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

# EMHS Research Governance
# **Standard Operating Procedures**

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# 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 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 was implemented to ensure that all human research conducted within WA Health meets the highest ethical, scientific and regulatory standards and complies with relevant national and state legislation, guidelines and codes of conduct. It is recognised that high quality, accountable and responsible research underpins the delivery of contemporary health policy and practice.

The policy establishes the framework through which research is reviewed, approved, conducted and monitored in an effective and efficient manner. In line with this framework, East Metropolitan Health Service (EMHS) has a three-tiered system of research governance consisting of:

- **Ethical and scientific approval** granted by a Human Research Ethics Committee (HREC)
- **Site authorisation** following research governance review.
- **Monitoring** by HRECs and sites throughout the project life cycle.

EMHS has a centralised process for research governance approvals and monitoring. The **EMHS Research Hub** oversees ethical and research governance reviews of proposed research and monitors approved projects for each of the EMHS hospitals and services. The purpose of these SOPs is to ensure EMHS has research governance processes that are effective but efficient and serve to facilitate high quality responsibly conducted research.

## 2.1 Scope

These procedures, and the mandatory WA Health Research Governance Policy and Procedures 2012 which they operationalise, apply to the governance of research projects only.

EMHS has specific processes in place for the review and approval of non-research projects, including **audits, quality assurance, service improvement and evaluation initiatives**. These processes are overseen by institutional safety and quality teams. Staff planning to conduct such projects should contact these teams.

| | | |
|---|---|---|
| Armadale Kalamunda Group | Safety, Quality, Education and Innovation | (08) 9391 2526 |
| Royal Perth Bentley Group | Clinical Safety & Quality Unit | (08) 9224 2238 |

The EMHS Research Hub can assist staff to correctly classify a project and ensure the required approvals are obtained. If this advice is required, staff should contact the Research Hub prior to commencing the project. The following guide will assist staff to classify projects:

*Quality Assurance versus Research Guide*

The publication of a **case report or series** is considered anecdotal and can proceed without research ethics and governance approval. The following guide provides for more information:

*Case Studies and Series*

## 2.2 Ethical and scientific review of research projects

The primary role of Human Research Ethics Committees (HRECs) is to protect the welfare and the rights of research participants. HRECs assess submissions against the ethical principles and parameters enshrined in the NHMRC National Statement on Ethical Conduct in Human Research (National Statement), to ensure projects are scientifically and ethically sound.

An HREC must review and approve human research to ensure it is:

- ethically sound according to the principles of merit, integrity, justice, beneficence and respect as specified in the National Statement;
- scientifically sound, designed using methods appropriate for achieving the aims of the research proposal and based on a thorough study of current and historical literature.

The **Royal Perth Hospital (RPH) HREC** is the EMHS-based research ethics committee and meets monthly at RPH. It is registered with the NHMRC and operates under Terms of Reference that comply with Chapter 5 of the National Statement.

In line with initiatives to reduce the duplication of ethical review of research, EMHS accepts the ethical approval of:

- other WA Health HRECs, under the WA Health Single Ethical Review process
- NHMRC-certified HRECs, under the National Mutual Acceptance (NMA) Scheme

The HREC must only consider the ethical and scientific issues when reviewing a research project. Matters of research governance and final authorisation related to the conduct of research at EMHS sites must be conducted by a Research Governance Officer (RGO) responsible for those sites.

## 2.3 Research governance review

Before a research project can start at an EMHS site, a research governance review must be completed, and the project receive 'site authorisation' from the Chief Executive or their Delegate at a specific site. The research governance review at all WA public health services involves review of a "Site Specific Assessment (SSA) Form" or "Access Request Form" and associated documents by a Research Governance Officer (RGO). Within EMHS, the RGOs are part of the EMHS Research Hub.

The research governance review includes a comprehensive assessment to confirm the project is:

- Feasible
- Adequately resourced (monetary; in-kind; physical resourcing and equipment)
- Conducted by authorised and appropriately qualified personnel working at suitably equipped sites
- Able to be conducted in a safe and responsible manner in compliance with regulatory and professional standards, legislation and codes of conduct at the State and national level 22

The RGO makes a recommendation to the Chief Executive (or Delegate; usually the hospital Executive Director) as to whether the research project should be authorised to commence at that specific health service site. EMHS retains the right not to authorise commencement of a research project, even if an HREC has granted ethical approval.

## 2.4 Monitoring of approved research

HRECs must monitor research to ensure that approved projects are conducted ethically, and in accordance with the approved protocol, including approving protocol amendments, reviewing safety reports and tracking progress via at least annual progress reports and final reports. Similarly, the EMHS Research Hub is responsible for site-specific monitoring of the conduct of research projects at EMHS sites, to ensure that authorised projects are conducted with integrity and in compliance with the protocol and any site-specific conditions of approval.

## 2.5 Research Governance Service (RGS)

The RGS is a centralised IT system for researchers, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices. It provides a single platform for the review, approval, monitoring and reporting of research projects through their life cycle including ethics approval, site authorisation, monitoring and publications.

The RGS must be used for all research ethics and governance applications involving WA public health organisations: www.rgs.health.wa.gov.au

The EMHS Research Hub has created a guide that takes first time RGS Users step-by-step through ethics and governance submissions with tips to help navigate the system:

*RGS User Guide*

# 3. CONTACTS

The **EMHS Research Hub** maintains extensive information about research governance processes and up-to-date contact information at: www.emhs.health.wa.gov.au/research

All contact with Research Hub staff, and correspondence with the RPH HREC and its Chairperson, must be via official emails and phone numbers.

**Location:** Level 2 (Ground Floor), Kirkman House, 10 Murray Street, Perth WA
**Phone:** +61 8 9224 2260 or +61 8 9224 2292
**Email:** EMHS.REG@health.wa.gov.au

The Research Hub has an ‘open door’ policy and encourages staff to visit to discuss current of planned projects. While appointments are not necessary, if a matter is complex or extensive advice is likely to be required it is preferable to book an appointment.

# 4. REFERENCE DOCUMENTS

Researchers should be familiar with the following key documents when developing research projects, assessing feasibility and preparing research ethics and governance submissions:

- WA Health Research Governance Policy and Procedures
- Multi-centre research Standard Operating Procedures
- National Statement on Ethical Conduct in Human Research (NHMRC)
- Australian Code for the Responsible Conduct of Research (NHMRC)
- Australian Clinical Trial Handbook (TGA)
- ICH Guideline for Good Clinical Practice (TGA)

# 5. STANDARD OPERATING PROCEDURES

## SOP001: Overview of research approvals and monitoring at EMHS

**Version:** 3.0 May 2021

**Review:** May 2024

001.1 All research involving humans conducted within EMHS requires both ethical (including scientific) approval and institutional site authorisation to commence. Research may involve patients, staff, data, samples or information.

001.2 Institutional approval for research will be granted only after an *ethical approval* has been obtained from a Human Research Ethics Committee (HREC) or alternative review mechanism and a governance review recommending *site authorisation* is received by the Chief Executive or Delegate.

001.3 Quality assurance/improvement/audit projects do not require research ethics or governance approval. These projects are reviewed and approved by institutional (typically Service-level) committees following submission via the *Governance, Evidence, Knowledge and Outcomes (GEKO)* online system. GEKO submissions and the review and monitoring of QI/audit projects are managed by institutional Safety and Quality Offices. See: Scope

001.4 Submissions for research ethics and governance review and subsequent monitoring reports must be made via the WA Health Research Governance Service (RGS). The RGS is a centralised IT system for researcher, sponsors, site administrators, HRECs and Research Governance Offices. It facilitates the submission, approval, monitoring and reporting of research projects through their life cycle including ethics approval, site authorisation, monitoring and publications. The RGS is specifically designed to support multi-centre research conducted across multiple WA Health Service Providers (HSPs) and Australia-wide multi-jurisdictional projects.

001.5 Research projects must receive ethical approval from an HREC or alternative review mechanism that is compliant with Chapter 5 of the National Statement. Institutions may also exempt some projects from ethical review (National Statement s5.1.22 & s5.1.23). See SOP106 for more information about when an exemption is warranted.

001.6 Where a project has already received ethical approval from a WA Health HREC, and this approval is current, EMHS sites can be added by amendment to the existing ethical approval with need for another review. See SOP102 for more information about the *WA Health Single Ethical Review Scheme.*

001.7 For research involving sites across multiple Australian jurisdictions, EMHS sites will accept ethical approval granted by an NHMRC-certified 'Lead' HREC.

001.8 Research that meets low or negligible risk criteria set out in National Statement may be approved via a non-HREC alternative review pathway, including the EMHS Low Risk Panel. The ethical review process for low risk applications within EMHS is described in SOP105. Where a waiver of consent is sought for low risk research, such a request must be reviewed by the HREC.

001.9 Research projects must also undergo a site governance review prior to institutional approval ('site authorisation') being granted and the project commencing at that site:

- Site governance reviews can occur concurrently with the ethical and scientific review, provided all documentation has been submitted, although the final Site Authorisation cannot be signed until the ethical approval is finalised.
- Refer to SOP201 for information about the governance review process and the documentation requirements for submissions.

001.10 EMHS will grant institutional approval ('site authorisation') to research projects that have received ethical (including scientific) approval and undergone a governance review at site, followed by site authorisation by the CE or Delegate.

001.11 **Delegation of Authority:** The WA Minister for Health (in their capacity as the deemed Board of the Metropolitan Public Hospitals) has appointed the Director General of the Department of Health as the accountable authority for the WA health system entities. The responsibility for research governance and the authority for signing agreements on behalf of the State are delegated from the Director General to the EMHS Chief Executive. Within EMHS this responsibility has been further delegated to the following positions, as documented in the Authorisations and Delegations Schedule:

- Executive Director, Armadale Kalamunda Group (AKG)
- Executive Director, Royal Perth Bentley Group (RPBG)

001.12 Site authorisation does not have an expiry date but is predicated on ongoing HREC approval and continued compliance with conditions of approval. If an HREC suspends ethical approval, a project must be suspended at all sites that rely on that ethical approval.

001.13 All approved and authorised research projects must be monitored by the Lead HREC, Specialist HREC (if applicable) and RGO(s) throughout the lifetime of the project. Monitoring ensures that research complies with the approved/authorised protocol and any special conditions of approval/authorisation, and that changes to project protocol only occur with prior approval of the HREC and authorisation by the site. Monitoring must occur via the receipt of amendments, progress reports, final reports and safety reports from the CPI and PI via RGS. Audits may also be used by the site, HREC or sponsor to further monitor the project.

# SECTION 1: ETHICAL REVIEW

## SOP101: Overview of research ethics approval

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101.1 The primary purpose of ethical review is to protect the welfare and the rights of research participants. HRECs, or alternative review mechanisms, assess proposed research projects against the ethical principles and parameters in the NHMRC National Statement, to ensure they are scientifically and ethically sound.

101.2 The HREC, or alternative review mechanism, must only consider the ethics and scientific merit of a proposed research project. Matters related to the conduct of research at EMHS sites must be considered by the RGOs and CE/Delegates responsible for those sites. This distinction, and separation of duties, is essential to single ethical review, where a single HREC will consider the ethical and scientific merits of a project but individual sites independently determine if the project is feasible and can be supported.

101.3 In line with efforts to streamline and reduce duplication of ethical review, the level and pathway of review depends on the nature and risk profile of the project and the number and location of sites. On overarching principle is that research projects that require ethical approval should only be reviewed once by a single 'Lead' HREC. An exception applies to projects that require additional specialist HREC review in WA (See SOP101.6).

101.4 The types of ethical review are:

- Review by a Human Research Ethics Committee (HREC) (See SOP107)
- Review by an alternative (low or negligible risk) review mechanism (See SOP105)
- Exemption from ethical review (See SOP106)

The type of ethical review required for any specific project is at the discretion of the site.

101.5 The HREC review may be conducted by:

- A WA Health HREC (under WA Health Single Ethical Review) (See SOP102)
- An NHMRC-certified HREC (under the NMA Scheme) (See SOP103)

101.6 In WA certain research projects require review by a specialist HREC *in addition* to being granted ethical approval by another HREC (including NMA-certified HRECs) (See SOP104). The specialist WA HRECs are:

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

101.7 An ethical approval confirms that a proposed research project is ethically acceptable. It does not provide authorisation to commence any active part of the project, including recruitment or data collection. A site-specific research governance review (SOP201) must be completed and authorisation to conduct the project granted by the relevant CE/Delegate before the project can commence at any given site. An ethical approval, listing the site, is a requirement for site authorisation to be granted.

# SOP102: WA Health Single Ethical Review

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102.1 For research projects involving only a single EMHS site or multiple sites within the WA Health public system, the WA Single Ethical Review process must be used. Under this process, all single and multi-site research projects must be ethically and scientifically approved only once by a WA Health HREC (the 'Lead HREC') or LNR alternative review mechanism. An exception applies to projects that require additional review by a specialist HREC (See SOP101.6).

102.2 The Lead HREC is typically the HREC for one of the participating sites, most often for the site where the Coordinating Principle Investigator (CPI) is based. However, any WA Health HREC may act as the Lead HREC if it agrees to undertake the ethics review and ongoing monitoring responsibilities for the project.

102.3 WA Health HRECs vary in their specialisations (types of research; expertise of medical/scientific members). For multi-site projects, the CPI and site Principle Investigators (PIs) should work together and liaise with the candidate HRECs to determine which HREC is ideally suited to review and monitor any given project. The intention of single ethical review is not only to reduce duplication of review, but to direct projects to the most suitable HREC. See the list of WA Health HRECs here.

102.4 WA Health Single Ethical Review can occur using either:

- the WA Health Ethics Application Form (WAHEAF)
- the Human Research Ethics Application (HREA) and WA-Specific Module (WASM)

In practice, the WAHEAF is better suited and preferred by HRECs for projects that will only be undertaken within WA Health while the HREA/WASM are optimised for multi-site, multi-jurisdictional projects.

# SOP103: National Mutual Acceptance (NMA)

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103.1 For research involving sites across multiple states including at least one EMHS site, the National Mutual Acceptance (NMA) scheme should be used to enable efficient ethical review by a single Lead HREC.

103.2 The NMA scheme is a national system for the mutual acceptance of ethical and scientific review of multi-site research projects conducted in publicly funded health services across multiple states. Like the WA Health Single Ethical Review process, it reduces the historic duplication of ethical review of multi-site, multi-jurisdictional research projects.

103.3 An NMA Memorandum of Understanding (MoU) is in place between all participating state and territory governments and sets out the arrangements to achieve single ethical and scientific review of multi-site research projects under the scheme. The Director General signs the NMA MoU on behalf of all WA Health Service Providers (HSP) including EMHS.

103.4 Under the NMA scheme a research project undergoes ethical and scientific review only once by a Lead HREC. An exception applies to projects that require additional Specialist HREC review within WA (See SOP101.6). The Lead HREC must be a *Certified Reviewing HREC* under the NMA scheme.

103.5 Three WA Health HRECs can provide Lead HREC approval for inter-jurisdictional research under the NMA scheme:

- Child and Adolescent Health Service HREC
- Sir Charles Gairdner and Osborne Park Health Care Group HREC
- South Metropolitan Health Service HREC

103.6 Each of the WA Health NMA certified HRECs is certified to undertake NMA review of research for specific certification categories, as detailed in the table below.

| HREC | Certification period | Certification categories |
|---|---|---|
| Child and Adolescent Health Service HREC | Continuous from 1 July 2020 | Clinical trials phase I, II, III, IV<br>Clinical trials drugs and devices<br>Clinical interventional research other than clinical trials<br>Population health and/or public health<br>Qualitative research<br>Mental health<br>Paediatric research<br>Other health and medical research (observational / non-clinical intervention) |
| Sir Charles Gairdner and Osborne Park Health Care Group HREC | Continuous from 1 July 2020 | Clinical trials phase I, II, III, IV<br>Clinical trials drugs and devices<br>Clinical interventional research other than clinical trials<br>Population health and/or public health<br>Qualitative research |
| South Metropolitan Health Service HREC | Continuous from 1 July 2020 | Clinical trials phase I, II, III, IV<br>Clinical trials drugs and devices<br>Clinical interventional research other than clinical trials |

103.7 EMHS staff initiating a national or multi-jurisdictional research project should approach one of these WA Health NMA certified HRECs to conduct the ethical and scientific review for their project. However, under the NMA a WA Health-based CPI can request that any of the NMA certified HRECs across the country conduct the ethical and scientific review for their project and should discuss which certified HREC is most suitable for their project with their interstate collaborators and candidate HRECs. The full list of NMA certified HRECs is available here.

103.8 The HREA must be used for ethics review under the NMA scheme. For projects conducted at EMHS sites, submission of the WASM is also required. The WASM is a WA-specific addendum to the HREA that assists the Lead HREC understand and apply WA legislative requirements that apply to the project.

103.9 EMHS staff initiating multi-site, multi-jurisdictional research projects must understand the functions and responsibilities of the Coordinating Principle Investigator, which include submitting the ethics application to the Lead HREC, wherever it is based in Australia, and acquitting all monitoring responsibilities for the life of the project.

# SOP104: Specialist Human Research Ethics Committees (HRECs)

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104.1 For some research projects, specialist HREC ethical approval may be required in addition to Lead HREC ethical approval.

104.2 The three specialist HRECs in WA are:

| HREC | Function |
|---|---|
| Department of Health HREC (DOH HREC) | Reviews all research projects that require the use and disclosure of personal health information from the Department of Health data collections, including data linkage research. |
| WA Aboriginal Health Ethics Committee (WAAHEC) | Must review all research projects that involve research in, or in relation to, Western Australia and where the following applies:<br>• the research is related to Aboriginal health and well-being; and<br>• the experience of Aboriginal and/or Torres Strait Islander people is an explicit focus of all or part of the research; or<br>• data collection is explicitly directed at Aboriginal people; or<br>• research outcomes explicitly related to Aboriginal people; or<br>• it is proposed to conduct sub-group analyses and separately analyse Aboriginal people in the results; or<br>• the information, potential over-representation in the dataset, or geographic location has an impact on one or more Aboriginal communities; or<br>• Government Aboriginal health funds are a source of funding. |
| Coronial Ethics Committee WA | Must review all research that 40 requires access to coronial samples, data or information |

104.3 Most research conducted within EMHS that requires specialist HREC review is either:

- specifically focussed on Aboriginal health and so requires WAAHEC review, or
- involves WA Health Data Linkage and so requires DOH HREC review.

Most of these projects proceed with Lead HREC review by the RPH HREC and obtain a secondary review by the relevant specialist HREC.

104.4 Some research projects only require specialist HREC review, such as when a project is only accessing data from the DOH central data collections. For these projects, the specialist HREC becomes the Lead HREC.

104.5 Prior to recommending Site Authorisation, the responsible RGO must ensure that any necessary specialist HREC approvals have been obtained so it is essential that the CPI understands when a specialist HREC review is required. Advice can be obtained from the EMHS Research Hub and all projects submitted for Lead HREC by the RPH HREC will be screened for this requirement by the HREC Coordinator.

# SOP105: Low and Negligible Risk (LNR) review

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105.1 The National Statement provides guidance regarding when research may be classified as low and negligible risk in relation to research participants.

105.2 Certain types of human research must be ethically and scientifically reviewed by an HREC and cannot be reviewed by an alternative low risk mechanism or be exempted from ethical review (See SOP106). The National Statement must be consulted for guidance on whether a research project must undergo HREC review. Research requiring review by a HREC includes:

- Any research that involves more than low risk to research participants.
- Projects involving personal information and utilising a waiver of consent.
- Use of an opt-out approach to recruitment where NHMRC Guidelines under Section 95 of the Privacy Act 1988 or Guidelines approved under Section 95A 22 of the Privacy Act 1988 apply.
- Research that uses identifiable personal health information from the Department of Health data collections.
- Research that:
  - involves active concealment or planned deception
  - aims to expose illegal activity.
- Research involving the derivation of embryonic stem cell lines or other products from a human embryo.
- Prospective collection of human biospecimens for research.
- In general, research including genomics unless no information that can identify an individual is used and no linkage of data is planned.
- Xenotransplantation research.
- Research that includes any of the following, except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review:
  - Women who are pregnant and the human fetus.
  - People highly dependent on medical care who may be unable to give consent.
  - People with a cognitive impairment, intellectual disability, or a mental illness.
  - People who may be involved in illegal activities.
  - Aboriginal peoples.
  - People in other countries.

105.3 EMHS sites accept the review of another WA Health Service LNR pathway under the WA Health Single Ethical Review process. Projects that have been ethically reviewed via an LNR review pathway must still undergo a standard site governance review and receive site authorisation to commence at EMHS site/s.

105.4 EMHS has established a non-HREC LNR panel review mechanism. If a research project carries only low or negligible risk and does not fall under any of the research categories requiring a full HREC review, the project is eligible for review by the EMHS Low Risk Panel.

105.5 The operations of the EMHS LNR Panel are fully described in its guideline that is available on the EMHS website. This SOP provides an overview of how the panel reviews proposed research projects and monitors those it has approved.

105.6 The EMHS Research Hub maintains a roster of inducted LNR Panel members drawn from staff and current or former HREC members experienced and trained in the ethical review of research proposals and the application of relevant local and national guidelines and legislation (including the NS and Privacy regulations).

105.7 LNR Panel members receive the same induction documents as RPH HREC members and are invited to HREC member training opportunities. Members receive a formal appointment letter.

105.8 LNR Panels are convened when required to review an application with each panel comprising:

- The EMHS Ethics Coordinator
- 2 x LNR Panel members

105.9 The requirements for submission to the LNR Panel are the same as for HREC review. The CPI must submit all documents via the RGS.

105.10 On receipt of a submission where the CPI has identified the project as being of low or negligible risk the EMHS Ethics Coordinator will pre-review the application to confirm the project meets National Statement LNR criteria and is eligible for LNR Panel review.

105.11 The CPI's judgement as to whether their project is suitable for non-HREC review is considered but the decision is ultimately made by the Ethics Coordinator and, if required, the LNR Panel.

105.12 Where an application is determined to be 'more than low risk' the submission will be allocated to the next available HREC agenda. The CPI will be informed of the decision by email with an explanation for why the research is not suitable for LNR review. Referral to HREC review can also occur at any time during LNR review, if additional information arises.

105.13 LNR Panel Review Process:

- The Ethics Coordinator will pre-review the submission and contact the CPI if further information or clarifications are required. This constitutes the beginning of the LNR review.
- LNR Panel members will be notified that there is a submission for review and all documents, along with the Ethics Coordinator's pre-review, will be sent to the members by email.
- LNR Panel members will complete their reviews and recommendations within 2 working days of being provided with the documents.
- LNR Panel members can make one of the following recommendations:
    - that the research be approved
    - that the research be approved subject to further information being provided
    - that the research is not approved.
- Member's responses will be collated by the Ethics Coordinator and the consensus recommendation recorded in the review template.
- The CPI will be advised in writing of the outcome of the panel decision including links to the relevant section/chapter/paragraph of the National Statement.
- If further information is requested, the Ethics Coordinator will expedite resolution of any queries or document edits using direct phone and email communication between the panel and the CPI.
- On finalisation of the approval, the CPI will be sent an approval letter via the RGS signed by the EMHS Ethics Coordinator.

105.14 Research that has been ethically reviewed by the EMHS LNR Panel (or an external LNR mechanism) must still undergo research governance review and receive EMHS site authorisation.

105.15 Projects approved by the EMHS LNR Panel (or an external LNR mechanism) must follow standard monitoring requirements throughout the project's lifespan, including submission of progress and final reports and requests for amendments. See SOP501 for information about the monitoring of approved research.

# SOP106: Exemption from ethical review

**Version:** 3.0 May 2021

**Review:** May 2024

106.1 The National Statement s5.1.22 permits institutions to exempt research from ethical review if it:

- is negligible risk (as defined in paragraph 2.1.7): and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings

106.2 If a CPI believes their project is eligible to be exempted from ethical review, they must provide the EMHS Research Hub with a copy of the research protocol and a brief statement addressing s5.1.22 (and associated relevant sections) of the National Statement.

106.3 The request will be reviewed by the EMHS Ethics Coordinator and Research Manager. If necessary, the RPH HREC Chairperson will be consulted.

106.4 If exempted from ethical review, the EMHS Research Hub will provide a letter to the CPI stating that the project meets the requirements of the National Statement and is ethically acceptable. This letter will be signed by the EMHS Director of Clinical Services.

106.5 The review process for ethical exemptions will be completed outside of the RGS. The Research Hub will ensure that adequate records are maintained to document decisions.

# SOP107: Royal Perth Hospital HREC

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107.1 The Royal Perth Hospital Human Research Ethics Committee (RPH HREC) is the East Metropolitan Health Service (EMHS)-based HREC and conducts scientific and ethical review of research projects to be conducted at EMHS sites and under the WA Health Single Ethical Review scheme.

107.2 The operations of the RPH HREC are fully described in the publicly available Committee's Terms of Reference (TORs). This SOP provides an overview of how the HREC reviews proposed research projects and other key aspects of its functions.

107.3 The HREC is accountable to the EMHS Chief Executive (CE) via the EMHS Area Director of Clinical Services (ADCS). It provides a financial year annual report to the EMHS Area Executive Group (AEG) and CE and calendar year reports to the National Health and Medical Research Council (NHMRC).

107.4 The RPH HREC's functions are to provide:

- Independent, consistent and timely review of the scientific merit and ethical acceptability of research projects involving humans, their data or tissue.
- Ethical oversight, monitoring and advice for research projects involving humans, their data or tissue.
- Advice to the EMHS on research ethics principles and policies to assist in the development of effective and ethical human research-related policies and procedures.

107.5 The membership of the HREC is in accordance with the National Statement Section 5, with minimum membership at any meeting being eight members, as far as possible an equal number of men and women, and at least one third of the members non-HREC staff.

- The Chairperson is appointed by the EMHS ADCS following nomination by the HREC members. In the absence of the Chairperson at a meeting, a proxy Chairperson elected by the HREC members will perform the role and duties of the Chairperson.
- Members are appointed to one of the membership categories defined in the National Statement (a)-(f). No member may be appointed in more than one category.
- Members are appointed as individuals for their knowledge, qualities and experience rather than as representatives of any institution or group.
- Members are appointed by the EMHS ADCS and receive a formal letter of appointment detailing the terms of appointment. The initial term of appointment is 3 years, with renewal by agreement.
- Where required, the HREC may seek advice from appropriate experts to assist with the review of a project.
- In the interests of transparency and for training/mentoring, any person may request attendance at an HREC meeting as an observer. Attendance will be at the discretion of the Chairperson. Observers may not participate in discussions about specific items on the agenda or HREC decisions.
- Members, and all other meeting attendees, are required to sign a confidentiality agreement and agree to the HREC Conflict of Interest policy and process.
- Members are not paid a sitting fee for attendance at HREC meetings. Members are reimbursed by EMHS for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses, by EMHS or free parking is provided.

- Members are provided with orientation and induction training and should attend continuing education or training programs in research ethics at least every three years. EMHS will support access to such education and training.

107.6 The RPH HREC meets eleven times a year (monthly, except for January) and publishes an annual schedule of meetings and submission dates on the EMHS website and in the RGS calendar, no later than 31 October of the preceding year.

107.7 While the HREC publishes deadlines for each meeting, the Ethics Coordinator will work collaboratively with applicants to ensure projects can be reviewed at the earliest available meeting.

107.8 All of the required forms and documents necessary for a complete submission must be made by the Coordinating Principle Investigator (CPI) or Delegate in the RGS.

107.9 All submissions are extensively pre-reviewed by the HREC Coordinator, who also provides general advice to WA Health staff and external researchers on research ethics principles and submission requirements. The HREC Chairperson, in consultation with the Coordinator, may withhold submissions they deem incomplete or underdeveloped from the HREC meeting. The Chairperson and Coordinator are responsible for ensuring only submissions of sufficient quality and completeness are included on HREC meeting agendas and, to the extent possible, assisting the CPI to meet the necessary standards.

107.10 The CPI is not routinely required to attend the HREC meeting. CPIs may request attendance, but this is at the discretion of the Chairperson who will assess the potential benefits of the applicant's attendance to the review process. The HREC may request the applicant supply further information in relation to an application and/or request the applicant attend the HREC meeting for the purpose of providing information to, and answering questions from, the members.

107.11 The HREC Coordinator will circulate applications and associated documents received with a meeting agenda to attending HREC members at least 7 days prior to the meeting.

107.12 The RPH HREC applies the National Statement's guidance to its scientific and ethical review of research, considering the four principles of merit and integrity, justice, respect and beneficence. In the interest of minimising duplication of review, the HREC will consider prior scientific review (such as conducted during a grant review process) and prior ethical review of applications.

107.13 Consistent with the National Statement a quorum will be deemed to have been reached where the minimum membership described in SOP107.5 has received the meeting papers and had an opportunity to provide comment in time for the meeting.

107.14 Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is considered, the member will withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. The member will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter. All declarations of interest and absence of the member(s) concerned will be minuted.

107.15 The HREC will endeavour to reach a decision about the scientific merit and ethical acceptability of a proposal by unanimous consensus. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, provided the majority includes at least one layperson. The minutes will note any minority view.

107.16 The HREC will notify the applicant in writing, advising whether their application has received ethical approval and any conditions of that approval:

- Approved
    - The approval will be reflected in the RGS
    - The approval letter must list:
        - Sites
        - Approved documents
        - Duration of approval and expiry date
        - Any specific conditions
        - Standard conditions
- Additional Information Required ('Conditional Approval')
    - Queries and additional/revised documents required for approval must be clearly explained, with reference to relevant sections in the National Statement, in a letter to the CPI.
    - The HREC Coordinator must request re-submission within 7 days to ensure efficient finalisation of the approval and provide direct assistance to the CPI to achieve this timeline.
    - The Chairperson is delegated to approve conditionally approved projects out-of-session. On receipt of the response the HREC Coordinator and Chairperson will review out-of-session and, if the requirements of the HREC are met, approve the study, with a summary of approvals provided at the next meeting.
- Additional Information Required ('Deferral')
    - Queries and additional/revised documents required for approval must be clearly explained, with reference to the National Statement, in a letter to the CPI.
    - The HREC Coordinator must request re-submission in time for the next HREC meeting to ensure efficient finalisation of the approval and provide direct assistance to the CPI to achieve this timeline.
    - On receipt of the response this will be pre-reviewed by the HREC Coordinator and Chairperson to confirm it is of sufficient quality and completeness for inclusion on the next HREC meeting agenda.
- Not Approved
    - The HREC letter must provide a clear explanation for why the project was not approved, referencing the relevant sections of the National Statement.

107.17 The CPI may withdraw an ethics application that has already been submitted at any time prior to approval. The CPI must submit an email or letter in the RGS and the HREC Coordinator will mark the application as withdrawn on the RGS.

107.18 In addition to formal written communication with applicants, the HREC, its Chairperson and Coordinator will use informal methods of communication, including phone calls and face-to-face meetings, to resolve expeditiously outstanding issues or queries relating to an application.

107.19 The RPH HREC will monitor approved projects in line with Chapter 5.5 of the National Statement by, at a minimum, requiring annual progress and final reports for all projects.

107.20 Furthermore, as a condition of approval of each project, the HREC will require that investigators report anything that could adversely affect the safety or wellbeing of participants or materially impact on the continued ethical acceptability of the project, including:

- Proposed amendments to the research protocol, other documents or conduct
- Unforeseen events that might affect continued ethical acceptability of the project (e.g. significant safety issues or serious breaches of the protocol)
- Early termination or suspension of the project for any reason
- Complaints (See SOP1001 and SOP1002).

107.21 The EMHS Research Hub will prepare and maintain electronic records of the HREC's activities and decisions, including agendas and minutes of all meetings and records of actions conducted out-of-session.

107.22 The HREC meeting minutes will document decisions for each project, including:

- the main scientific and ethical issues and the outcome of the review
- whether additional information is required and the process by which the new/revised information will be reviewed
- whether any additional ethical approval is required from a specialist HREC
- all standard and special conditions that apply to the ethical approval (if granted).

107.23 Minutes must be reviewed and approved by the HREC Chair, then endorsed by the HREC at the next meeting.

107.24 EMHS Research Hub will prepare and maintain an electronic file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the HREC. Records will be held securely and confidentially in accordance with the requirements of the Health Services (Conciliation and Review) Act 1995 (WA), The State Records Act (2000) and the Privacy Act-Cwth (1988).

# SOP108: Duration of ethical approval

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**Review:** May 2024

108.1 Duration of ethical approval must be appropriate for the proposed research project and based on the duration foreshadowed in the protocol, as well as the complexity and risk of the project.

108.2 Under WA Health Single Ethical Review, the duration of ethical approval should be a maximum of 5 years but is at the discretion of the Lead HREC. Extensions must be requested via an ethics amendment request in the RGS, and the extension period must be limited to three years per extension. While the first extension to this initial approval period may be approved out of session, subsequent extensions must be reviewed at an HREC committee meeting.

108.3 Under NMA, the duration of ethical approval may be up to five years. NMA Standard Principles for Operation allow approval for up to 5 years or rolling approval on receipt of an annual/progress report. Extension of the ethical approval period may be requested by the CPI and submitted to the Lead HREC through an amendment process prior to expiry of the current approval period. The process to be followed depends on the relevant jurisdiction of the Lead HREC.

# SECTION 2: SITE AUTHORISATION

## SOP201: Research governance review

**Version:** 3.0 May 2021

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

201.2 Research governance submissions must be made via the WA Health Research Governance Service (RGS). The RGS is a centralised IT system for researchers, sponsors, site administrators, HRECs and Research Governance Offices. It facilitates the submission, approval, monitoring and reporting of research projects through their life cycle including ethics approval, site authorisation, monitoring and publications. The RGS is specifically designed to support multi-centre research conducted across multiple WA Health Service Providers (HSPs) and Australia-wide multi-jurisdictional projects.

201.3 Research governance review is, by definition, site-specific. The purpose is to determine that all the resources required to conduct the study (financial, human, equipment and infrastructure) are available, the project is feasible and can be conducted in a way that meets all regulatory, legislative and policy requirements. Those Departments and individuals on site who are requested or required to be involved in the project must agree by reviewing and approving the submission. See 2. Introduction.

201.4 **Project Development:** It is expected that the information provided in the research governance submission will represent the end product of a period of project development and site engagement. Depending on the nature of the project and the level of site involvement, this may involve the CPI and/or Site PI meeting with local staff, Heads of Department and key stakeholders to explain the project and gain support. A copy of the research protocol should be provided to the site staff and the research team must be clear to identify a Site PI, a PI Delegate (if applicable) and determine via Departmental contacts who the relevant signatories for the SSA/AR Form and Budget are.

All EMHS site stakeholders (Heads of Department, Business/Operations Managers, other support staff such as Nurse Managers) who are supporting the project, regardless of whether the project CPI is internal or external to the site, must carefully read the study information (protocol etc) to determine the impact on their Department and confirm their ability to participate.

If completed as part of a well-planned period of project development, the completion of the SSA and Budget and obtaining formal sign off in the RGS is straightforward.

201.5 Research governance submissions are prepared and submitted by the EMHS Site Principal Investigator (PI) or their Delegate. There are two types of application form:

- Site Specific Assessment (SSA) form
- Access Request (AR) form

201.6 **Site Specific Assessment (SSA) Form:** If the project will be conducted at the EMHS site/s (that is, protocol activities will be completed at the site) an SSA form, and associated Budget form must be used to apply for site authorisation. Examples of research activities requiring the use of an SSA include:

- participant enrolment and consent
- conducting research procedures with or on participants at the site
- managing and analysing data, biospecimens and/or responses from surveys and questionnaires at the site
- administration of surveys and questionnaires to site participants or staff that requires oversight by investigators or site personnel.

201.7 **Access Request (AR) Form:** If research activities are not occurring at the EMHS site/s, and only support in the form of access to the site's participants, their biospecimens or data is being requested, then an AR form may be used, at the discretion of the RGO. Examples of research activities where the use of an AR may be appropriate include:

- participant recruitment through posters, leaflets, handouts or letters of invitation
- administration of surveys and questionnaires to site participants or staff that do not require oversight by investigators or site personnel (such as e-surveys)
- access to data or biospecimens held at the site (but not processing or analysis at that site).

Where significant resources are involved in the retrieval, preparation and/or transport of data or biospecimens, the RGO may require the use of an SSA form rather than an AR form, such that costs associated with these activities may be considered in the budget form.

201.8 All research governance submissions for EMHS sites are reviewed by RGOs within the EMHS Research Hub. The RGO will complete the review and provide a recommendation to the CE/delegate who will then decide to authorise or not authorise the project at site, with consideration of the RGO recommendation. See SOP001.11.

201.9 Authorisation via the RGS by the CE/delegate and receipt of an authorisation letter by the Site PI is required before research commences at that site.

201.10 **Review Timeline:** The RGO review must be completed within 60 calendar days of submission of a valid site application. Time spent waiting for the PI to provide extra information is excluded from the 60-day clock. During the review process, the RGO may mark a submission as 'Additional Information Required (AIR)' to request clarification or additional information from the PI. If the PI does not supply the requested information within 4 months of the request, the RGO may withdraw the application.

201.11 Submissions are first **validated** by the RGO to ensure that all the required documents have been submitted, are accurate and complete and all required signatories are present. If there are missing documents or any aspects of the submission are incomplete or incorrect the application will be "AIR'd" (Additional Information Required) in the RGS and the Site PI/Delegate will be contacted directly by the RGO to explain what is required and assist the PI/Delegate to amend or complete the submission. A 'valid' submission is one that contains all documentation required for the governance review to be completed.

201.12 **Documents:** The RGO will review the following documentation and, if required, request further information or clarification from the Site Principal Investigator (PI)/Delegate/Site contact person:

- WA Health Site Specific Assessment (SSA) Form or Access Request (AR) Form
- HREA or WA Health Ethics Application form (WAHEAF)
- 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.

201.13 The RGO must review to ensure that information between the SSA/AR, research protocol, application for data (if applicable) and any agreements are consistent and remains consistent when amendments are made.

201.14 **Review:** The RGO must review the SSA/AR and all associated forms and documents. Before determining if the application can be recommended or not recommended for site authorisation by the CE/delegate decision, the RGO must ensure that:

- No information in project details is missing
- Investigators have adequate credentials and training
- The budget form is appropriately completed with funding and costings
- Adequate insurance and indemnity are provided (SOP204; SOP205)
- Appropriate research agreements are in place (SOP203)
- IP arrangements have been considered (SOP206)
- Relevant approvals from regulatory bodies are provided (e.g. Radiological Council, Reproductive Technology Council) (SOP202)
- Declarations of confidentiality and conflicts of interest are provided where relevant (Section 8; Section 9)
- Sign offs from the relevant hospital administrators (e.g. head of department, business manager, divisional director and/or regional manager) are complete and appropriate
- Risks to the site or participants are identified, acceptable and have been properly mitigated.

To inform their review, the RGO may request advice from external parties such as:

- The lead or specialist HREC
- Legal services (e.g. Department of Health Legal and Legislative Services)
- The insurer (e.g. Insurance Commission of WA)
- The funder.

The time taken to obtain this advice is considered part of the site authorisation review 60-day clock.

201.15 **Budget:** The RGO must ensure that the site's budget form contains:

- Costs of all items to be utilised in each department at the site
- Funding amounts and sources, including monetary, in-kind and self-funded
- Signatures of all relevant Heads of Department

- Details and contacts for the Research Department, Supporting Department(s) and relevant Third-Party Agencies.

201.16 **Process:** Ongoing communications between the RGO and the Site PI/Delegate will occur via email and phone.

- In the interest of efficiency RGOs will first compile any questions arising from their review of the governance submission and phone the PI/Delegate to obtain critical information or clarifications.
- An email assessment will only be sent after this phone call and if required to provide written feedback or document revisions/templates.

RGOs will follow a "1 + 1" rule when completing reviews: 1 phone + 1 email. This is to avoid protracted review periods and excessive delays in receiving complete responses to queries from the Site PI/Delegate.

Site PIs/Delegates (and any relevant external parties) will be requested to contact the RGO via phone or to visit the EMHS Research Hub in person, to provide additional information or clarification expeditiously on request, and to take any steps necessary to ensure a speedy completion of the review.

201.17 **Research protocol:** The research protocol is reviewed by the RGO to ensure that the research activities described in the protocol are consistent with the information in the site SSA/AR form, Budget and site-specific PICFs. For example, if patients are to undergo CT scans, the 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 for the EMHS site/s.

201.18 **Ethical Approval and Application:** The research governance review does not re-prosecute the ethical review. However, the information contained in the ethics application form is critical to the site governance review as it includes information about the study method, participant groups, treatment of participants, privacy and confidentiality, informed consent, professional safety, data transfer and storage and other matters of significance for a research study. By reviewing the ethics submission and approval, the RGO is required to ensure that the Site PI/study team are aware of and compliant with relevant laws, policies and codes of conduct.

201.19 Once all the issues have been resolved or addressed, the RGO will recommend approval or non-approval to the CE or Delegate. Within EMHS, the delegated authority to approve research projects is with the Executive Directors of the Armadale Kelmscott Group (AKG) and Royal Perth Bentley (RPBG).

201.20 The Site PI may withdraw a research governance application that has already been submitted at any time prior to approval. The PI must submit an email or letter in the RGS and the RGO will mark the application as withdrawn on the RGS.

# SOP202: Research requiring special consideration

**Version:** 3.0 May 2021

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202.1 Certain research projects involving ionising radiation, human embryos or gametes, biospecimens, coronial and non-coronial post-mortem material or genetic information require registration with a regulatory body, close consideration of the relevant legislation and thorough risk assessment and mitigation.

202.2 Risk mitigation mechanisms must be detailed in the site authorisation application and the RGO must review compliance with relevant the legislation and regulatory body requirements through initial review and ongoing monitoring.

202.3 Research types requiring special legislative and regulatory consideration:

| Type | Legislation | Guidelines | Regulatory Body | Requirements |
|---|---|---|---|---|
| **Ionising Radiation** | *Radiation Safety Act 1975, Australian Radiation Protection and Nuclear Safety Act 1998* | Australian Radiation Protection and Nuclear Safety Agency Regulations, Radiological Council | Radiological Council (for radiation greater than 20mSv under advice of the Site Medical Physicist and Radiation Safety Officer) | Appointment of a Radiation Safety Officer and consultation with the Site Imaging Service Head of Department is required. |
| **Human Embryos or Gametes** | *Research Involving Human Embryos Act 2002*, *Human Reproductive Technology Act 1991*, *Human Tissue and Transplant Act 1982* | NHMRC Ethical Guidelines for Assisted Reproductive Technology | Reproductive Technology Council<br>Embryo Research Licensing Committee | HREC approval is required before consideration by the Reproductive Technology Council. |
| **Biospecimens** | *Human Tissue and Transplant Act 1982* | N/A | N/A | Infectious or genetically modified biospecimens may require review by an Institutional Biosafety Committee (IBC). |
| **Coronial and Non-Coronial Post-Mortem Material** | *Coroners Act 1996* | *Non-Coronial Post-Mortem Examinations Code of Practice 2007* | WA Government Coroner's Court of WA: Coronial Ethics Committee | Additional ethical approval by the *Coronial Ethics Committee* is required. |
| **Genetic Information** | *Gene Technology Act 2000* (Cwth), *Gene Technology Act 2006* (WA), *Gene Technology Regulations 2001* | NHMRC Genomics resources for clinicians and researchers | Gene Technology Regulator or an IBC | N/A |

# SOP203: Research agreements

**Version:** 3.0 May 2021

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203.1 Research involving EMHS employees, participants, data or biospecimens that is undertaken in collaboration with an external entity, both commercial (e.g., a pharmaceutical company) and non-commercial (a university or research institute), must be the subject of a written agreement. The type of the agreement required will be dependent on the nature of the research project.

203.2 Research agreements are legally binding agreements between two or more parties that establish the respective responsibilities and obligations of the parties conducting a research project. Agreements are also critical to the successful execution of collaborative research projects.

203.3 The type of research activity and entities party to the project will determine the type of research agreement required. Standard research agreement templates are publicly available for download on the RGS documents templates page. The EMHS RGO must assist the EMHS Site PI to identify the appropriate agreement to use and facilitate negotiations with the external entity regarding the research agreement. See SOP402 & SOP403 for more information on types of research agreements required for clinical trials.

203.4 The draft research agreement can be submitted to the RGO via the RGS at any time prior to or during submission of the site governance application. However, given that execution of the agreement is required prior to, or simultaneously with site authorisation, researchers must give priority to preparing the draft submission as soon as possible.

203.5 The RGO will review the research agreement along with the research protocol. Review may include direct negotiation with the external entity and referral of the research agreement to WA Health Legal and Legislative Services (LLS).

203.6 It is recommended that amendments to the standard research agreements are set out in a Special Conditions Schedule to the agreement and not in the body of the agreement. Bespoke research agreement templates, incorporating an external entity's amendments for use across the WA health system, may be established for external entities seeking to conduct research with more than one WA health system entity. This avoids the need for each WA health system entity to individually review the same external entity's amendments to the standard template. Establishment and maintenance of entity-specific research agreement templates for use across the WA health system must occur through the Research Contracts Review Working Group (RCRWG). The RCRWG is chaired by the Department of Health and includes representation from each WA health system entity.

203.7 Once the RGO has reviewed and the CE/Delegate has authorised and signed the research agreement, the agreement must be sent to the external entity for signing.

203.8 The RGO must ensure that all relevant research agreements are properly executed (i.e. have been signed by all parties) and current, as part of the research governance process.

# SOP204: Indemnity

**Version:** 3.0 May 2021

**Review:** May 2024

204.1 Indemnity refers to an agreement by one party to another that it will cover losses incurred by the other party due to the acts of the indemnitee or any other party. The CE/Delegate must ensure that EMHS does not assume liabilities attached to external entities. Indemnity must be mutual and specifically tailored to the risks and liabilities associated with the project.

204.2 For commercially sponsored research projects, the RGO, as part of site governance review, must ensure that EMHS and, if applicable, the RPH HREC are indemnified by the sponsor. The details of the indemnity may be included in the research agreement with the sponsor, and the indemnity form must be signed and uploaded to the RGS as a site authorisation application supporting document.

204.3 For non-commercially sponsored projects, HRECs must be indemnified by EMHS for their decisions in reviewing research projects. Under the NMA scheme, each participating jurisdiction is required to ensure that the NMA certified HRECs within its jurisdiction are indemnified with respect to the HREC's decisions in reviewing each non-commercially sponsored project.

204.4 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 is appropriate. The most recent templates are publicly available for download on the RGS documents templates page.

# SOP205: Insurance

**Version:** 3.0 May 2021

**Review:** May 2024

205.1 Insurance refers to a policy taken out by an institution to cover its own risks or liabilities. The party providing indemnity must have and maintain appropriate insurance.

- For commercially sponsored research projects, the party responsible for this is the sponsor. Details of the insurance must be in Schedule 4 of the research agreement (See SOP403).
- For non-commercially sponsored projects, the responsible party is EMHS.

205.2 Confirming the insurance arrangements of all parties to a research project is a risk management requirement that ensures research projects are adequately covered by robust insurance provisions. This not only protects the interests of EMHS but importantly also protects the interests of research participants, as well as sponsors and Clinical Research Organisations (CROs).

205.3 The Insurance Commission of Western Australia (ICWA) manages the WA Government's self-insurance arrangements, which incorporate the WA health system, including research activities. ICWA also provides a support service for scrutiny and advice regarding external parties' insurances. RGOs must operate under ICWA's guidelines and should seek advice from ICWA as required.

205.4 Where insurance is provided by the sponsor, an insurance certificate of currency must be submitted in the RGS as part of the site authorisation application and be reviewed by the RGO. The RGO must review the insurance certificate of currency, in consultation with ICWA if required, to ensure the insurance will meet any liabilities and does not contain relevant exclusions.

205.5 Consideration must be given to clinical trial, product and public liability cover, the availability of legal liability cover and whether the commercial insurer is Australian Prudential Regulation Authority approved. The RGO must also ensure that insurance policies do not prevent legal action from being heard in Australian courts. For the period of the required research liability cover, updated insurance policies must be reviewed and approved by the RGO following submission in the RGS as an amendment.

# SOP206: Intellectual Property

**Version:** 3.0 May 2021

**Review:** May 2024

206.1 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. 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.

206.2 If there are reasonable grounds to anticipate that IP could be developed during a research project, the CPI/PI must inform the RGO as part of their research governance submission. As noted below, IP must be anticipated to ensure it is adequately addressed in any relevant research agreements. IP clauses in agreements can require negotiation and legal input so failure to raise potential IP as early as possible during the governance review can lead to delays in commencing the research.

206.3 As part of site governance review, RGOs must ensure that research conducted in EMHS complies with the DOH Intellectual Property Policy and the Western Australian Government Intellectual Property Policy 2015.

206.4 RGOs must ensure that research agreements state the arrangements for use of existing IP and the parties' rights in relation to ownership and use of all new IP developed through the research project. Collaborative research projects and those procuring services from external sources may require extra consideration.

206.5 IP questions and issues should be referred to the EMHS Research Hub in the first instance.

206.6 Further information and assistance is available from the Department of Health IP Coordinator and the DOH Intellectual Property Management website.

# SECTION 3: SPECIFIC PARTICIPANT GROUPS

## SOP301: Groups requiring additional consideration

**Version:** 3.0 May 2021

**Review:** May 2024

301.1 Special consideration must be given in terms of research project design, consent process and risk mitigation as per the National Statement Chapter 4 for participant groups including:

- Women who are pregnant and the human fetus
- Children and young people
- People in dependent or unequal relationships
- 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
- People who may be involved in illegal activities
- Aboriginal peoples
- People in other countries.

301.2 HRECs must ensure, as part of ethical review, that the appropriate risk mitigation mechanisms and special considerations are detailed in the ethics application for projects involving the participant groups mentioned above.

301.3 RGOs must ensure that the relevant legislation and guidance has been considered by researchers and the HREC and that the project complies with state-specific legislation and guidance.

## **SOP302:** Children and young people

**Version:** 3.0 May 2021

**Review:** May 2024

302.1 Regarding research projects involving children and/or young people, the HREC must ensure that all aspects of the recruitment and participation by children and/or young people is consistent with the National Statement chapter 4 and fully documented in the protocol.

302.2 The Site PI and RGO must ensure that:

- all investigators with direct contact with participants under 18 years of age (Age of Majority Act 1972) have or obtain a WA Government "Working with Children Check" (Working with Children (Criminal Record Checking) Act 2004)
- the process of recruitment and consent of minors detailed in the protocol is consistent with the DOH Consent to Treatment Policy, the National Statement Chapter 4.2 and the Children and Community Services Act 2004
- the protocol accounts for the how the consent of a young person is to be re-established to continue/resume their participation in the research once the young person has reached the age of 18 years (if applicable).

302.3 The composition of the Lead HREC must be appropriate for review of paediatric projects by having access to the expertise necessary to enable it to address the ethical issues arising from research involving minors. The most appropriate HREC in WA Health is the Child and Adolescent Health Service (CAHS) HREC.

- The EMHS Ethics Coordinator will advise EMHS researcher whose project primarily focusses on children and young people of the most appropriate HREC to review their project.
- The RPH HREC routinely reviews projects that coincidentally include patients aged 16-17 years who fit the category defined in the National Statement Chapter 4 as: *"young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian."*

# **SOP303:** Adults who lack capacity to consent

**Version:** 3.0 May 2021

**Review:** May 2024

303.1 The *Guardianship and Administration Act 1990* (Part 9E – Medical Research) prescribes how the recruitment of adults who lack the capacity to give consent into research may occur in Western Australia.

303.2 CPIs and PIs whose project involves recruitment under the GAA Part 9E must familiarise themselves with the requirements of the Act while developing their project so recruitment and consent processes compliant with the Act are clearly specified in the protocol and reflected in project documents, notably PICFs, prior to ethical and site governance review.

303.3 A guide and associated document templates are available on the RGS website.

303.4 HRECs must ensure that all health and medical research involving the participation of adults who lack the capacity to provide consent is in line with the Department of Health Guide.

303.5 RGOs must ensure that proposed processes to enrol patients who lack capacity to provide consent at the site are in line with both the Guardianship and Administration Act (Part 9E) and any specific conditions applied by the HREC.

# SOP304: Aboriginal people

**Version:** 3.0 May 2021

**Review:** May 2024

304.1 Research involving Aboriginal Peoples must be informed by and abide by the National Statement, the NHMRC *Ethical conduct in research with Aboriginal people and communities: Guidelines for researchers and stakeholders* and the NHMRC *Keeping Research on Track II*.

304.2 In addition to Lead HREC approval, approval from the WA Aboriginal Health Ethics Committee (WAAHEC) is required when research projects involve research in, or in relation to, Western Australia, and the following applies:

- the research is related to health and well-being; and
- the experience of Aboriginal and/or Torres Strait Islander people is an explicit focus of all or part of the research; or
- data collection is explicitly directed at Aboriginal people; or
- research outcomes explicitly related to Aboriginal people; or
- it is proposed to conduct sub-group analyses and separately analyse Aboriginal people in the results; or
- the information, potential over-representation in the dataset, or geographic location has an impact on one or more Aboriginal communities; or
- Government Aboriginal health funds are a source of funding.

304.3 The WAAHEC undertakes review of research applications that are related to the health and well-being of Aboriginal and Torres Strait Islander people. The definition of health for this purpose is as defined by the National Aboriginal Community Controlled Health Organisation: *"Aboriginal health" means not just the physical well-being of an individual but refers to the social, emotional and cultural well-being of the whole Community in which each individual is able to achieve their full potential as a human being thereby bringing about the total well-being of their Community. It is a whole of life view and includes the cyclical concept of life-death-life"*

304.4 EMHS CPIs whose project meets the criteria in SOP303.7 must independently submit to WAAHEC (see their website for more information). This specialist HREC review can occur concurrently with submission to the RPH HREC as 'Lead HREC'. The EMHS Ethics Coordinator can (1) advise if the criteria in SOP 303.7 are met for a specific project, and (2) ensure the RPH HREC review runs efficiently with a concurrent review by WAAHEC.

# SECTION 4: CLINICAL TRIALS

## SOP401: Clinical trial governance requirements

**Version:** 3.0 May 2021

**Review:** May 2024

401.1 Clinical trials are research investigations in which people volunteer to test new treatments, interventions or tests to prevent, detect, treat or manage various diseases or medical conditions.

401.2 Clinical trials conducted with EMHS require specific approvals. Depending on the nature of the trial and medicines, devices or tests under investigation, these may include:

- The requirement for the institution to sign a Confidentiality Disclosure Agreement (CDA) with the sponsor
- Specific forms of research agreements (e.g., CTRA; CIRA)
- Notification to the Therapeutic Goods Administration (TGA)
- Registration on a public clinical trials registry.

# SOP402: Confidentiality Disclosure Agreements

**Version:** 3.0 May 2021

**Review:** May 2024

402.1 Confidentiality Disclosure Agreements (CDAs) are legal agreements between a clinical trial sponsor and a WA Health institution (e.g., Royal Perth Hospital).

402.2 The CDA indicates the sponsor's interest in conducting a trial at the site and permits the proposed site investigator, and other relevant staff, to receive a copy of the trial protocol and other commercially sensitive trial or product information so they can complete site feasibility and determine if the site can conduct the trial on behalf of the sponsor.

402.3 Where appropriate, a CDA must be signed between the EMHS site and the sponsor or Contract Research Organisation (CRO). The RGO, in consultation with LLS, must negotiate the CDA with the external entity prior to signing by the CE/Delegate. Standard CDAs ensure expedited execution and are strongly encouraged. Templates can be found on the RGS website.

402.4 EMHS staff may receive requests from external sponsors to personally sign a CDA relating to a proposed research project. The State Solicitor's Office (SSO) recommends that WA Health Service employees do not sign CDAs. CDAs are legally binding agreements that can give rise to legal liability and should only be signed by the EMHS authorised signatory (CE/Delegate), not the individual.

# SOP403: Clinical Trial Research Agreements (CTRA and CIRA)

**Version:** 3.0 May 2021

**Review:** May 2024

403.1 Externally sponsored clinical trials must be subject to either a Clinical Trial Research Agreement (CTRA) or Clinical Investigation Research Agreement (CIRA).

- CTRAs must be used for clinical trials involving the use of medicine products, biotherapeutic products and vaccines.
- CIRAs must be used for clinical trials involving the use of non-pharmaceutical medical technologies, including devices.

403.2 Clinical trial agreements are legally binding contracts between two or more parties that establishes the respective responsibilities and obligations of the parties conducting a clinical trial. Research Governance review of the CTRA/CIRA is essential to ensure the interests of EMHS are protected and funds are preserved and adequately managed. It is particularly important for commercially sponsored studies that the CTRA/CIRA adequately addresses issues including indemnity (SOP204), insurance (SOP205) and intellectual property (SOP206).

403.3 The latest templates for these research agreements can be found on the RGS Documents Template page.

403.4 The standard templates for CTRAs and CIRAs available from the RGS are based on templates from Medicines Australia (representing the pharmaceutical industry) (CTRA) and the Medical Technology Association of Australia (CIRA). These standard templates must be used when conducting commercial clinical trials within EMHS.

403.5 Where a Sponsor or CRG submits, without amendment, the current version of a WA Health template CTRA/CIRA, that document will be accepted by the RGO and expedite the EMHS site authorisation.

403.6 If a Sponsor or CRG submits a CTRA/CIRA template containing material changes, the RGO will assess the effect of those changes on the integrity of the CTRA. This may require requesting advice from DOH Legal and Legislative Services. In such instances the Sponsor/CRG will be expected to provide an electronic version of the CTRA to facilitate editing and tracking changes. Legal review of modified or bespoke research agreements will delay finalisation of the site governance review and authorisation of the project.

403.7 EMHS staff may receive requests from external sponsors to personally sign a CTRA/CIRA. As for CDAs EMHS employees must not sign CTRAs/CIRAs as individual. Because they are legally binding agreements that can give rise to legal liability and should only be signed by the EMHS authorised signatory (CE/Delegate).

403.8 Once the terms of the agreements are finalised and the rest of the site governance review completed, the RGO will facilitate execution of the agreement at the same time the site authorisation letter is signed by the CE/Delegate.

403.9 More information about the general requirements for research agreements is in SOP203.

# SOP404: TGA notification / approval (CTN/CTA)

**Version:** 3.0 May 2021

**Review:** May 2024

404.1 The Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods in Australia. Products for which therapeutic claims are made must be entered into the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

404.2 Clinical trials involving the use of any medicine, biological or device not entered in the ARTG, or the use of a marketed medicine, biological or device beyond the conditions of its marketing approval, must occur in line with the TGA's Australian Clinical Trial Handbook. A CTN/CTA is required when using:

- A product not entered on the ARTG, including any new formulation of an existing product or any new route of administration; or
- A registered or listed product outside the conditions of its marketing approval.

404.3 Clinical trials using unapproved therapeutic goods must occur under the Clinical Trial Approval (CTA) scheme (previously Clinical Trial Exemption scheme) or Clinical Trial Notification (CTN) scheme.

404.4 The choice of which scheme to use (CTN or CTA) lies firstly with the trial sponsor and then with the Lead HREC (except for certain Class 4 biologicals, which must be approved under the CTA scheme). For more information on which scheme a project may come under, see the Australian Clinical Trial Handbook or contact the TGA. Most clinical trials that are conducted within EMHS use the CTN scheme.

404.5 The EMHS RGO will assist the Site PI/Delegate to ensure a CTN/CTA is in place and confirm that a CTN/CTA reference number has been provided for the trial. Enrolment of patients into the trial cannot occur until the CTN reference number has been provided and so is usually a requirement for the site authorisation to be finalised by the CE/Delegate.

404.6 The trial sponsor is responsible for correspondence with the TGA, as per the Australian Clinical Trial Handbook. Where EMHS is the sponsor, these responsibilities lie with the CPI/EMHS Site PI. Where EMHS is the sponsor the Site PI is responsible for contacting the EMHS Research Hub to request a user ID, drafting of 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.

404.7 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.

404.8 The TGA has an online system for the submission of CTN/CTX at TGA's website.

404.9 At the time the CTN online form is submitted to the TGA the email confirmation should be forwarded to the EMHS Research Hub via email.

# SOP405: Clinical trial registration

**Version:** 3.0 May 2021

**Review:** May 2024

405.1 The International Committee of Medical Journal Editors (ICMJE) member journals require registration in a public trials registry as a condition of consideration for publication. Registration must be completed prior to recruitment commencing. For more information on criteria for registration, see the ICMJE website.

405.2 Trial registration is also important for participant recruitment. Registration allows people interested in participating in a clinical trial to search for relevant clinical trials on a single website. Registration also assists health professionals to identify relevant trials for their patients.

405.3 The two most widely used trials registries are:

- Australian New Zealand Clinical Trials Registry
- Clinicaltrials.gov

405.4 In addition to registering a trial as early as possible, and prior to recruitment, the CPI should ensure information such as contact details and trial status is kept up-to-date.

# SECTION 5: PROJECT MONITORING

## SOP501: Overview of project monitoring

**Version:** 3.0 May 2021

**Review:** May 2024

501.1 All approved and authorised research projects must be monitored by the Lead HREC, Specialist HREC (if applicable) and RGO(s) for all site/s throughout the lifetime of the project, in line with the National Statement Chapter 5.5 and the Australian Code for the Responsible Conduct of Research.

501.2 Monitoring ensures the research is conducted in line with the approved/authorised protocol and any special conditions required by the Lead HREC and/or site/s, as well as ensures any amendments to the project are approved by the Lead HREC and site/s prior to being implemented.

501.3 Routine monitoring consists of ethical and site review and approval/acknowledgement of:

- Safety Reports – see SOP502
- Amendments – see SOP503
- Progress Reports – see SOP504
- Final Reports – see SOP505

501.4 All monitoring submissions must be made via the Research Governance Service (RGS) under the Monitoring Tab in the project workspace.

501.5 On-site monitoring by sponsors and audits by the EMHS Research Hub (SOP509) are also used to monitor specific projects and to randomly review the conduct of research in the service to inform planning, educational initiatives and priorities and to ensure a high standard of research conduct is being maintained.

501.6 EMHS researchers must understand and attend to all monitoring requirements over the lifetime of their project. Failure to comply with monitoring obligations, such as submitting annual progress reports, meeting safety reporting timelines or implementing protocol amendments prior to obtaining ethical approval and site authorisation, can result in consequences including suspension of ethical approval or site authorisation (SOP506).

501.7 All Section 5 SOPs are written in accordance with:

- Chapter 5.5 of the National Statement
- RPH HREC Terms of Reference
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods

# SOP502: Safety reports

**Version:** 3.0 May 2021

**Review:** May 2024

502.1 Safety reports must be received by the RGO(s) and HREC Coordinator of the Lead and Specialist (if applicable) HREC via the RGS when an individual Adverse Event (AE) occurs, as per the National Statement.

502.2 Individual events that require the submission of a safety report in the RGS are:

- Serious Breaches of protocol
- Significant Safety Issues (SSI)
- Sudden Unexpected Serious Adverse Reactions (SUSAR)
- Unanticipated Serious Adverse Device Effect (USADE)

502.3 These events are defined in the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods guide. It is essential that all EMHS clinical trial Site PIs and Delegates (Trial Coordinators) understand safety reporting requirements and ensure they follow the NHMRC Guide that is designed to ensure only potentially serious and consequential safety events are reported, and none of these are missed.

502.4 On receipt of a safety report:

- If submitted to the RPH HREC and urgent, the Ethics Coordinator will forward the report to the HREC Chair and any other relevant HREC members
- The Coordinator will assign the report to the next HREC meeting
- The HREC will review or note the report, even if review has been expedited out-of-session prior to the meeting
- The Coordinator will notify the CPI of the outcome of the HREC review, if relevant
- The RGO will review the report (in concert with the HREC Coordinator if applicable)
- The RGO will notify the PI of the outcome of the RGO review.

The order of these items depends on the origin of the safety report and the location of the HREC.

502.5 Review of a safety report may include the following actions by the HREC and/or the RGO:

- Acknowledging receipt of report
- Noting of the event
- Referral to an HREC subcommittee for advice
- Immediate request for additional information
- Immediate suspension of ethical approval and/or site authorisation
- Immediate discontinuation of ethical approval and/or site authorisation
- other action as recommended by the HREC or CE/delegate.

502.6 If additional information is required, the CPI/PI/Delegates will be contacted directly and expeditiously, although the additional information will need to be recorded in RGS as well.

502.7 Where the HREC or RGO considers that the project requires immediate suspension or discontinuation of the ethical approval and/or site authorisation, the HREC/RGO must immediately notify the CPI/PI and sponsor, and the relevant EMHS CE/Delegate to action this. Notification must be made in RGS, including updating the project's ethical and/or site approval status.

502.8 **Annual Safety Report:** For research projects with a protocol mandated intervention (generally clinical trials), the following must be provided at least annually to the HREC and RGO(s):

- Annual safety report including sponsor comments detailing any planned actions based on the reports.
- Current approved product information (e.g. Investigator's Brochure, IB), if appropriate.
- Executive summary from the Data Safety Monitoring Board (DSMB) or equivalent if appropriate.
- Any other reports consistent with TGA Good Clinical Practice Guidelines.

502.9 IB updates, aggregate safety reports and DSMB meeting minutes provided to EMHS sites during an annual reporting period which state that the risk/benefit analysis for the investigational drug/device is unchanged and that no amendments to the trial protocol are required should not be submitted to the RPH HREC or the EMHS site(s) ad hoc. Instead, this data should be summarised in the annual safety report.

502.10 Review of annual safety reports will follow the procedure in SOP502.4 and SOP502.5.

502.11 As part of ethical review, HRECs must ensure that research projects involving an intervention have a Data Safety Monitoring Board (DSMB) or equivalent, as per the National Statement and NHRMC Data Safety Monitoring Boards (DSMBs). The DSMB/equivalent's function and responsibilities must be described in the project protocol.

502.12 A DSMB/equivalent executive summary should be submitted to the HREC as part of the annual safety report.

# **SOP503:** Amendments

**Version:** 3.0 May 2021

**Review:** May 2024

503.1 Changes to a project, including amendments to the protocol and study documents or the addition of sites must be approved by the Lead HREC and authorised by the site via an Amendment Form submitted in the RGS, prior to being implemented. Exceptions to this are changes that only involve administrative aspects of the project and changes that are urgently required to eliminate hazards to participants.

503.2 Amendments to the conduct of the project that have potential ethical or scientific implications must be submitted as an **Amendment Form** which is first submitted to the HREC, and when approved, submitted to the RGO(s).

503.3 Amendments to the conduct/administration of the project that have potential site implications, including budgetary changes, but no ethical or scientific implications, must be submitted using a **Governance Only Amendment Form** to the RGO(s) for review.

503.4 Additional EMHS sites can be added to the ethical approval for a project approved by a WA Health HREC via submission of an Amendment Form in the RGS. Addition of a new EMHS site to a project with ethical approval by a non-WA Health HREC under the NMA must be completed by following the HRECs processes.

503.5 Amendment Forms must include a plain language summary of the nature of, and reasons for, the changes. Tracked and clean copies of any amended documents must be submitted for clarity and to aid the efficient review of the request.

503.6 When submitting a Governance Only Amendment Form, evidence of the HREC approval must be included if the Lead HREC is not a WA Health HREC.

503.7 Amendments that are submitted to the HREC and/or RGO(s) will be reviewed and the investigator(s) notified of the outcome after the HREC meeting or site review. The RGO will review then recommend the amendment for authorisation by the CE/Delegate.

503.8 The outcome of the review may be approved/authorised or additional information requested. The outcome of the review will be sent to the CPI/PI via the RGS. Approved/authorised amendments may be implemented. If additional information is required, a revised Amendment Form must be submitted.

503.9 Once the amendment is approved the EMHS Research Hub will issue approval letters via the RGS.

# SOP504: Progress reports

**Version:** 3.0 May 2021

**Review:** May 2024

504.1 Continuation of ethical approval and site authorisation is contingent upon receipt of annual progress reports.

504.2 Once site authorisation has been granted by EMHS the Site Principal Investigator (PI) is required to submit, as a minimum, an annual progress report for each EMHS site/s via the RGS. If the RPH HREC is the reviewing HREC, the project Coordinating Principal Investigator (CPI) is required to submit an annual project progress report to the HREC.

504.3 Progress reports to the HREC are due on the anniversary of the HREC approval.

504.4 When finalising EMHS site authorisations, the reviewing RGO will endeavour to align the site progress report due date with the HREC report due date (regardless of which HREC has approved the project) to harmonise reporting timelines and reduce the administrative burden on the Site PI/Delegate.

504.5 The RGS progress report template includes fields covering:

- A summary of project progress and any difficulties/challenges
- Participant recruitment
- Data collection and storage
- Adverse events (SAE's, SUSAR, SAR, SADR) and any changes arising from these events, including a summary of amendments during the year
- If multi-site, site specific recruitment numbers and progress
- Personnel changes

504.6 Progress reports submitted to the RPH HREC are processed in RGS by the Administrative Officer (AO) and summarised by the AO and Ethics Coordinator for tabling at the next available HREC meeting. If the report contains information that might be of concern (significant delays in commencing research; concerns about participant safety or data security) this is raised with the HREC Chairperson prior to the meeting.

504.7 Receipt of reports and confirmation of review by the HREC is acknowledged via an RGS letter completed by the AO.

504.8 Progress reports submitted for EMHS sites are processed by the AO. If the reports contain information that might be of concern relating to the conduct of the project at the site, this is taken to the EMHS Research Manager (RM) for review and possible escalation to the relevant Executive Director.

504.9 Receipt of site reports is acknowledged via an RGS letter completed by the AO.

504.10 The RGS sends automatic email reminders to the CPI and PI, and their delegates, *6 weeks* prior to progress report due dates.

504.11 Overdue progress reports can lead to a project's ethical approval or site authorisation being halted temporarily. The Research Hub actively monitors report due dates to assist researchers to meet their monitoring obligations.

504.12 The AO will track pending and overdue progress reports for both EMHS sites and the RPH HREC using the Research Hub Project Tracker, reconciling this with reports as they are submitted in the RGS.

504.13 When a progress report becomes overdue, the AO will:

- Email the responsible person (CPI or PI) and their delegate/s requesting that the report is submitted in RGS as soon as possible and offering assistance if required.
- If a report has not been submitted within 7 days, the AO will phone the responsible person re-iterating the need to submit a report and offering assistance.
- If a report has not been submitted after a further 3 days, the AO will inform the RM who will again phone the responsible person. The RM will explain that if the required report is not submitted within 24 hours, a recommendation will be made:
  - To the relevant Executive Director that the Site Authorisation be 'temporarily halted' (suspended) (for a site progress report).
  - To the RPH HREC Chairperson that the ethical approval be 'temporarily halted' (suspended) (for a project progress report).

504.14 If the decision is made by the Executive Director or RPH HREC Chairperson to suspend the ethical or site approval, a letter to this effect will be sent to the CPI/PI via RGS. The processes in SOP506 will be followed.

# SOP505: Final reports

**Version:** 3.0 May 2021

**Review:** May 2024

505.1 Once a research project has been completed, the site Principal Investigator (PI) must submit a final site report to the relevant research governance office. Once all sites have reviewed and acknowledged the final report and changed their site status in the RGS to 'closed', the Coordinating Principal Investigator (CPI) must submit a final project report to the Lead HREC.

505.2 The RGS final report template includes fields covering:

- A summary of the project's progress to completion and if was as planned
- A statement regarding whether the broad aims of the project have been met
- If available, results or publications arising from the project
- Any examples of how the findings have been translated into practice
- A summary of participant recruitment
- A description of the collection and storage of data and, if applicable, the conditions under which data will be retained.

505.3 Final reports submitted to the RPH HREC are processed in RGS by the Administrative Officer (AO) and summarised by the AO and Ethics Coordinator for tabling at the next available HREC meeting. If the report contains information that might be of concern (e.g., failure to meet aims, inability to recruit enough participants or early termination) this is raised with the HREC Chairperson prior to the meeting and flagged in the tabled papers.

505.4 Receipt of reports and confirmation of review by the HREC is acknowledged via an RGS letter completed by the AO.

505.5 Final reports submitted for EMHS sites are processed by the AO. If the reports contain information that might be of concern relating to the conduct of the project at the site, this is taken to the EMHS Research Manager (RM) for review and possible escalation to the relevant Executive Director.

505.6 Receipt of site final reports is acknowledged via an RGS letter completed by the AO.

505.7 Preparation of final reports is prompted by the researchers themselves when they determine that they have completed the project. However, there are situations where the EMHS Research Hub may become aware of overdue final site or HREC reports:

- Final site reports have been submitted for non-EMHS sites but not for EMHS sites and/or the RPH HREC (as reviewing HREC).
- All sites have been closed but a final project report has not been submitted to the RPH HREC.

505.8 The Research Hub actively monitors projects to assist researchers to meet their monitoring obligations, including when closing out projects.

505.9 The AO will track and respond to overdue final reports as they become evident.

505.10 When a final report is overdue, the AO will:

- Email the responsible person (CPI or PI) and their delegate/s requesting that the report is submitted in RGS as soon as possible and helping if required.
- If a report has not been submitted within 7 days, the AO will phone the responsible person re-iterating the need to submit a report and helping.
- If a report has not been submitted after a further 3 days, the AO will inform the RM who will again phone the responsible person and offer support to ensure the final report is submitted.

# SOP506: Suspension of a project

**Version:** 3.0 May 2021

**Review:** May 2024

506.1 Research projects may be suspended by the sponsor, CPI, HREC or site CE/Delegate for any reason, including issues that are identified as part of the monitoring processes described in section.

506.2 If the HREC or EMHS site CE/Delegate suspends the project, this decision and reasons for this decision will be communicated to investigators and other relevant parties, along with any recommended actions or conditions required to reactive the project.

506.3 If the CPI suspends the project, this decision must be communicated to the HREC and RGO(s) via an amendment or safety report, depending on the circumstances of suspension.

506.4 If the RPH HREC or EMHS CE/Delegate suspend approval/authorisation for a project, the CPI/PI will be notified in writing of the reasons for this decision any actions and conditions required to reactivate the project.

506.5 Regardless of which party initiated the suspension, primary attention must be given by all parties to the safety and ongoing care of participants (if applicable). The notification via an amendment or safety report must include an explanation of any implications for participants and steps to be taken to mitigate any risks and prevent any adverse outcomes. The process for communicating the suspension to participants must also be explained.

506.6 After the period of suspension, the project may either be reactivated or closed (See SOP508). If a project is to be reactivated, the approval of the Lead HREC and re-authorisation by the EMHS site CE/Delegate must be documented.

# SOP507: Early termination of project

**Version:** 3.0 May 2021

**Review:** May 2024

507.1 The HREC(s) and RGO(s) must be notified when a research project is:

- Prematurely terminated - commenced at the site but terminated on ethical, safety, financial or other grounds
- Suspended - commenced at the site but temporarily stopped for any reason
- Completed ahead of schedule.

507.2 Notification, including the reason for early termination, must be submitted to the HREC(s) by the CPI and the RGO by the PI at each site. Wherever possible, the PI must notify research participants if the research project is to be discontinued before the expected date of completion and discuss their ongoing management or care, if applicable.

507.3 Any project that is terminated early must submit the site final report to both the HREC and the RGO. Submission of the site final report must only occur after the ongoing management of the participants has been approved by the HREC and RGO, if applicable.

# **SOP508:** Project Completion

**Version:** 3.0 May 2021

**Review:** May 2024

508.1 When a research project site is closed, the PI is required to notify the RGO via a **Site Final Report** on the RGS.

508.2 When a research project is closed at all sites under the HREC's approval, the CPI is required to notify the HREC via a **Project Final Report** in the RGS.

508.3 The RGO/EO must validate, review and authorise/approve the Site/Project Final Report before the project is marked as closed in the RGS.

508.4 Research findings must be communicated to research participants as required and as per the National Statement. If applicable, the ongoing care of the participants must be considered.

508.5 EMHS CPIs/PIs are encouraged to log publications and other outputs, including a description of how the project findings have translated into routine practice, into the Publications Tab in the RGS project workspace.

# SOP509: Research Audit Program

**Version:** 3.0 May 2021

**Review:** May 2024

509.1 EMHS strives to achieve excellence in research and part of maintaining this high standard is the regular auditing of selected approved projects. Auditing of approved projects is a necessary component of the overall monitoring of health research and is required of EMHS by the National Statement.

509.2 The purpose of the EMHS research audit program is to review how research is being conducted, to detect and correct non-compliance with good clinical practice, project-specific ethical and site conditions, and to identify any practical, logistical or resourcing issues that might be hindering project progress of research projects undertaken with EMHS. The audit program complements routine minimum monitoring of active research projects as described in SOP501.

509.3 The specific objectives of the program are:

- To ensure research is conducted ethically, safely, legally and in compliance with the protocol, conditions of HREC approval and institutional policies and procedures
- To raise awareness of the requirements of and promote researcher accountability
- To inform the research education planning and the review of research policies and procedures
- To ensure that the conduct of research does not compromise the integrity of the results.

509.4 The audit program is designed to be collaborative and supportive, with broad, systemic and generalisable learnings guiding research education planning and policy and process reviews.

509.5 The EMHS Research Hub audits 5-10 projects each year (5-10% or annual new site authorisations) to provide a snapshot of compliance and capacity across a selected sample of the wide variety of research projects conducted within EMHS. Projects will be selected based on a number of criteria and priority points:

- Based on the risk-rating applied during the EMHS research governance review to ensure limited auditing capacity is assigned to higher risk/complexity projects
- To ensure coverage of the full range of project types conducted within each year (i.e., retrospective data; prospective observational; interventional)
- HREC request for specific monitoring (typically due to the application of special conditions)
- Random selection
- Following a complaint (Noting such audits will be conducted in accordance with the complaints handling process).

509.6 Audits will be conducted by and RGO, Ethics Coordinator or Research Manager on a rotational basis.

509.7 The audit process is fully outlined in the following document:

*EMHS Research Audit Program Guide*

509.8 The Guide explains how audits are conducted and what is expected of the research team prior to, during and after the audit, including the information that is needed for the audit visit. The audit process utilises the following tools:

 *Self-Audit Tool*

 *Audit Program Tool*

509.9 Following the visit, the auditor will complete the audit tool findings, comments and actions based on notes taken during the visit. The comments and actions will focus on key issues, including but not limited to:

- Breaches or neglect of the conditions of HREC or site approval
- Non-compliance with the protocol
- Non-compliance with other requirements.

509.10 The completed audit tool will be sent to the PI within two weeks of the visit and the follow-up process will be as follows:

- From the date the report is sent, the PI will have two weeks to respond to any actions, unless an urgent resolution is indicated
- The PI can discuss any of the items with the auditor and, if they detect any errors or inaccuracies, can also seek to correct these
- The PI's Head of Department will also be sent a copy of the audit tool and may be asked to oversee the resolution of the issue and the PI's response
- The responses will be reviewed by the auditor and EMHS Research Manager and 'closed' if the response details an acceptable and effective resolution
- If the items are not resolved, an 'outstanding issues' reminder will be sent to the PI and Head of Department.

509.11 Findings that are considered to have a potentially significant and/or urgent negative impact on any of the following may be escalated to the approving HREC (if applicable) or to the EMHS Area Director of Clinical Services (if relevant primarily to site governance) and may require response within a shorter time frame (i.e. days or weeks rather than 1 month):

- The risks to the research participants
- The ethical acceptability of the study.

509.12 The Audit Tool, PI's responses and all records of the audit will be securely stored within EMHS Research Hub records.

509.13 The Hub uses the results of all audits, and its broader monitoring of research projects, to inform future training opportunities and the ongoing review and improvement of research policies and procedures. As such, the findings of all audits may be used in these ways, but no specific project or investigator/personnel will be named in any public communication or correspondence.

# SECTION 6: CONSENT

## SOP601: Informed Consent

**Version:** 3.0 May 2021

**Review:** May 2024

601.1 Informed consent must be obtained from research participants, or their legal guardian/decision maker as appropriate (SOP302; SOP303), for their participation in research, including the use of their data or biospecimens. Under certain circumstances, alternatives to informed consent (i.e. a waiver of consent or the opt-out approach) may be justified if all ethical, policy and legislative requirements are met.

601.2 HRECs and RGOs must check that the secondary use of biospecimens or data for research purposes is covered by the original informed consent provided by participants, or that it fulfils the requirements for alternatives to informed consent. If informed consent is required but has not been obtained under the original consent form, HRECs and RGOs must ensure that new consent is obtained from participants.

601.3 HRECs must review all materials used in recruiting potential research participants (such as the master PICF) and ensure all requirements for alternatives to informed consent are met (if applicable).

601.4 RGOs must ensure that site-specific requirements for consent are met, including reviewing the master PICF against site-specific PICFs. RGOs are also responsible for ensuring that relevant policies and legislation are adhered to.

601.5 HRECs and RGOs must be aware of the specific legal requirements for consent under the Health Services Act 2016 that apply to the disclosure of personal information for research purposes. If no personal information is involved, then no legal requirement for consent applies (See SOP702).

601.6 RGOs and HRECs must apply special considerations and/or additional requirements for consent that apply to certain types of research projects. This includes any additional requirements set out in the National Statement, site-specific policies and relevant legislation, such as for research projects involving biobanks and the use of participant/patient data. If a waiver of consent or the use of the opt-out approach is granted by an HREC, the RGO must also ensure that the research satisfies all legislative requirements for consent that apply to the information being used for research. Some of the specific legislative requirements relating to waiver of consent/opt-out approach are described in SOP602 and SOP603.

601.7 The National Statement provides ethical guidance on obtaining consent for research, whereas relevant legislation (such as the Health Services Act 2016) set out legal obligations relating to confidentiality and the circumstances under which information can be disclosed. HRECs and RGOs must be aware that research that satisfies ethical requirements may not always satisfy legal obligations. This is particularly important for RGOs when reviewing research that has been approved by a non-WA HREC via the NMA scheme (See SOP103), as state-specific legislative requirements differ.

# SOP602: Waiver of consent

**Version:** 3.0 May 2021

**Review:** May 2024

602.1 The National Statement provides that a HREC may grant a waiver of consent for research if, along with other conditions, it is impracticable to obtain consent (for example, due to the quantity, age or accessibility or records).

602.2 The Health Services Act 2016 allows the disclosure of information for the purpose of research in according with the Health Services (Information) Regulations 2017. Regulation 3(2) of the Information Regulations states, among other things, that consent must be obtained for the disclosure of personal information for research purposes, unless it is impracticable to obtain the consent of the individual to whom the information relates.

602.3 The threshold for being "impracticable" to obtain consent is relatively high, Notably, the term "impracticable" is not synonymous with "difficult" or "undesirable". It means that something more than expenditure of reasonable resources or effort must be demonstrated. For example, if the contact details of the potential research participants are known, then the cost and difficulty of obtaining consent may not satisfy the "impracticable" threshold. Whether the legislation permits the disclosure of personal information without consent must be determined on a case-by-case basis. Depending on the complexity of the research project in relation to the legislation, RGOs may obtain legal advice specific to the research project as part of site-specific authorisation review.

602.4 HRECs must consider these above requirements when ethically reviewing research projects involving waivers of consent. Only a fully constituted HREC may grant approval of research where the requirement for consent may be justifiably waived.

602.5 The purpose, meaning and criteria for a waiver of consent for research is poorly understood by many researchers. CPIs whose projects rely on the granting of a waiver of consent must familiarise themselves with the relevant section of the National Statement and seek advice from the reviewing HREC's Coordinator when completing the ethics application. Consultation with RGOs for each Health Service from where health information will be obtained should also be consulted during preparation of the ethics and site governance submissions.

602.6 If the HREC grants a waiver of consent, this will be specifically stated in the HREC approval letter.

# SOP603: Opt-out approach

**Version:** 3.0 May 2021

**Review:** May 2024

603.1 As per the National Statement, the opt-out approach is a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement, and where their participation is presumed unless they act to decline participation.

603.2 While an opt-out approach makes it possible for people to make an informed choice about their participation, this choice can only be made if participants receive and read the information provided, and they understand that they are able to act on this information to decline to participate.

603.3 The National Statement provides that an opt-out approach to participant recruitment may be ethically appropriate when it is feasible to contact the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible. However, the use of an opt-out approach carries with it a significant risk, because there cannot be certainty of why a participant has not objected to the proposed disclosure of their personal information.

603.4 The use of an opt-out approach does not satisfy the legal requirements set out by the Health Services Act 2016 for consent to the disclosure of personal information. Therefore, HRECs and RGOs must ensure that the legal requirements for a waiver of consent (See SOP602) are also applied to research utilising an opt-out approach.

603.5 The purpose, meaning and criteria for application of an opt-out approach is poorly understood by many researchers. CPIs whose projects rely on the HREC approving use of the opt-out approach must familiarise themselves with the relevant section of the National Statement and seek advice from the reviewing HREC's Coordinator when completing the ethics application. Consultation with RGOs for each Health Service from where health information will be obtained should also be consulted during preparation of the ethics and site governance submissions.

603.6 If the HREC approves use of the opt-out approach, this will be specifically stated in the HREC approval letter.

# SECTION 7: DATA AND PRIVACY

## SOP701: Principles

**Version:** 3.0 May 2021

**Review:** May 2024

701.1 Protecting participants and the responsible handling of their information is extremely important in human research. Confidentiality and privacy processes must be implemented for all research projects conducted within the WA health system.

701.2 **Data Stewardship and Custodianship:** Every state-wide health data collection containing health information from WA health system patients must be overseen by a Data Steward and governed by a Data Custodian. Approval to access data from these collections, including linked and unlinked data, must be obtained from the relevant Data Steward. This approval is required in addition to obtaining ethical approval and site authorisation. The Data Steward may delegate the responsibility for approving access to data to a Data Custodian.

701.3 RGOs must consult the WA health system Information Register for information on the data collections held within the WA health system, including the names of Data Stewards and Data Custodians.

701.4 RGOs and/or Data Stewards must ensure that the project's proposed process of collection, storage/retention, access, disclosure, use and disposal of data in research projects complies with all requirements in the DOH Research Governance Policy and Procedures.

701.5 Data Stewards must only approve access and disclosure of data in line with the above policies, and when:

- consent has been provided by the participant for their data to be used for research purposes
- the empowering legislation governing the relevant data collection(s) allows for patient information to be released for a specific research project in absence of patient consent or
- if the information being requested is non-personal health information and the disclosure of information in absence of consent is not prohibited by legislation.

# SOP702: Types of Information

**Version:** 3.0 May 2021

**Review:** May 2024

702.1 Information that is accessed, used or disclosed for the purposes of research is defined according to WA Health Information Access, Use and Disclosure Policy. The different types of information described in the policy are:

- non-personal information
- personal information (noting this has the same meaning given in the Freedom of Information Act 1992)
- reasonably identifiable information
- sensitive information.

702.2 Sensitivity of information should be determined in line with the WA Health Information Classification Policy, which provides a consistent approach across WA Health for the classification of information assets by outlining the minimum requirements and responsibilities of WA Health Services.

702.3 The level of risk associated with the proposed type of information to be collected, analysed, and stored, and the security measures in place to mitigate this risk, must be assessed by the HREC as part of the ethical review.

702.4 The RGO must consider relevant legislative and policy requirements when conducting site governance review of research involving the disclosure of information. It is particularly important to consider if an individual's consent is required to disclose the information, as this is dependent on the type of information that is being disclosed. The Data Steward/s of the relevant 36 datasets is responsible for determining the type of information being disclosed.

# SOP703: Department of Health Data Collections and Linkage

**Version:** 3.0 May 2021

**Review:** May 2024

703.1 Data Steward approval for access to data held within the Department of Health's data collections, including linked data, must be coordinated through the Department of Health Research Data Services (DoH RDS) team. Requests to the EMHS Research Hub from researchers for information relating to the Data Steward approval process will be directed to the DoH RDS team and/or the Data Linkage WA website.

703.2 Research projects that propose the use of health information from one or more of the Department of Health's data collections must:

- Receive a feasibility letter from the Research Data Services team or relevant 3 Data Steward/s
- Be reviewed and approved by the Department of Health HREC
- Receive approval from the relevant Data Steward/s
- Undergo site specific assessment through the Department of Health RGO
- Be granted site authorisation by the DG (or delegate)
- Be monitored by the Department of Health HREC and RGO throughout the life of the project.

703.3 Some projects involve research activities that occur at EMHS sites and, in addition, have a Data Linkage component. For example, a cohort of patients may be recruited at an EMHS site while receiving treatment and consented to participate but will be followed long term using the Department of Health data collections. These projects will generally require both a Lead HREC (e.g., RPH HREC) approval plus specialist DOH HREC approval and both EMHS and DOH site authorisations.

# SOP704: Information Security, Retention and Disposal

**Version:** 3.0 May 2021

**Review:** May 2024

704.1 Researchers must ensure research information is:

- protected against theft, loss and unauthorised access, use and disclosure
- protected against unauthorised copying and modification
- retained, transferred and disposed of in a secure manner as per the DOH Information Storage Policy
- managed in line with Information Security Policy.

704.2 For all projects involving WA health system information, the RGO must ensure as part of site authorisation review, that there is an adequate plan to manage and dispose of the data, including a data security plan addressing the protection of identity, physical and technological security, and transport.

704.3 RGOs must confirm, through site review and subsequent monitoring, that investigators are ensuring that information is retained and managed in accordance with the DOH Information Storage Policy and Information Retention and Disposal Policy.

704.4 The HREC and relevant RGO(s) must be notified of the following details when the destruction of the health information is complete:

- RGS Project Reference Number
- Title of the project/information
- When the information was destroyed
- How the information was destroyed
- Who destroyed information
- Who approved the destruction.

# SOP705: Information Breaches

**Version:** 3.0 May 2021

**Review:** May 2024

705.1 Breaches and suspected breaches of the approved use of information must be reported using an Information Breach Notification Form to notify the line manager or other appropriate contact and the Data Steward/s if appropriate. The breach must then be managed according to the DOH Information Breach Policy.

705.2 If the information breach is also identified as an adverse event, the breach must also be handled with the generation of a safety report and notification of the HREC and RGO/s.

# SECTION 8: BIOBANKS

## SOP801: Establishment and governance of biobanks

**Version:** 3.0 May 2021

**Review:** May 2024

801.1 HRECs and RGOs must ensure that all research projects involving biospecimens and/or data from biobanks follow the:

- National Statement
- NHMRC Biobanks Information Paper
- WA Health Guidelines for human biobanks, genetic research databases and associated data

801.2 When reviewing research that involves the establishment of a biobank, or the donation of biospecimens or data to a biobank, HRECs and RGOs must ensure that:

- The biobank has a clearly articulated current and future purpose(s), focus and proposal for operation
- Approval to access biospecimens or data from the biobank is governed by a Biobank Custodian, and that any relevant approvals have been obtained
- An appropriate governance structure is in place for the biobank prior to its establishment, including the nomination of the Biobank Custodian
- Requirements for informed consent have been met for the collection, storage, access and use of biospecimens and/or data for research purposes (See SOP section 18 16).
- Any ownership rights (legal or ethical) that apply to the biospecimens or data in the biobank are considered during HREC and/or RGO review
- There is an established plan for closing the biobank if it no longer meets a need or encounters an unforeseen demise (e.g. end of funding), including a disposal plan for biospecimens and data.

# SECTION 9: CONFIDENTIALITY

## SOP901: Confidentiality of research data

**Version:** 3.0 May 2021

**Review:** May 2024

901.1 **WA Health Staff:** All WA Health System employees, including investigators/research team members, research ethics and governance staff and HREC members are subject to the DOH Practice Code for the Use of Personal Health Information and the Public Sector Management Act 1994 to keep information confidential.

901.2 **External Researchers:** Research project members external to the EMHS that are accessing identifiable information within EMHS must be added as project members in the RGS and must sign a project-specific *Declaration of Confidentiality*. This declaration is signed either when creating a new project workspace as a CPI or accepting an invitation to a research project in the RGS. All research project members must comply with the provisions of the Privacy Act 1988.

901.3 **Student Researchers:** Additionally, the *Student Research and Confidentiality Declaration* must be completed by all research personnel undertaking research as part of their studies (irrespective of whether they are WA health system/EMHS employees). In the RGS, the *Student Research and Confidentiality Declaration* must be attached as a supporting document to the site authorisation application or an amendment form if the project is in the monitoring phase.

# SECTION 10: CONFLICTS OF INTEREST

## SOP1001: Researcher Conflicts of Interest

**Version:** 3.0 May 2021

**Review:** May 2024

1001.1 This SOP is written in accordance with Section 5.4 of the National Statement 2007 (Updated 2018), the Australian Code (2018) and the WA Health Managing Conflicts of Interest Policy (11 June 2020).

1001.2 Conflicts of interest are related to either:

- Financial and material interests: where an investigator could gain or lose financially because of the way the investigator conducts a project (e.g. intellectual property interests, business partnerships, travel and gifts)
- Non-financial and partiality interests: where an investigator's personal involvement, relationships or values may influence the way they conduct a project (e.g. membership of associations, relationships).

1001.3 Any EMHS employee who is an investigator or research team member who has a personal or professional interest that may constitute an actual or perceived conflict of interest must complete a Conflict of Interest Form in the Declarations Tab of the project workspace in the RGS, describing:

- The nature of the conflict of interest
- Proposed actions to resolve or manage the conflict.

1001.4 It is the responsibility of all investigators/team members to make such declarations as part of the HREC and site governance submissions for a new project and, subsequently, at any time new conflicts arise during the course of the project.

1001.5 If the RGO identifies a potential conflict of interest that has not been declared during review of the project, they must discuss this with the relevant investigator/team member and ensure they understand their obligations.

1001.6 Where an investigator/team member declares a conflict this will be reviewed by the RGO and/or EEO in accordance with the WA Health Research Governance Policy and Procedures (2012), the WA Health Managing Conflicts of Interest Policy (11 June 2020) and the WA Health Managing Conflicts of Interest Information. The RGO and/or EEO will review the conflict and consider actions for resolution or management, which may include:

- No action beyond mandatory registration WA Health Conflicts of Interest Registry
- Declaration of the conflict in the PICF, along with any actions taken (if applicable)
- Removing the investigator/team member from the project
- Restricting the investigator/team member's involvement in the project (e.g., not being involved in the analysis and publication of the findings)
- the investigator/team member relinquishing a private interest that is, or may be perceived to be, in conflict with the unbiased conduct of the project.

1001.7 The RGO and/or EEO will contact the investigator/team member if clarification is required and to discuss the proposed actions. The Investigator /team member will have the opportunity to amend the planned project to remove the conflict if necessary.

1001.8 If the declaration requires consideration by the HREC, the EEO will ensure the declaration and a summary of any additional discussions or correspondence with the investigator/team member is tabled at the next available HREC meeting for a determination from the HREC on the necessary course of action.

1001.9 When finalised, the action/s to be taken will be documented by the RGO and/or EEO and acknowledged by the Investigator/team member and submitted to the EMHS Director of Research who is the Authorised Person to approve the agreed management plan.

1001.10 The research must not be authorised until the conflict of interest is addressed to the satisfaction of the CE/Delegate.

1001.11 The Investigator/team member must register the conflict and the management plan in the WA Health Conflict of Interest Register (COIR) and this must be approved by the EMHS Director of Research.

# SOP1002: HREC Member Conflicts of Interest

**Version:** 3.0 May 2021

**Review:** May 2024

1002.1 This SOP is written in accordance with Section 5.4 of the National Statement 2007 (Updated 2018), the Australian Code (2018), the WA Health Managing Conflicts of Interest Policy (11 June 2020) and the RPH HREC Terms of Reference.

1002.2 Conflicts of interest are related to either:

- Financial and material interests: where an investigator could gain or lose financially because of the way the investigator conducts a project (e.g. intellectual property interests, business partnerships, travel and gifts)
- Non-financial and partiality interests: where an investigator's personal involvement, relationships or values may influence the way they conduct a project (e.g. membership of associations, relationships).

1002.3 Any RPH HREC member, or member of the LNR Panel, who identifies a personal or professional interest that may constitute an actual or perceived conflict of interest in relation to a research ethics application under review must as soon as practicable declare the interest and withdraw from review of the application.

1002.4 If the member is present at a meeting at which the application is the subject of consideration:

- The member must declare the conflict at the beginning of the meeting when the Chairperson call for such declarations under the standing agenda item
- The member must withdraw from the meeting during the HREC's consideration of the relevant application and not take part in the discussion or decision
- The declaration of interest and absence of the member concerned during the item in question must be minuted.

1002.5 If the member is asked to contribute to an LNR Panel to review an application for which they have an actual or perceived conflict:

- The panel member must inform the HREC Coordinator as soon as practicable and withdraw from review of that application
- The HREC Coordinator will invite another panel member from the pool to replace the member with the conflict
- The HREC Coordinator will document the conflict and withdrawal of the member on the LNR Panel Review Form.

# OP1003: Hospital Administrator Conflicts of Interest

**Version:** 3.0 May 2021

**Review:** May 2024

1003.1 This SOP is written in accordance with the WA Health Managing Conflicts of Interest Policy (11 June 2020).

1003.2 Conflicts of interest are related to either:

- Financial and material interests: where an investigator could gain or lose financially because of the way the investigator conducts a project (e.g. intellectual property interests, business partnerships, travel and gifts)
- Non-financial and partiality interests: where an investigator's personal involvement, relationships or values may influence the way they conduct a project (e.g. membership of associations, relationships).

1003.3 If a Hospital Administrator is both the Head of the Department in which the research project will be conducted, and an investigator, the department budget for the project must be authorised by an alternative Administrator (usually the Head of Department's line manager/Service Director).

1003.4 If a Hospital Administrator identifies any other personal or professional interest that may constitute an actual or perceived conflict of interest in relation to their consideration of research project support or approval, they must as soon as practicable declare the interest remove themselves from consideration of the project.

1003.5 When a Hospital Administrator declares a conflict of interest and must withdraw from consideration of the project, the RGO will arrange an alternative signatory based on discussion with all parties, including the researchers, relevant Heads of Department and Service Directors.

# SECTION 11: COMPLAINT MANAGEMENT

## SOP1101: Complaints about the conduct of a research project

**Version:** 3.0 May 2021

**Review:** May 2024

1101.1 This SOP is written in accordance with:

- Section 5.6 of the National Statement
- Section 7.1 of the RPH HREC Terms of Reference (2020)
- The Australian Code (2018)
- Guide to managing and investigating potential breached of the Australian Code for the Responsible Conduct of Research (2018)
- WA Health Research Governance Policy and Procedures (2012)
- The WA Health Complaints Management Policy (3 February 2020)

1101.2 This SOP aims to ensure that the investigation of complaints about the conduct of research projects and potential breaches of the Australian Code (2018) ('The Code') is rigorous, but proportional, procedurally fair, impartial, timely, transparent, confidential, and handled with sensitivity.

1101.3 Complaints may be received from research participants, researchers, staff of institutions, or other interest parties, including relatives of participants or members of the public.

1101.4 Complaints may be received verbally or in writing via letter or email. Anonymous complaints will be investigated. Complainants will be encouraged to provide all information relevant to the situation as they are able to.

1101.5 Complaints relating to the conduct of research projects or potential breaches of The Code may be made to the HREC, the site or both.

1101.6 Given that medical research is increasingly multi-institutional and multi-jurisdictional, institutions should cooperate to ensure only one investigation is completed, particularly where a potential breach of The Code is identified. This should be considered on a case-by-case basis, considering where the complaint was lodged, contractual arrangements or where relevant events occurred.

1101.7 The nominated complaints handling officer relating to the conduct of research projects at EMHS sites is the EMHS Research Manager. Complaints received by another staff member of the EMHS Research Hub or other interested party should be directed to the EMHS Research Manager.

1101.8 The nominated position to receive complaints for the HREC will be defined by the HREC's Terms of Reference, noting that the reviewing HREC may be any WA Health HREC or NMA-certified HREC. The nominated Complaints Handling Officer (CHO) for complaints made to the RPH HREC about projects it has approved is the EMHS Ethics Coordinator.

1101.9 The Designated Officer (DO) to oversee management and (where required) investigation of complaints about the conduct of research or potential breaches of The Code is the Area Director of Clinical Services (ADCS).

1101.10 The CHO will provide details of the complaint to the DO within 24 hours of receipt, or as soon as practically possible.

1101.11 The CHO will send a letter of acknowledgement to the complainant within 24 hours of receipt, outlining the complaint, the mechanism for investigation and how to contact the CHO.

1101.12 The DO will conduct a preliminary assessment of the complaint and determine if there has been a potential breach of The Code, as per the definitions and processes outlined in the following guidance:

- The Australian Code (2018)
- Guide to managing and investigating potential breached of the Australian Code for the Responsible Conduct of Research (2018)

1101.13 Where the preliminary investigation determines that the matter is unrelated to the conduct of a research project the DO will refer the complaint to be managed the relevant department or service.

1101.14 Where the preliminary investigation determines that the complaint is related to the conduct of the project but there is no evidence of a breach of The Code, the DO will consider the complaint and make recommendations that may include:

- The requirement for amendments to the project
- Temporary suspension of the project
- Termination of the project
- Other action to resolve the complaint.

1101.15 Investigation of complaints where there is no evidence of a breach of The Code should take no longer than 30 working days from the time of notification of the complaint, unless exceptional circumstances exist.

1101.16 Where 1101.13 or 1101.14 apply, the DO will inform the complainant and the respondent of the outcome of the investigation within 5 calendar days of finalisation of the investigation.

1101.17 Where the preliminary investigation finds evidence of a potential breach of The Code, a breach of discipline or misconduct, the DO will refer the matter to EMHS Human Resources where it will be managed in line with the WA Health Discipline Policy.

1101.18 The CHO and DO will provide prompt information as required to assist with the EMHS investigation.

1101.19 Complaints relating to the conduct of a research project or breaches of The Code will be recorded in the *EMHS Research Hub Complaints Register*.

# SOP1102: Complaints about ethical review

**Version:** 3.0 May 2021

**Review:** May 2024

1102.1 This SOP is written in accordance with:

- Section 5.6 of the National Statement
- The Australian Code (2018)
- WA Health Research Governance Policy and Procedures (2012)
- The WA Health Complaints Management Policy (3 February 2020)
- Section 7.2 of the RPH HREC Terms of Reference (2020)

1102.2 Research projects conducted within EMHS may be ethically reviewed and approved by any WA Health HREC, by an NMA-certified HREC or by an institutional alternative review mechanism. Complaints about an HREC should be made according to the processes established by the reviewing HREC or the institution conducting the alternative review.

1102.3 Concerns or complaints relating to review by the RPH HREC must be made by the project's Coordinating Principle Investigator (CPI) to the attention of the HREC Chairperson. While initial complaints can be made verbally, via letter or email, the CPI should complete a complaint form in the RGS detailing the nature of the concern or complaint.

1102.4 The HREC Ethics Coordinator will send an acknowledgement of receipt and explanation of the review process within 7 calendar days of the date of the complaint.

1102.5 The HREC Chairperson will investigate the complaint and its validity and make a recommendation to the HREC on any necessary action. In considering the complaint, the HREC Chairperson will determine if the HREC acted in accordance with the National Statement and its TORs, completed its review in an unfair or biased manner or were insufficiently timely in their review.

1102.6 This investigation must take no longer than 30 calendar days from the date of the complaint, unless exceptional circumstances exist. The HREC Chairperson will maintain open communication with the complainant during the review and request further information or clarification as required.

1102.7 The complainant will be informed in writing of the outcomes of the review within 7 calendar days of a determination by the HREC Chairperson.

1102.8 If the complainant is not satisfied with the outcome of the HREC review, the complaint will be escalated to the EMHS Area Director of Clinical Services (ADCS) for review.

1102.9 The ADCS will consider the complaint, ensuring that both the CPI and the HREC provide submissions, and determine whether there is to be a further investigation. In considering the complaint, the ADCS will determine if the HREC acted in accordance with the National Statement and its TORs, completed its review in an unfair or biased manner or were insufficiently timely in their review.

1102.10 Where the previous determination by the HREC Chairperson/HREC is upheld and no further investigation is to occur and, the ADCS will inform the CPI and the HREC.

1102.11 If a further investigation is conducted, the ADCS will notify the CPI and HREC of the outcome and any arising recommendations.

1102.12 This further investigation must take no longer than 30 calendar days from the date of the escalation, unless exceptional circumstances exist.

1102.13 Where a resolution cannot be achieved following ADCS review, the ADCS may arrange for an external party to conduct an independent review.

1102.14 Complaints relating to research ethics reviews will be recorded in the *EMHS Research Hub Complaints Register* and in a deidentified format in the RGS complaint record.

# SOP1103: Complaints about research governance review

**Version:** 3.0 May 2021

**Review:** May 2024

1103.1 This SOP is written in accordance with:

- Section 5.6 of the National Statement
- The Australian Code (2018)
- WA Health Research Governance Policy and Procedures (2012)
- The WA Health Complaints Management Policy (3 February 2020)

1103.2 Concerns or complaints about EMHS site governance reviews must be sent by the EMHS Site Principle Investigator (PI) to the attention of the EMHS Research Manager. While initial complaints can be made verbally, via letter or email, the PI should complete a complaint form in the RGS detailing the nature of the complaint.

1103.3 The EMHS Research Manager will send an acknowledgement of receipt and explanation of the review process within 7 calendar days of the date of the complaint.

1103.4 The Research Manager will investigate the complaint and determine any action to be taken. In considering the complaint, the Research Manager will determine whether the research governance review was conducted in accordance with WA Health policy, was fair, unbiased and timely.

1103.5 This investigation must take no longer than 30 calendar days from the date of the complaint, unless exceptional circumstances exist. The Research Manager will maintain open communication with the complainant during the review and request further information or clarification as required.

1103.6 The complainant will be informed in writing of the outcomes of the review within 7 calendar days of finalisation of the review.

1103.7 If the complainant is not satisfied with the outcome of the Research Manager's review, the complaint will be escalated to the EMHS Area Director of Clinical Services (ADCS) for review.

1103.8 The ADCS will consider the complaint, ensuring that both the PI and Research Manager provide submissions, and determine whether there is to be a further investigation. In considering the complaint, the ADCS will determine if the research governance review was conducted in accordance with WA Health policy, was fair, unbiased and timely.

1103.9 Where the previous determination by the Research Manager is upheld and no further investigation is to occur and, the ADCS will inform the PI and the Research Manager. The ADCS may also make additional determinations and recommend internal actions arising from the review.

1103.10 If a further investigation is conducted, the ADCS will notify the PI and Research Manager of the outcome and any arising recommendations.

1103.11 This further investigation must take no longer than 30 calendar days from the date of escalation, unless exceptional circumstances exist.

1103.12 Where a resolution cannot be achieved following ADCS review, the ADCS may arrange for an external party to conduct an independent review.

1103.13 Complaints relating to research governance reviews will be recorded in the *EMHS Research Hub Complaints Register* and in a deidentified format in the RGS complaint record.

# SECTION 12: REVIEW FEES

## SOP1201: Schedule of fees

**Version:** 3.0 May 2021

**Review:** May 2024

1201.1 New applications for research projects that are sponsored by external commercial organisations (e.g. pharmaceutical companies or other commercial entities) attract a review fee. See table below.

1201.2 Additional fees may be charged for amendments, particularly those of a substantial nature requiring detailed review by an RGO and/or must be submitted for review by the RPH HREC.

1201.3 Applications by individual investigators for non-sponsored or for grant funded applications do not attract a review fee.

1201.4 Fees are published in the *EMHS Research Ethics & Governance Review Schedule of Administrative Fees*.

1201.5 Fees are subject to change and are formally reviewed every 2 years to ensure currency with state and national trends and consistency with policy requirements.

1201.6 Formal review is completed by the EMHS Research Manager who will (a) liaise with other WA Health HSPs to determine any changes to their fee structure and (b) conduct an environmental scan of a representative sample of interstate health service ethics and governance review fee structures.

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

* 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. Fees will only be charged when review by an RGO is warranted.

# SOP1202: Invoicing for ethics and governance reviews

**Version:** 3.0 May 2021

**Review:** May 2024

1202.1 New applications for research projects that are sponsored by commercial organisations (e.g. pharmaceutical companies or other commercial entities) attract a review fee. Substantial amendments to these projects that require RGO or HREC review also attract a fee. See SOP1201.

1202.2 To ensure billable reviews are correctly identified and processed, the Administrative Officer (AO) will flag these reviews when 'validating' new research governance submissions and amendments in RGS and record them on an Excel *Invoicing Tracker*. For new ethics submissions, the Ethics Coordinator will, following each HREC meeting, provide a list of billable reviews (both new submissions and amendments) to the AO to record on the *Invoicing Tracker*.

1202.3 On completion of governance reviews for either new projects or amendments, Research Governance Officers (RGOs) will indicate billable reviews when completing the hardcopy record of signing taken to the RPH Executive Director (or emailed to the AKG Executive Director). This record will be cross-checked by the AO to ensure billable reviews are not missed.

1202.4 Once a month (first week of each month, following the HREC meeting), the AO will:

- Reconcile the information in the *Invoicing Tracker* with the Executive Director signing record to ensure no billable reviews are missed.
- Prepare s60 Debtor Advice Forms for all billable reviews and email these to EMHS Accounts Receivable.
- Run an *AR Billing and Receipt History Report* in Oracle Discover Plus to confirm invoices that have been paid over the preceding month, updating the *Invoicing Tracker.*
- Identify invoices that are overdue (greater than the 30-day term) and, for invoices that remain unpaid after 60 days, contact EMHS Accounts Receivable to ascertain if they have followed-up with the debtor and if additional information is required from the Research Hub.