Review: July 2019

301.1 The RPH HREC each meet eleven times a year (monthly except for January when there is no meeting). The next year's submission and meeting schedule is approved by the RPH HREC at the November meeting of the current year.

301.2 All members of the HREC will receive a copy of the submission and meeting schedule. The HREC members' schedule will also show what deputy member is to attend each meeting.

301.3 The most recent version of these dates can be found on the EMHS Research Ethics and Governance website

Related Standard Operating Procedures

SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP104: Submission of research deemed to be Low Risk for ethical review
SOP105: Single site review of multicentre research within WA Health
SOP303: Human Research Ethics Committee (HREC) meeting agendas
SOP307: Human Research Ethics Committee (HREC) meetings and review process

SOP302: The collation and distribution of papers for Human Research Ethics Committee (HREC) meetings

Function: To describe the process by which the papers for the HREC are compiled and circulated to the committee members

Applicable to: All applications submitted for review by the HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

302.1 All submission paperwork must be received by the deadline as stated in SOP301. No late or incomplete applications will be accepted under any circumstances.

302.2 When a research application is received, it will be logged into the database.

302.3 The REGU Executive Officer (EO) for each committee is responsible for creating the agenda and collating the meeting paperwork for each committee member and circulating them at least seven days prior to the meeting date. Any member not receiving their paperwork within this time frame will contact the EO notifying them that the paperwork has not been received.

302.4 The meeting paperwork is emailed, or in some instances delivered either by courier, internal mail or hand delivered to those on site.

302.5 If a core member is unable to attend a meeting, and does not have a proxy, they shall be provided with the meeting's paperwork to enable them to submit written comments for consideration by the committee during the meeting. These comments are emailed to the REGU prior to the meeting. It is the EO's responsibility to circulate these to all committee members attending the meeting.

Related Standard Operating Procedures

SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP104: Submission of research deemed to be Low Risk for ethical review
SOP105: Single site review of multicentre research within WA Health
SOP301: Submission and meeting schedule
SOP303: Human Research Ethics Committee (HREC) meeting agenda
SOP307: Minutes of the meeting

SOP303: Human Research Ethics Committee (HREC) meeting agenda

Function: To describe the process by which the agenda for each HREC is developed

Applicable to: All applications submitted for review by the HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

303.1 The agenda for each meeting is produced by the REGU after all the applications for that round of meetings have been received and the details entered in the database.

303.2 The order of agenda papers is as follows:

1. Agenda
2. Minutes of the previous HREC meeting
3. Resubmissions
4. New Applications
5. Amendments
6. Other Business

303.3 The agenda will be circulated to all Committee members with the application documentation.

Related Standard Operating Procedures

SOP001: Overview of research approval at EMHS sites

SOP304: The Human Research Ethics Committee (HREC) meetings and review process

Function: To provide investigators with information on the HREC meeting

Applicable to: All investigators submitting research applications to the HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

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

304.2 The REGU will compile the paperwork for the meeting. The paperwork for the meeting will be delivered to the members seven (7) days prior to the meeting date.

304.3 Meetings require a quorum to commence, as described in the HREC Terms of Reference. In the absence of a quorum, a meeting may still be held but any decisions made will be subject to ratification at the next full meeting of the Committee.

304.4 Core members (according to the *National Statement S5.1.29,*) are required to be present at all meetings, or represented by a proxy/deputy member.

304.5 Members unable to attend a meeting are to notify the REGU as soon as possible to ensure their apologies can be tendered at the meeting, and/or a replacement member is organised if they are a core HREC member.

304.6 Members unable to attend are able to submitted written comments in lieu of attendance which are provided to other members prior to or at the meeting. If written comments are submitted the member will be considered as part of the quorum.

304.7 During this review process the committee members may identify problems with, or question the ethical conduct of the proposed research. These issues are then discussed at the meeting. If the committee upholds these concerns the following steps are taken:

- where minor ethical issues are identified during the HREC review, the investigator will be notified in writing by the REGU and asked to make the necessary changes and submit the revised documents to the REGU.
- where substantial ethical issues are identified, the investigator will be notified in writing by the REGU and requested to resubmit their application with the required changes having been made and outlined in a covering letter to the next scheduled HREC meeting.

304.8 The Delegate of the Chair (DoC) can be empowered by the Committee to review and approve changes requested by the Committee. The DoC can then provide HREC approval.

If the DoC identifies further issues with the submitted changes they can either request further amendments or refer the application back to the HREC for consideration.

304.9 At the discretion of the HREC Chairperson, study investigators may attend a meeting to resolve any issue(s) that cannot be addressed effectively in correspondence. The

investigator will be present to discuss the application but will be required to leave prior to any decisions being made.

304.10 If there is a difference of opinion amongst HREC members on any matter arising in discussion of an application, the issue will be resolved by a show of hands. On these occasions, the Chairperson will abstain from voting.

304.11 If no ethical issues are identified during the HREC review the HREC will grant ethical approval of the research project.

304.12 Written HREC approval is provided listing the approved documentation for the research.

Related Standard Operating Procedures

SOP307: Minutes of the meeting
SOP308: Delegate of the Chair
SOP309: Investigator attendance at Human Research Ethics Committee (HREC) meetings

SOP305: Conflicts of Interest (CoI) - members of RPH HREC

Function: To describe how conflicts of interest of HREC members are managed

Applicable to: The RPH HREC and its subcommittees

Version: 2.0 dated July 2016

Due for Review: July 2019

305.1 All committee members are required to sign a Conflict of Interest (CoI) declaration upon the commencement of their term.

305.2 If a committee member identifies a CoI they have before or during a meeting, they must verbally declare that interest to the Committee at the meeting and this is to be recorded in the minutes of the meeting. CoIs will be managed in accordance with the WA Department of Health Managing Conflict of Interest Policy and Guidelines.

305.3 The committee member will leave the room and will not participate in any decision-making associated with the research application with which they have an identified conflict of interest. Scientific experts invited to meetings to assist in the review of research will also be subject to the same requirements and must declare any known conflict of interest.

305.4 Where a committee member is involved in a study under review, they will be required to declare a CoI. At the time when the project is reviewed at the HREC meeting, the member may remain in the room to answer questions on the study protocol but must leave the room whilst the committee makes its deliberation on whether to approve the study. The member must not be informed of the HREC's decision at the time of the meeting but be advised in the normal manner as for any study.

305.5 The committee member's absence and return to the meeting pertaining to a CoI will be noted in the HREC minutes.

Related Standard Operating Procedures

SOP304: Human Research Ethics Committee (HREC) meetings and review process
SOP307: Minutes of the meeting

Related Website

WA Health Managing Conflict of Interest Policy and Guidelines

SOP306: Resubmission of a research application that was not approved

Function: To describe the process of submission, review and approval of an application that was not granted approval upon initial review

Applicable to: All investigators resubmitting a research application to the HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

306.1 This SOP is written in accordance with sections 5.2.13 to 5.2.15 of the National Statement, regarding communication with investigators.

306.2 If a research application has been reviewed by a EMHS HREC and has not been granted approval, a letter from the REGU will be sent to the investigator notifying them of the committee's decision. This letter will outline the issues that the committee identified during its review and encourage the applicant to resubmit the application with the changes made.

306.3 Upon receipt of this letter the investigator has two options:

1. the investigator can make the changes requested by the committee. Once the changes have been made, the investigator is required to submit the amended documentation to the REGU by the relevant submission date for the next round of meetings.
2. If the investigator has an objection to one or more of the requested changes they are able to submit these objections in a covering letter to the committee with sufficient justification for disregarding the committee's recommendations, along with any amended paperwork to the REGU prior to the submission day for review at the upcoming meeting. The committee may invite the investigator to attend the meeting to discuss these objections.

306.4 The resubmission to the HREC requesting changes should be emailed to EMHS.REG@health.wa.gov.au

306.5 Once received by the REGU, the resubmitted application will be circulated to the HREC members with the rest of the papers for the next HREC meeting.

306.6 Resubmitted applications are the first applications reviewed in any HREC meeting.

306.7 The HREC will review the resubmission and ensure the requested changes have been made.

306.8 In the case of an investigator raising objection to the HREC's requests, the committee will decide on the validity of the objections. If the investigator has been invited to attend the meeting then the investigator will be asked to answer questions and discuss the objections they have to the requested changes. The investigator is required to leave the meeting prior to the committee making its decision.

306.9 The arrival and departure of the investigator will be minuted and they will not be present during discussions regarding any application other than their own.

306.10 If the committee has not recommended the application receive approval then the process outlined above is repeated. This will continue until the committee approves the application or the investigator withdraws the application.

Related Standard Operating Procedures

SOP103: Submission to a EMHS Human Research Ethics Committee (HREC) for standard ethical review
SOP304: The Human Research Ethics Committee (HREC) meetings and review process

SOP307: Minutes of the meeting

Function: To describe the requirements and procedures governing the minuting of committee meetings

Applicable to: The Human Research Ethics Committee (HREC)

Version: 2.0 dated July 2016

Due for Review: July 2019

307.1 This SOP is written in accordance with section 5.1.37 of the National Statement and the Terms of Reference for the HREC.

307.2 It is the responsibility of the Executive Officer (EO) of each HREC to prepare the draft minutes of the HREC meeting. The minutes will be checked by the HREC Chairperson to ensure they accurately reflect both the discussions at the meeting and the decisions made by the HREC.

307.3 The minutes of the meeting will document at a minimum, the following:

- research application registration number
- title of project
- documentation submitted
- date of approval or conditional approval
- terms and conditions, if any, of approval of the project
- review stream
- the relevance, if any, of the Guidelines Under Section 95 and Section 95A of the *Privacy Act 1988* (Cth).

307.4 The minutes of the meeting will record if a core member was not present and whether a proxy/deputy was present and/or if the absent member provided written comments.

307.5 The minutes will be circulated as part of the paperwork for the next HREC meeting for ratification prior to signature by the HREC Chairperson.

307.6 The minutes of the previous month's HREC meeting will be included in the agenda papers for the HREC meeting.

Related Standard Operating Procedures

SOP303: Human Research Ethics Committee (HREC) meeting agenda
SOP304: The Human Research Ethics Committee (HREC) meetings and review process
SOP308: Delegate of the Chair
SOP401: EMHS Human Research Ethics Committee (HREC) approval

SOP308: Delegate of the Chair

Function: To describe the role of the Delegate of the Chair (DoC) of the HRECs in the review and approval process

Applicable to: All investigators submitting research applications, amendments or reports to the RPH HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

308.1 Due to the volume of administrative tasks associated with gaining ethical approval, the HREC has delegated certain duties to the position of Delegate of Chair (DoC).

308.2 The Terms of Reference of the EMHS HRECs outline the duties of the DoC.

308.3 The duties of the DoC are outlined in a letter of appointment signed by the HREC Chairperson, and given to the person nominated as DoC with a copy kept in the REGU. The DoC must be employed by EMHS and have suitable experience to undertake the duties required.

308.4 The HREC can assign, during a meeting, the responsibility of reviewing any requested changes to an application (and its documents) to the DoC.

308.5 The DoC is able to review and approve the administrative requirements necessary for the ongoing approval of research conducted within EMHS.

308.6 The DoC has the discretionary power to recommend amendments or reports have a full HREC review.

Related Standard Operating Procedures

SOP304: The Human Research Ethics Committee (HREC) meetings and review process
SOP307: Minutes of the meeting

SOP309: Investigator attendance at Human Research Ethics Committee (HREC) meetings

Function: To describe the process for having investigators attend a RPH HREC meeting

Applicable to: Investigators invited to attend HREC Meetings

Version: 2.0 dated July 2016

Due for Review: July 2019

309.1 This SOP is written in accordance with section 5.2.18 of the National Statement. The RPH HREC does not routinely invite researchers to attend its meetings to present new applications.

309.2 Investigators may be invited to attend a HREC meeting when written or telephone communication between investigators and the REGU is unable to resolve issues with a research application or; where the HREC committee requires more information from an investigator to be able to make a decision regarding an application, an investigator may be invited to attend a HREC meeting.

309.3 When attending a HREC meeting investigators are asked to answer the committee's questions and/or address the concerns members may have with the proposed conduct of the research.

309.4 Once the committee has had its questions answered the investigator is requested to leave the meeting room while the committee makes their deliberation and proceeds with the rest of the meeting.

309.5 The invited investigator is notified of the outcome of the meeting in the same manner as any investigator of research reviewed at that meeting.

Related Standard Operating Procedures

SOP304: The Human Research Ethics Committee (HREC) meetings and review process
SOP307: Minutes of the meeting
SOP308: Delegate of the Chair
SOP401: EMHS Human Research Ethics Committee (HREC) approval

SECTION 4: APPROVAL

SOP401: RPH Human Research Ethics Committee (HREC) approval

Function: To describe the process that follows ethical approval of research by the RPH HREC

Applicable to: Investigators submitting applications to the RPH HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

401.1 Once any required changes required by the HREC have been made to a submission, a HREC approval document will be created by the REGU and sent to the Coordinating Principle Investigator.

The terms of approval will be attached to the letter.

401.2 The HREC approval document will list the following information:

- Registration Number
- Site investigator and Department
- Study title
- Meeting dates
- All approved study documents (including version and date)
- The document outlines the investigator's responsibilities and obligations.

401.3 The document will be signed by the HREC Chairperson or Delegate of the Chair (DoC).

401.4 Where this is the first submission to an HREC the approval can be provided to other WA Health HREC's as evidence of prior approval. The RPH HREC becomes the 'lead' HREC for WA Health institutions in this instance.

401.5 A HREC approval is valid for a period of three years - this can be extended to a maximum of five if justified. Continued HREC endorsement is conditional on adherence to the terms of approval. The HREC can suspend HREC approval or recommend termination of the project to the Institution where necessary.

An extension to the approval period can be given once, for a period of three years. Any further extension requests will require a resubmission and be considered at the discretion of the HREC.

The HREC has the capacity to set a specific approval period depending on the level of risk and complexity of the project.

Related Standard Operating Procedures

SOP304: The Human Research Ethics Committee (HREC) meetings and review process
SOP307: Minutes of the meeting
SOP308: Delegate of the Chair

SOP402: Site authorisation

Function: To describe the process of approval once the Human Research Ethics Committee (HREC) and Research Governance have both reviewed and approved an application and recommended it for site authorisation

Applicable to: All research reviewed and approved by the HREC (its relevant subcommittee) and Research Governance

Version: 2.0 dated July 2016

Due for Review: July 2019

402.1 The HREC and the Research Governance Officer (RGO) are the reviewing bodies for the institution. It is the institution that grants final approval to conduct research at EMHS sites.

402.2 Once a review has been conducted by the HREC and RGO and approval recommended by all, the application will be presented to the authorised member of the EMHS Executive for institutional authorisation.

402.3 Once authorisation has been granted by the institution the site investigator will be notified by the REGU in writing that the research has been granted approval and that the project may commence.

402.4 The terms of approval will be attached to the letter sent to the site investigator and these must be abided by to prevent withdrawal of approval as stated in the SOP705.

402.5 A memo advising investigators of reporting requirements for SAEs, SUSARS etc will be provided with the institutional approval letter. Investigators are required to adhere to this memo as part of the conditions of approval.

402.6 All research approved by the EMHS needs to submit annual reports to the REGU. The REGU will send out a reminder one (1) month prior to the deadline for the annual report.

Related Standard Operating Procedures

SOP401: EMHS Human Research Ethics Committee (HREC) approval
SOP403: Expiry of approval
SOP404: Communication with sponsors
SOP705: Withdrawal or termination of approval to conduct research by EMHS

SOP403: Expiry of approval

Function: To explain the administrative process for granting an extension to the approval to conduct research

Applicable to: All investigators conducting research on site

Version: 2.0 dated July 2016

Due for Review: July 2019

403.1 A HREC approval is valid for a period of three years; this can be extended to a maximum of five if justified. Continued HREC endorsement is conditional on the receipt of annual reports. The HREC can suspend HREC approval or recommend termination of the project to the institution where necessary.

403.2 This expiry date will be included in the annual report form sent to all investigators at the time the annual report is due.

403.3 If the research is to continue beyond the given expiry date the investigator must submit a written request for an extension of approval to the REGU. The research should not continue beyond the expiry date without an extension being granted.

403.4 An extension to the approval period can be given once, for a period of three years. Any further extension requests will require a resubmission and be considered at the discretion of the HREC

The HREC has the capacity to set a specific approval period depending on the level of risk and complexity of the project.

The Delegate of the Chair is given the authority by the Institution to grant this extension to the approval period.

Related Standard Operating Procedures

SOP401: EMHS Human Research Ethics Committee (HREC) approval
SOP402: Site authorisation

SOP404: Communication with sponsors

Function: To describe the process of communicating with a research sponsor

Applicable to: RPH Human Research Ethics Committee (HREC)

Version: 2.0 dated July 2016

Due for Review: July 2019

404.1 This SOP is written in accordance with Section 5.2.20 of the National Statement

404.2 There will be no communication by HREC members with research sponsors in their capacity as committee members.

404.3 If a committee member identifies a potential conflict of interest (COI) with a particular sponsored research application they are required to absent themselves from the meeting and the HREC will record their identified COI in accordance with the National Statement and the WA Health Managing Conflict of Interest Policy and Guidelines.

404.4 The HREC members and HREC Executive Officer has no correspondence with sponsors. All correspondence with sponsors is undertaken by the Research Governance Officers.

Related Standard Operating Procedures

SOP106: Conflict of Interest - Investigator
SOP201: Research governance review process
SOP305: Conflict of Interest (CoI) – members of EMHS HREC

SECTION 5: FEES

SOP501: Schedule of fees

Function: To notify investigators of the fees that the EMHS charge for research review

Applicable to: All investigators submitting either a new research application or amendment for review

Version: 2.0 dated July 2016

Due for Review: July 2019

501.1 Applications for studies that are fully sponsored by external commercial agencies, e.g. pharmaceutical companies or other commercial bodies attract a submission fee. Fees are payable on submission. Additional fees may be charged for amendments, particularly those of a substantive nature. See table 501.1.

501.2 Applications by individual investigators for non-sponsored research or for grant funded applications do not attract a submission fee.

Table 501.1: 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

NOTE: Fees are exclusive of GST

* Amendments include any changes to the protocol (excluding minor administrative changes) and any contractual amendments including budget and legal revisions.

SECTION 6: AMENDMENTS

SOP601: Types of amendments

Function: To inform investigators of their responsibilities to advise the HREC of any changes to their research once approval has been granted

Applicable to: Investigators submitting amendments

Version: 2.0 dated July 2016

Due for Review: July 2019

601.1 All amendments to research projects must be submitted for review and approval by the HREC which granted approval. In the case of projects being conducted across multiple sites within WA Health, all amendments must be reviewed by the 'lead' HREC granting initial approval and this approval should then be disseminated to all other sites.

Amendments can only be made to a research project once it has received its initial institutional approval from EMHS.

601.2 Amendments are categorised as either Substantial or Administrative.

601.3 An Administrative amendment is defined as:

- corrections of typographical or grammatical mistakes
- changes in specimen handling or specimen analysis procedures
- changes in co-investigator
- changes in sponsor personnel
- changes in drug descriptor (adopting new approved name, for example, not a change in drug identity)

For the process of review for administrative amendments, please refer to SOP 602.

601.4 A Substantial amendment is defined as any change to the protocol that lies outside the definition of an "Administrative Amendment".

For the process of review for Substantial amendments, please refer to SOP 603

Related Standard Operating Procedures

SOP605: Amendments for review by Research Governance
SOP308: Delegate of the Chair
SOP602: Administrative amendments
SOP603: Substantial amendments for review by the Human Research Ethics Committee (HREC)
SOP604: Substantial amendments for WA Health multicentre research

SOP602: Administrative amendments

Function: To describe the process for the submission and approval of administrative ethics amendments

Applicable to: Investigators submitting administrative amendments to the HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

602.1 To submit an administrative amendment the following documentation is required where applicable:

- WA Health Ethics Administrative Amendment form
- Amended document with tracked changes is required for protocol amendments but is not required for investigator brochures.
- Amended Document (clean copy)

Documents should be submitted by email to the REGU at EMHS.REG@health.wa.gov.au

602.2 Administrative amendments are not reviewed by a HREC. Administrative amendments are reviewed by the Delegate of the Chair (DoC) on behalf of the HREC. Details of the amendment will be entered on the database.

602.3 If the amendment is the inclusion of a new document (e.g. an advertisement or poster) then a tracked copy is not required.

602.4 When submitting a revised investigator brochure that is not part of a protocol or information sheet amendment, the investigator should advise the HREC that they have read the document and whether or not the changes in the brochure will impact on the conduct of the trial.

602.5 Once the amendment is approved the REGU will then issue a letter. All amendments are tabled at the next month's HREC meeting as information only.

602.6 The Terms of Reference of the EMHS HRECs designate the power of approval for all amendments to the DoC. An amendment is considered approved from the date the letter is signed.

602.7 The DoC has the capacity to refer any amendment to the relevant HREC for review.

Related Standard Operating Procedures

SOP308: Delegate of the Chair
SOP601: Types of amendments

SOP603: Substantial amendments for review by the Human Research Ethics Committee (HREC)

Function: To describe the process for the submission and approval of substantial amendments by the HREC

Applicable to: Investigators submitting substantial amendments for research which was reviewed and approved by the HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

603.1 This SOP is only applicable where the RPH HREC is the initial approving WA Health HREC (the 'lead' HREC). Projects where ethical approval has been gained elsewhere in WA Health should submit ethics amendments to the lead HREC and provide the REGU with a copy of the amendment and the subsequent approval. In cases where the substantive amendment warrants a change to site specific documentation these documents must be submitted to the EMHS Research Governance Officer (RGO) within the REGU.

603.2 The submission deadlines for substantial amendments are dictated by the submission schedule as substantial amendments are reviewed by the full HREC. This schedule is available on the EMHS Research Ethics and Governance website.

603.3 Substantial amendments must be submitted to the REGU on the WA Health Substantial Ethics Amendment Form.

In addition to the WA Health Substantial Ethics Amendment Form, investigators must also submit:

- amended documents with tracked changes
- a clean copy of the amended documents

REGU request investigators to include in their submission a list of documents being submitted including version numbers and dates.

For Investigator's Brochure amendments a tracked changes version is not required.

603.4 Once received by the REGU and entered onto the database the amendment application will be distributed to the HREC.

603.5 Substantial amendments are reviewed after the new trials. The HREC may request further information or changes from investigators before approving amendments.

603.6 If the HREC has requested changes to the amendment a letter will be sent to the investigator by the Executive Officer notifying them of the requested changes. The reply may then be reviewed by the Chairperson of the HREC.

603.7 Following HREC approval of a substantial amendment, site authorisation still needs to be obtained before the amendment can be implemented.

Related Standard Operating Procedures

SOP304: The Human Research Ethics Committee (HREC) meetings and review process
SOP601: Types of amendments

SOP604: Substantial amendments for WA Health multicentre research

Function: To describe the process for the submission and approval of substantial amendments to a WA Health HREC

Applicable to: Investigators submitting substantial amendments where a WA Health HREC has approved the research

Version: 2.0 dated July 2016

Due for Review: July 2019

604.1 Where the RPH HREC is an accepting HREC (ie. the research has had ethical approval from another HREC) the HREC approval from the lead HREC should be submitted along with a copy of the approved documentation.

604.2 All substantial amendments of multicentre research being undertaken at EMHS will require a site specific review by Research Governance prior to the amendment being approved at EMHS (see SOP605).

Related Standard Operating Procedures

SOP101: Types of ethical review of submitted applications
SOP601: Types of amendments

SOP605: Amendments for review by Research Governance

Function: To describe the process for the submission and approval of amendments by Research Governance

Applicable to: Investigators and Study Coordinators

Version: 2.0 dated July 2016

Due for Review: July 2019

605.1 The definition, submission requirements, review and approval process of amendments are outlined in SOP601-604. There are two categories of amendments:

1. Administrative amendments
2. Substantial amendments

605.2 In line with the two-part approval process for all research studies, amendments to research projects must satisfy both ethical and institutional requirements in order to be approved.

WA Health has developed specific Governance amendment submission forms.

The RGO must review the proposed amendment and ensure the continuation of the ethical, legal and professional standards of the research study. The review also ensures that the amendment does not impact on the safety of study participants or increase the risk to the staff and institution.

605.3 Substantial amendments must be submitted to the REGU on the WA Health Substantial Governance Amendment Form.

Unless already provided as part of the Substantial Ethics Amendment to REGU (see SOP603), in addition to the WA Health Substantial Governance Amendment Form, investigators must also submit:

- amended documents with tracked changes
- a clean copy of the amended documents

The REGU requests investigators to include in their submission a list of documents being submitted including version numbers and dates.

For Investigator's Brochure amendments a tracked changes version is not required.

605.4 Where the RPH HREC is an accepting HREC it is necessary to include:

- amended documents with tracked changes
- a clean copy of the amended documents

The REGU requests investigators to include in their submission a list of documents being submitted including version numbers and dates.

For Investigator's Brochure amendments a tracked changes version is not required.

605.5 Upon review, the RGO will:

- determine if the amendment will result in any changes to the research study's vital documents (e.g. CTRA or CTN)

- assess if the amendment will be included under the existing insurance provisions.
- conduct a site specific assessment to determine if the amendment has additional impact on any department within EMHS
- assess whether the amendment documentation includes all the required changes and updated documents.

605.6 Where the amendment has been assessed as complete and correct, and ethical approval has been obtained, the RGO will recommend the amendment be approved. The amendment can then be implemented.

605.7 Where RGO determines the amendment documentation is incomplete or identifies issues that have not been addressed or considered by the study team, the study team will be contacted by email and the issues outlined. The RGO will request further information or updated documentation where required.

605.8 Once the study team has responded to the RGO and clarified or corrected any outstanding issues, the RGO will recommend approval of the amendment to Executive or delegate.

Related Standard Operating Procedures

SOP402: Site authorisation
SOP601: Types of amendments

SECTION 7: MONITORING

SOP701: Adverse Event Reporting

Function: To inform investigators conducting research of their responsibilities for the reporting of Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs) and Protocol Deviations or Violations

Applicable to: All investigators conducting research approved by the RPH HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

701.1 Please be advised that RPH HREC does not require sponsors or investigators to submit individual reports of Serious Adverse Events (SAEs) that do not occur at EMHS sites. EMHS has adopted the reporting requirements outlined in the NHMRC AHEC Position Statement May 2009.

701.2 Where multicentre research is conducted within WA Health, adverse event reporting should be submitted to the lead HREC in line with its reporting requirements.

701.3 Reporting requirements are summarised in the Table 701.1 below.

701.4 Investigators are required to review submitted SAE reports, SUSAR reports and other safety reports and indicate whether any action will be taken as result of the event.

701.5 Depending on the event being reported the WA Health monitoring forms must be used. These forms are available on the WA Health website and include:

- WA Health Adverse Event Notification Form
- WA Health Protocol Deviation/Violation Notification Form

Forms must be completed and submitted to the REGU by email EMHS.REG@health.wa.gov.au

701.6 When submitting a revised investigator brochure that is not part of a protocol or information sheet amendment, the investigator should advise the HREC that they have read the document and whether or not the changes in the brochure will impact on the conduct of the trial.

701.7 Protocol violations are those variations to a protocol that implicate participant consent, participant safety or data integrity that compromise the ethical acceptability of the project, and, require retrospective notification to or review by a HREC, only when they impact upon the safety of the participant. Protocol deviations relate to other matters and do not require notification to or review by a HREC.

701.8 The Delegate of the Chair (DoC) has the discretion to send any of the above reports to the HREC Chairperson (that conducted the initial review) or HREC for review. The HREC Chairperson will take the matter to the next meeting or it can be dealt with out of session if the matter is urgent. The Chairperson will then recommend a course of action to the DoC.

701.9 The DoC will either outline a course of action to be taken or acknowledge any of the above reports.

Table 701.1

Type of Reporting	Event
24 hours (death) 72 hours (other)	SAE occurring on site
In a prompt manner	Information which materially impacts the continued ethical acceptability of the study; or Information that requires, or indicates the need for a change to the study protocol including changes to safety monitoring as recommended by the Investigator or Sponsor.
Six monthly	A list of all SUSARS, Australian and international, related to the use of a compound, including Sponsor and Investigator comments regarding any planned action based on the events reported
Annually	An updated Investigator's Brochure; or an EU ASR (or similar format report); or current, approved Product Information, if appropriate, e.g., in a study for a product approved in Australia or where an Investigator's Brochure is no longer maintained; or other reports consistent with *section 5.5.5* of the National Statement and Good Clinical Practice as adopted by the Therapeutic Goods Administration.

Related Standard Operating Procedures

SOP308: Delegate of the Chair
SOP705: Withdrawal or termination of approval to conduct research by EMHS

SOP702: Annual reports

Function: To describe the requirement for investigators to submit annual reports to the RPH Human Research Ethics Committee (HREC)

Applicable to: All investigators who have had research approved by the RPH HREC

Version: 2.0 dated July 2016

Due for Review: July 2019

702.1 This SOP is written in accordance with section 5.5.5 of the National Statement and the Terms of Reference EMHS HRECs.

702.2 Once site authorisation has been granted by EMHS the investigator is required to submit annual reports on the progress of the approved research regardless of which WA Health HREC granted approval. Each site investigator is required to submit an annual report specific to the running of the study at their site. The lead HREC will receive both an annual report for their site and a state-wide annual report.

702.3 Annual reports are due on the anniversary of the date that the research was granted HREC approval. The REGU will send a reminder email to the investigator one (1) month prior to the due date.

702.4 The WA Health Annual Progress Report Form must be completed correctly and returned to the REGU by the due date.

702.5 The progress report should include but is not limited to:

- publications
- adverse events (SAE's, SUSAR, SAR, SADR) and any changes arising from these events
- staffing changes
- findings
- slower or better than expected recruitment or results
- whether the project is progressing as expected.

702.6 Failing to submit annual reports can lead to suspension of approval for the research.

702.7 For clarity of process, annual reports should be submitted separately to any amendments or other requests.

702.8 Annual reports are to be submitted to the REGU where they will be entered on the database.

The report is then forwarded to the Delegate of the Chair (DoC) for review. Once approved a letter is sent to the investigator and the report tabled at the next HREC meeting.

Related Standard Operating Procedures

SOP303: Human Research Ethics Committee (HREC) meeting agenda
SOP307: Minutes of the meeting
SOP308: Delegate of the Chair
SOP403: Expiry of approval
SOP705: Withdrawal or termination of approval to conduct research by EMHS

SOP703: Final reports

Function: To describe the process for the submission of a final report

Applicable to: All investigators that have had research reviewed and approved by the RPH Human Research Ethics Committee (HREC)

Version: 2.0 dated July 2016

Due for Review: July 2019

703.1 This SOP is written in accordance with section 5.5.5 of the National Statement and the Terms of Reference EMHS HREC.

703.2 Once the research project has been closed and/or the final close out visit with the investigator is completed a final report and project summary for WA Health as a whole is required to be sent to the lead HREC. Once this final report is received and approved, this final report and the acknowledgement letter from the lead HREC should be circulated to all other WA Health institutions where the research has been conducted.

For single site research projects the investigator should provide the HREC with a final report and trial summary.

703.3 The WA Health Final Progress Report Form is only to be submitted to the HREC once all involvement with the research has been or is being finalised. A report should not be listed as final in the case of recruitment completion or at the close of any other than the final stage of the project.

703.4 It is the responsibility of the investigator to complete and submit final reports.

703.5 In addition to the final report form investigators are required to submit a progress report on the outcome of the project. This should include but is not limited to:

- publications arising as a result of the research
- adverse events (SAE's, SUSAR, SAR, SADR) and any changes arising from these events
- staffing changes
- findings
- slower or better than expected recruitment or results
- whether the project has progressed as expected
- whether the aims of the research have been met.

703.6 Final reports should be emailed to the REGU at EMHS.REG@health.wa.gov.au

703.7 When a final report has been received by the REGU it will be processed and given to the Delegate of the Chair (DoC) for review and approval. Once approved the report will be tabled at the next HREC meeting. A letter will be sent to the investigator stating that the research is closed and that all documentation held by the REGU in relation to this study will be archived.

Related Standard Operating Procedures

SOP303: Human Research Ethics Committee (HREC) meeting agenda
SOP307: Minutes of the meeting
SOP308: Delegate of the Chair
SOP403: Expiry of approval
SOP702: Annual reports

SOP704: Suspension or early termination of research by sponsor or investigator

Function: To describe the procedures governing the suspension or early termination of a research project granted approval by the RPH HREC

Applicable to: All research that has RPH HREC approval where early termination occurs

Version: 2.0 dated July 2016

Due for Review: July 2019

704.1 This SOP is written in accordance with section 5.5.6 of the National Statement.

704.2 When notifying the RPH HREC of the suspension or termination of research by investigators or a sponsor it is required (as stated in the Terms of Approval) that the investigator provide the HREC with the reasons for the decision.

704.3 Notification of suspension or early termination must be done using the WA Health Suspension/Early Termination Notification Form which should be emailed to the REGU at EMHS.REG@health.wa.gov.au

704.4 On receipt of the notification, the REGU will enter it on the database and forward it to the Delegate of the Chair (DoC) for review.

If the research is terminated the DoC will request a final report and information (if not provided) of what action is being taken to ensure the safety and ongoing care of participants.

If the research is suspended the DoC will request information (if not provided) of what action is being taken to ensure the safety and ongoing care of participants.

704.5 If a suspended project is to be recommenced, the investigator is required to notify the REGU and receive written notification from the RPH HREC and EMHS Executive that this is acceptable prior to restarting research within the EMHS.

704.6 The DoC has the discretion to refer both the initial notification of research termination/suspension and the request to recommence such research to the relevant HREC and EMHS Executive.

Related Standard Operating Procedures

SOP308: Delegate of the Chair
SOP401: EMHS Human Research Ethics Committee (HREC) approval
SOP402: Site authorisation
SOP703: Final reports

SOP705: Withdrawal or termination of approval to conduct research by EMHS

Function: To describe the process EMHS will undertake in the event that research breaches the Terms of Approval

Applicable to: Any research that has failed to meet the terms of approval or whose conduct has breached the National Statement

Version: 2.0 dated July 2016

Due for Review: July 2019

705.1 This SOP is written in accordance with sections 5.5.7 and 5.5.8 of the National Statement.

705.2 All research granted approval by EMHS must continue to meet the standards described in the National Statement as well as the Terms of Approval set down by EMHS.

705.3 If research does not meet the requirements as stated above, then the Human Research Ethics Committee (HREC) or Research Governance Officer (RGO) may recommend suspension of the approval of a research project to the EMHS Executive.

The EMHS Executive reserves the right to suspend institutional approval of any previously approved research project without recommendation from the HREC or RGO.

705.4 This process must ensure that the investigators and all those associated with the project are treated with fairness and respect.

705.5 The EMHS Executive may withdraw approval for research in accordance with Section 5.5.7 of the National Statement. The investigator will be notified in writing by EMHS that approval has been withdrawn including the reasons for this decision.

705.6 If approval is withdrawn from a research project, the investigator should immediately suspend the research.

705.7 Investigators and the institution should make arrangements to meet the needs of the participants in the research in accordance with Section 5.5.8 of the National Statement.

705.8 If the EMHS Executive considers that urgent suspension of research is necessary, this notification will come via the Executive of the EMHS in the form of a telephone call or email. Such suspension will be confirmed in writing within 24 hours.

705.9 Investigators will be given the opportunity to assure the EMHS Executive that the conditions set out in 5.5.8(c) of the National Statement have been met. This will be reviewed by the HREC and RGO and a recommendation made to the EMHS Executive as to whether the research should recommence.

705.10 If the case for recommencement of the research is accepted by the EMHS Executive the investigator will be notified in writing by the EMHS Executive that the trial can resume.

705.11 If the case for recommencement of the research is not accepted by the EMHS Executive the withdrawal of approval will stand and the research will be closed.

Related Standard Operating Procedures

SOP308: Delegate of the Chair
SOP401: EMHS Human Research Ethics Committee (HREC) approval
SOP402: Site authorisation
SOP703: Final reports

SOP706: Record keeping

Function: To describe the process for the retention and handling of research project data and paperwork

Applicable to: The Research Ethics and Governance Unit

Version: 2.0 dated July 2016

Due for Review: July 2019

706.1 **Research Records**

All records of research proposals received and reviewed are maintained in accordance with the National Statement 5.2.24 and the WA Department of Health Operational Directives such as Patient Information Retention and Disposal Schedule Version 4, 2014.

706.2 **Confidentiality**

All data provided to the REGU, including details of research and contact information is kept private and confidential.

706.3 Only those staff members involved in the research that is the subject of an inquiry may access the REGU records.

706.4 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 REGU.

706.5 **Archiving**

The REGU retains and archives records in accordance with the Department of Health Record Keeping Plan.

When paperwork is received in the REGU it is processed and filed. After a file grows beyond what can be retained in a single volume the original volume will be closed and a new volume opened.

Active project files are kept in the REGU until a final report is received. Once a final report is received the database is updated to indicate the project is closed and the files will be archived.

SECTION 8: COMPLAINTS

SOP801: Complaints about the conduct of a research project

Function: To describe the mechanism for receiving, handling and responding to complaints concerning the conduct of an approved research project

Applicable to: All participants, research and other interested persons

Version: 2.0 dated July 2016

Due for Review: July 2019

801.1 This SOP is written in accordance with section 5.6 of the National Statement and the Terms of Reference EMHS HRECs.

801.2 Regardless of which WA Health HREC provided ethical approval for the project if the complainant attended and/or the complaint is regarding a research project that was undertaken in a EMHS hospital / Health Service, the complaint should be directed to the REGU.

801.3 The REGU and contact details are provided on all consent forms used for research projects conducted within EMHS. These contact details are also available from the EMHS Research Ethics and Governance website.

The REGU shall nominate a person to whom complaints from research participants, investigators or other interested persons about the conduct of approved research projects may be made in the first instance. Currently the nominated person is the Education and Compliance Monitoring Officer.

801.4 The nominated person is responsible for obtaining in writing the grounds of the concern or complaint and shall notify the RPH HREC Chairperson and EMHS Executive Director (or delegate) as soon as possible after a complaint is received.

801.5 The REGU will send a letter of acknowledgement to the complainant and a letter of notification to the principle investigator within 5 working days, outlining the complaint and the mechanism for investigating the complaint, as set out below.

801.6 The REGU nominated person will instigate an investigation of the complaint and its validity and provide a report to the relevant HREC. This investigation shall take no longer than 30 working days from the time of notification of the complaint or concern, unless exceptional circumstances exist.

801.7 The report will be tabled at the relevant HRECs next available meeting for discussion and decision. If the complaint is substantiated, the HREC actions may include:

- the requirement for amendments to the project, including increased monitoring by the HREC
- suspension of the project
- termination of the project
- other action to resolve the complaint.

801.8 The complainant shall be informed of the HREC's decision.

801.9 If the complainant is not satisfied with the outcome of the investigation and the HRECs decision, then he/she can refer the complaint to the EMHS Executive Director or his/her nominee, or request the REGU to do so.

801.10 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, REGU and the HREC Chairperson of this.

801.11 Where the complaint concerns a matter other than the conduct of a research project the complaint shall be referred to Patient Liaison Services and the Executive Director informed.

Related Websites

National Statement on Ethical Conduct in Human Research 2007
Australian Code for the Responsible Conduct of Research 2007
WA Health Complaint Management Policy

SOP802: Complaints concerning the HREC's review process

Function: To describe the procedure for receiving and handling concerns or complaints from investigators about the HREC's review process

Applicable to: All participants, research and other interested persons

Version: 2.0 dated July 2016

Due for Review: July 2019

802.1 This SOP is written in accordance with section 5.6 of the National Statement National Statement and the Terms of Reference EMHS HRECs.

802.2 Any concern or complaint received about a HREC's review process should be directed to the attention of the HREC Chairperson, detailing in writing the grounds of the concern or complaint. Such complaints should be sent to the REGU. The information can be sent by either letter or email.

802.3 The REGU will send a letter of acknowledgement to the complainant within 5 working days outlining the following mechanism that will be followed.

802.4 The HREC Chairperson will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than 30 working days from the time the notification of the complaint or concern, unless exceptional circumstances exist.

802.5 The complainant shall be informed of the outcomes of the HREC Chairperson's investigation.

802.6 If the complainant is not satisfied with the outcome of the HREC Chairperson's investigation, then he/she can refer the complaint to the Director of Research Development, or his/her nominee, or request the HREC Chairperson to do so.

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

802.8 The Director of Research Development will notify the complainant and the HREC of the outcome of any further investigation.

Related Websites

National Statement on Ethical Conduct in Human Research