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

EMHS Research Governance
Standard Operating Procedures

1. TABLE OF CONTENTS

2. INTRODUCTION

This document provides employees of the East Metropolitan Health Service (EMHS) and external research partners with the requirements for the approval and monitoring of research and clinical trials involving human participants within EMHS. It outlines the functions and responsibilities of the various stakeholders involved in the conduct of projects and is designed to promote best practice and ensure compliance with the Australian Code for the Responsible Conduct of Research, 2018 ('the Code') and the National Statement on Ethical Conduct in Human Research 2023 ('National Statement').

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, including clinical trials, 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.

The WA Health Research Governance Framework (Policy and Procedures) outlines how single and multi-centre research at WA Health sites is to be conducted. All human research conducted in WA Health must undergo ethics and scientific review by a HREC registered with the NHMRC and operating in accordance with the National Statement. In addition, all research projects must receive site authorisation at each WA Health site at which it is to be conducted. *Both ethical approval and site authorisation are required before a project can commence.*

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, 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 research projects and clinical trials and monitors approved projects for all EMHS hospitals and services.

The purpose of these Standard Operating Procedures (SOPs) is to ensure EMHS has research governance processes that are effective but efficient and serve to facilitate high quality responsibly conducted research and clinical trials.

2.1 Scope

These procedures, and the mandatory WA Health Research Governance Framework (Policy and Procedures) 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 research and clinical trial submissions against the ethical principles and parameters enshrined in the NHMRC National Statement on Ethical Conduct in Human Research 2023 (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 HREC only considers 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.

The WA Health Central Human Research Ethics Committee (HREC) provides ethical review and oversight of research conducted within the WA Health System involving humans, their biospecimens and/or their information, and the use and linkage of data.

The WA Health Central HREC is an NHMRC-registered HREC (EC00481), is bound by state and national policies and legislation and operates with administrative support from the **Central Office for Research Ethics (CORE)**, based at the WA Department of Health on Royal Street.

The EMHS Research Hub provides project development support to EMHS staff and partners planning to submit to the WA Health Central HREC. However, CORE staff provide direct support at the time of submission and can be contacted at: hrec@health.wa.gov.au or on (08) 9222 4214.

National Mutual Acceptance

The National Mutual Acceptance (NMA) scheme involves all public health organisations across Australia, including WA. Multi-centre research projects, including clinical trials, being conducted at public health organisations can be reviewed once by 'Lead' HREC certified under the NMA Scheme.

In line with initiatives to reduce the duplication of ethical review of research and speed up clinical trial start up timeframes, EMHS accepts the ethical approval of NHMRC-certified HRECs, under the National Mutual Acceptance (NMA) Scheme.

Most clinical trials conducted within EMHS have ethical approval from an interstate NHMRC-certified HREC.

The WA Health Central HREC is not currently certified by the NHMRC under the NMA Scheme but will be from late 2025.

Three WA Health HRECs are certified to conduct multi-site ethical reviews under the NMA Scheme and EMHS researchers seeking a local 'Lead' HREC for a national project or trial can contact these HRECs:

- Child and Adolescent Health Service HREC (EC00268)
- Sir Charles Gairdner and Osborne Park Health Care Group HREC (EC00271)
- South Metropolitan Health Service HREC (EC00265)

2.3 Research governance review and site authorisation

Before a research project or clinical trial 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, which also includes a Research Finance team that supports the effective budgeting and financial acquittal or commercially-funded and grant supported research and trials.

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
- Approved by the relevant Hospital Administrators

The RGO makes a recommendation to the Chief Executive (or Delegate; usually the hospital Executive Director, or equivalent Area Executive Group (AEG) member) 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 Additional approvals

Research involving specific groups and/or data sources may require additional approvals before commencing.

Aboriginal or Torres Strait Islander Peoples

In addition to approval from the WA Health Central HREC or an NMA 'Lead' HREC, research that substantially involves Aboriginal or Torres Strait Islander participants must also be submitted to the WA Aboriginal Health and Ethics Committee (WAAHEC).

Projects should be submitted to WAAHEC if one or more of the following apply:

- Indigenous status is a key determinant
- Data collection is explicitly directed at Indigenous peoples
- Indigenous people, as a group, will be examined in the results
- The information or outcomes may have an impact on one or more Indigenous communities
- Indigenous health funds are a source of funding.

WA Health Data Collections

Research that requires access to WA Health Data Collections and/or involves data linkage via WA Health Data Linkage Services should must be reviewed ethically by the WA Health Central HREC and receive authorisation from the Department of Health RGO.

Note that this requirement relates only to the WA Health centrally held data collections and not data held in 'local' Hospital/Health Service data sources.

US Department of Health and Human Services

EMHS maintains a Federal Wide Assurance (FWA) with the US Office of Human Research Protections (OHRP). This is a type of registration through which institutions conducting research that involves US Federal funding commit to complying with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46, the US equivalents of the National Statement and related research and clinical trial processes.

The FWA is renewed regularly the FWA number is available on request from the EMHS Research Hub.

2.5 Monitoring of approved research

HRECs must monitor research projects and clinical trials to ensure that they 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 and clinical trials 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.

Detailed procedures for the submission and review of monitoring reports, including specific requirements for monitoring clinical trials, are provided in Section 5.

2.6 Research Governance Service (RGS)

The WA Research Governance Service (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 team provides support and guidance to EMHS staff and external partners who are planning or conducting research and clinical trials across EMHS sites and services.

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

4. REFERENCE DOCUMENTS

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

The documents are also essential references for any medical researcher, Principal Investigator responsible for a clinical trial of member of the wider research and trials workforce (such as Clinical Trials Coordinators) working within EMHS and the WA Health system.

Knowing your broad responsibilities as a researcher in Australia:

- National Health and Medical Research Council, Australian Research Council and Universities Australia Australian Code for the Responsible Conduct of Research (2018)

How to design and conduct ethically acceptable research:

- NHMRC National Statement on Ethical Conduct in Human Research (2023)
- World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2018)

How to design research about and to the benefit of Aboriginal people:

- NHMRC Ethical guidelines for research with Aboriginal and Torres Strait Islander peoples
- AIATSIS Code of Ethics 2020
- Seek advice and review from the WA Aboriginal Health and Ethics Committee (WAAHEC).

Processes and responsibilities when conducting clinical trials:

- Therapeutics Goods Administration (TGA) Australian Clinical Trial Handbook which includes information about the role of site Principal Investigators.
- ICH Guidelines for Good Clinical Practice with TGA Annotations
- WA Health Translation Network (WAHTN) GCP in Australia online training

NHMRC requirements for safety reporting and monitoring of clinical trials:

- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods

How research and clinical trials are governed within WA Health:

- The WA Health Research Governance Framework (Policy and Procedures)
- How to conduct multi-centre research within WA Health

5. ABBREVIATIONS

AE	Adverse Event
CDA	Confidentiality Disclosure Agreement
CIRA	Clinical Investigation Research Agreement
CORE	Central Office of Research Ethics (DoHWA)
CPI	Coordinating Principal Investigator
CRG	Collaborative Research Group
CRO	Contract Research Organisation
CTA	Clinical Trial Application
CTN	Clinical Trial Notification
CTRA	Clinical Trial Research Agreement
DoHWA	WA Department of Health
DSMB	Data Safety Monitoring Board
EMHS	East Metropolitan Health Service
GAA	Guardianship and Administration Act 1990 (WA)
GCP	Good Clinical Practice
GEKO	Governance Evidence Knowledge Outcomes
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
IB	Investigator Brochure
ICMJE	International Committee of Medical Journal Editors
IMP	Independent Medical Practitioner
IP	Investigational Product
MRI	Medical Research Institute
National Statement	National Statement on Ethical Conduct in Human Research
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance Scheme
PI	Principal Investigator
OMRI	Office of Medical Research and Innovation (DoHWA)
PICF	Participant Information and Consent Form
PRN	Project Reference Number
QA	Quality Assurance

QI	Quality Improvement
RDM	Research Decision Maker
REG	Research Ethics and Governance
RGO	Research Governance Office or Officer
RGS	Research Governance Service (WA)
SAE	Serious Adverse Events
SOPs	Standard Operating Procedures
SSA	Site Specific Assessment
SSI	Significant Safety Issue
SUSAR	Suspected Unexpected Serious Adverse Reactions
TGA	Therapeutic Goods Administration
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measures
WAHEAF	WA Health Ethics Application Form
WASM	WA-Specific Module

6. STANDARD OPERATING PROCEDURES

SOP001: Overview of research approvals and monitoring at EMHS

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, samples or data.

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 and clinical trials 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 without 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 low risk review conducted by the WA Health Central HREC Lower Risk Review (LRR) Panel.

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 To ensure the research is ethically and scientifically sound, only personnel with appropriate professional qualifications, credentials and institutional approvals, as required by the protocol, will be accepted as Site Principal Investigator (PI).

001.11 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.

001.12 Once the governance review has been completed, a recommendation will be made to the relevant EMHS Executive, as documented in the EMHS Authorisations and Delegations Schedule:

- EMHS Chief Executive
- Executive Director, Armadale Kalamunda Group (AKG)
- Executive Director, Royal Perth Bentley Group (RPBG)
- Other EMHS Area Executive Group (AEG) member responsible for an EMHS Service

001.13 Site authorisation does not have an expiry date but is predicated on ongoing HREC approval and continued compliance with standard and specific conditions of approval, including on time annual progress reporting. If an HREC suspends ethical approval, a project must be suspended at all sites that rely on that ethical approval. EMHS can also suspend or terminate a project.

001.14 All approved and authorised research projects must be monitored by the Lead HREC, Specialist HREC (if applicable) and EMHS 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.

001.15 All submissions for ethical and governance review, and subsequent monitoring throughout the life of a project, are may via the Research Governance Service (RGS), beginning with creation of a 'workspace' and RGS Project Reference Number (PRN) used to identify the project. This PRN must be included in all correspondence to the HREC and site RGO. Detailed instructions for using RGS are provided via the EMHS RGS Guide.

SECTION 1: ETHICAL REVIEW

SOP101: Overview of research ethics approval

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 SOP102 and SOP103)
- 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:

- The WA Health Central HREC (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 WA Health Central HREC for all projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage.

101.7 An ethical approval confirms that a proposed research project or clinical trial is ethically acceptable. It does not provide authorisation to commence any active part of the project, including recruitment or data collection at any site. 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 a given site. An ethical approval, listing the site, and if reviewed by a non-WA Health HREC, the WA Specific Module (WASM) is a requirement for site authorisation to be granted.

101.8 For multi-site projects, the Coordinating Principal Investigator (CPI) and site Principal Investigators (PIs) should work together with any Sponsors to determine the best HREC to review their project.

SOP102: WA Health Central HREC

102.1 For research projects involving only a single EMHS site or multiple sites within the WA Health public system, the WA Health Central HREC is the preferred HREC to provide ethical approval.

102.2 The WA Health Central HREC provides ethical review and oversight of research conducted within WA Health involving humans, their biospecimens and/or their information, and the use and linkage of data. It is bound by state and national policies and legislation and operates with administrative support from the Central Office for Research Ethics (CORE), based at the WA Department of Health on Royal Street.

102.3 The project's CPI is responsible for obtaining ethical approval. If the CPI is based within EMHS or an EMHS site is the single or 'lead' site for a project led by a CPI from a partner organisation (e.g., a University or MRI) then pre-HREC submission advice can be sought from the EMHS Research Hub.

102.4 The CPI and their Delegate should see the WA Health Central HREC's website for detailed information about submission requirements, meeting and deadline dates.

SOP103: National Mutual Acceptance (NMA) Scheme

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 NHMRC-certified 'Lead' HREC.

103.2 The majority of national multi-site research projects and clinical trials conducted at EMHS sites have ethical approval from an interstate NHMRC-certified HREC.

103.3 The NMA scheme is a national system for the mutual acceptance of ethical and scientific review of multi-site research projects and clinical trials conducted in publicly funded health services across multiple states. It aims to reduce the historic duplication of ethical review of multi-site, multi-jurisdictional research projects and, especially, clinical trials.

103.4 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.

103.5 Under the NMA scheme a research project or clinical trial 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).

103.6 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

103.7 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 Clinical trials drugs and devices Clinical interventional research other than clinical trials Population health and/or public health Qualitative research Mental health Paediatric research 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 Clinical trials drugs and devices Clinical interventional research other than clinical trials Population health and/or public health Qualitative research
South Metropolitan Health Service HREC	Continuous from 1 July 2020	Clinical trials phase I, II, III, IV Clinical trials drugs and devices Clinical interventional research other than clinical trials

103.8 It is intended that the WA Health Central HREC, established in 2024, will be certified to conduct multi-site ethical reviews by late 2025, after which the three WA Health HRECs in SOP 103.6 will be disbanded.

103.9 EMHS staff initiating a national or multi-jurisdictional research project or clinical trial should approach one of the currently NHMRC-certified WA Health 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.

103.10 The Human Research Ethics Application (HREA) must be used for ethics review under the NMA scheme.

103.11 For projects conducted at EMHS sites, submission of the WA Specific Module (WASM) (via the RGS workspace) is also required. The WASM is a WA-specific addendum to the HREA that assists the Lead HREC to understand and apply WA legislative requirements that apply to the project. Review of the WASM by the NMA certified HREC must be evidenced in the HREC letter/certificate of approval listing the WA Health sites.

103.12 EMHS staff initiating multi-site, multi-jurisdictional research projects must understand the functions and responsibilities of the Coordinating Principal Investigator (CPI), which include submitting the ethics application and WASM 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)

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

104.2 The specialist HRECs in WA are:

HREC	Function
WA Health Central HREC	Reviews all research projects that require the use and disclosure of personal health information from the WA Health Data Collections and/or involving linkage via WA Health Data Linkage Services. .
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: • the research is related to Aboriginal 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.

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.

104.4 Some research projects only require specialist HREC review, such as when a project is only accessing data from the WA Health 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. It is also essential that the CPI understands when a specialist HREC review is required and advice should be sought from either the EMHS Research Hub or the WA Central HREC (Central Office of Research Ethics).

SOP105: Lower Risk Ethical Review

105.1 The National Statement defines lower risk research as *"research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden."* Further, the Statement defines minimal risk research as *"research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience."*

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 should be consulted for guidance on whether a research project must undergo HREC review.

105.3 EMHS accepts ethical approvals conducted via an acceptable lower risk review pathway that complies with the requirements of the National Statement Section 5.1.12, including the Lower risk review pathway established by the WA Health Central HREC.

105.4 The CPI should indicate their understanding of the risk level of a project as part of their submission to the HREC, although the final determination of the appropriate review pathway is made by the HREC office and members.

105.5 Projects that have been ethically reviewed via an alternative lower risk review pathway must still undergo a governance review and receive site authorisation to commence at EMHS site/s.

105.6 Projects that have been ethically reviewed via an alternative lower risk review pathway must still follow standard monitoring requirements throughout the project's lifespan, including submission of progress and final reports, safety notifications and requests for amendments. See SOP501 for information about the monitoring of approved research.

SOP106: Exemption from ethical review

106.1 The National Statement (s5.1.15-5.1.18) permits institutions to exempt research from ethical review if it:

- Only lower risk to participants and/or the community, and
- Satisfies at least one of the conditions listed in the National Statement s5.1.17 (a-d).

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 s5.1.15 to 5.1.18 of the National Statement.

106.3 The request will be reviewed by the EMHS Research Hub. The WA Health Central HREC and CORE staff may be consulted if required.

106.4 If a project is multi-site, especially involving non-WA Health sites, the CPI may need to consult the relevant research support and governance offices to ensure there is agreement as to the validity of an exemption.

106.5 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 to be exempted from ethical review. This letter will be signed by the EMHS Director of Clinical Services.

106.6 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.

SECTION 2: SITE AUTHORISATION

SOP201: Research governance review process

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

Purpose of research governance review

201.2 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.

201.3 It is expected that the information provided in the research governance submission will represent the end 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.

201.4 For externally-led projects and trials, a copy of the research protocol should be provided to the EMHS site staff and the research team must identify a Site PI, a PI Delegate (if applicable) and determine via Departmental contacts, or through staff in the EMHS Research Hub, who the relevant signatories for the Site-Specific Assessment (SSA) and Budget or Access Request (AR) are.

201.5 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 support the project. 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.

Research Governance Service (RGS)

201.6 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 designed to support multi-centre research conducted across multiple WA Health Service Providers (HSPs) and Australia-wide multi-jurisdictional projects.

201.7 Researchers must register for RGS access using the “New User Sign Up” accessible on the RGS website.

201.8 Once both RGS access and subsequent project workspace approval have been granted, researchers must complete an RGS submission (made up of ethics and site authorisation components for each project), including the provision of requested information.

Preparing and submitting research governance applications

201.9 The site Principal Investigator (PI) or their delegate (EMHS employees) are responsible for submitting the site governance application in the RGS, while the CPI or delegate is responsible for the submission of the ethics application.

201.10 There are two types of research governance application:

- Site Specific Assessment (SSA) form & Budget Form
- Access Request (AR) form

201.11 Completion of the SSA and Budget Forms may take some time and researchers should begin completing these as soon as possible, including during the ethical review. More time will be required where multiple Support Departments need to approve the Budget and where the project or trial involves radiation exposure or other matters requiring additional external approvals.

201.12 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 completed in the Site Authorisation section of the RGS Applications Tab. 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.

201.13 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 patients, staff, patient biospecimens or data is being requested, then an AR form may be used. The decision should be made by the CPI, PI and EMHS Research Hub.

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).

Primarily this form is used where the researchers are external, there is no research activity at the site and thereby no costs to EMHS. 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.

201.14 Research and Support Department Approval**:** In the Budget Form the 'Research Department' is the EMHS Department or Service where the PI is based and/or where most project activities will occur. If other Departments or Services within EMHS are needed to support the project (e.g., Pharmacy), these are added with their own section as 'Support Departments'. All applications must include a Research Department. Once Budget line items for a department are completed, the PI or Delegate should contact the Head of Department (or other authoriser) to discuss the project with them and advise that they will receive an invitation from RGS to authorise the department's Budget.

Researchers must give the authorisers of the relevant departments sufficient time to read through the study information to:

- assess the feasibility of providing the support needed.
- assess any costs incurred by their department in providing the services, especially where these are 'in-kind' (i.e., absorbed into the work of the Department).
- Consider any other impacts of supporting the project on their department.
- If able to support the project, 'authorise' their section of the Budget Form within RGS.

201.15 Where the Head of (Research or Support) Department is an investigator on the project, they are not able to authorise their Department Budget. Instead, the relevant Divisional Co-Director should be invited to authorise that Department.

201.16 All research governance applications that involve the use of a pharmaceutical or device for delivery of a pharmaceutical (or both) must obtain sign off from the respective hospital Pharmacy. Pharmacy must be responsible for the handling of all Investigational Medicinal Products (IMP) and associated devices. In exceptional circumstances where it is not possible for Pharmacy to manage the IMP (for example standard medications administered in operating theatres as part of a research protocol), the researcher should ensure that they have liaised with Pharmacy regarding the project. Approval via a Support Department Budget form signed by the Clinical Trials pharmacist is required to indicate they have reviewed and approved the handling procedures for management and documentation of IMP by the PI.

201.17 In the RGS, three fields appear automatically within the 'Research Department' budget:

- Clinical services – Overhead Charge: EMHS charges overheads on commercially funded research and trials. No overhead is charged on most Investigator-initiated and other non-commercial projects, in which case 0 should be entered here.
- Ethics approval – Ethics review: EMHS no longer hosts an HREC and so the Budget for all EMHS sites is also 0 for this item.
- Site specific assessment – Site process and review: The nominal fee is the same for all projects and the sponsor for commercially funded projects should be listed as the Funder in the relevant Budget form column in section 3. For non-commercial projects, EMHS covers the fee as in-kind support, which is reflected in the relevant Budget column in section 3. Note: The Sponsor name or EMHS need to be listed in Project Details -Governance Information Section 7 for them to be included as a Funder in the Budget form.

201.18 Documents: Only the latest ethically approved versions should be uploaded in RGS and submitted. The corresponding HREC approval letter(s) must also be provided as part of the ethics documentation (if approved by an HREC other than the WA Health Central HREC).

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)
- WA Specific Module (WASM)
- Research protocol
- Participant Information and Consent Form (site specific) (PICF)
- HREC approval letters for projects approved under the NMA only

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.
- Student Research and Confidentiality Declaration – for investigators who are students utilising project data as part of a higher degree, including WA Health/EMHS staff conducting the research project in their student capacity).

Review of research governance applications

201.19 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.

201.20 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.

201.21 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.

201.22 Submissions are first validated by the RGO. This validation is to confirm that the forms/documents that have been submitted through RGS are what they say they are and does not mean that they are approved.

201.23 Once the review of the submission is commenced, the RGO will confirm that all 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.

201.24 The RGO will 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.

201.25 Review: The RGO will 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 reports are provided (e.g. Radiation Risk Assessment from the Medical Physics Department, if the project involves exposure to ionising radiation).
- 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, or EMHS General Counsel)
- 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.

201.26 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 (or delegates), including Supporting Department where relevant.
- Details and contacts for the Research Department, Supporting Department(s) and relevant Third-Party Agencies.

201.27 Process: Ongoing communications between the RGO and the Site PI/Delegate will primarily 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. Alternatively, they may organise a face-to face meeting in person, or on MS Teams.
- An email assessment will only be sent after this phone call and if required to provide written feedback or document revisions/templates.
- Site PIs/Delegates (and any relevant external parties) will be requested to contact the RGO via Teams or 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.

201.28 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.

201.29 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.

201.30 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), another Tier 2A Executive (e.g., the relevant EMHS Area Executive Member) or the EMHS Chief Executive.

201.31 The RGO will send the Site PI/Delegate the EMHS Site Authorisation Letter and signed copies of relevant agreements/indemnities via RGS and via email, copying in other relevant parties (e.g., the CPI).

201.32 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

202.1 Certain research projects and clinical trials 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 governance submission (and in the ethics submission) 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 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).
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

203.1 Collaborative research between institutions can take various forms and includes research partners in industry, universities, other Health Service Providers (HSPs) and not-for-profit organisations, notably Medical Research Institutes. The nature of collaborative research projects, including the respective roles and contributions, must be negotiated before the project commences and these details are typically highly relevant to site governance review and even ethical review.

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 A research agreement is a requirement of the Australian Code. The Code states that organisations involved in a joint research project should execute an agreement about how the parties will manage the research. This agreement should align with the principles of this Code, including integrity, honesty and a commitment to excellence and cover:

- intellectual property, copyright issues and commercialisation terms
- responsibility for obtaining ethical and site approvals
- reporting to appropriate agencies, safety oversight and monitoring
- confidentiality and data management
- dissemination of the research outcomes
- management of primary research materials and research data

203.4 Research involving EMHS employees, patients, 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 research agreement. The type of the agreement required will be dependent on the nature of the research project and nature of the collaboration and some research projects may require multiple agreements. Researchers should seek advice about the appropriate form of agreement for their project from the EMHS Research Hub early in project development.

203.5 The type of research activity and entities party to the project will determine the type of research agreement/s required. Template agreements are publicly available for download on the RGS documents templates page. The EMHS Research Hub can assist the EMHS Site PI and their partners to identify the appropriate agreement to use and facilitate negotiations with the external entity regarding the research agreement.

203.6 Clinical Trials: See SOP402 & SOP403 for more information on types of research agreements required for clinical trials.

203.7 Investigator-Initiated Projects: Researchers should seek advice from the EMHS Research Hub about the appropriate form of agreement for non-clinical trial research. Commonly used agreement templates include:

- Research Collaboration Agreements
- Material Transfer Agreement
- Material and Data Transfer Agreement
- Funding Agreement
- Service Agreement – WA Health providing the service
- Service Agreement – WA Health receiving the service
- Research Access Agreement

203.8 The draft research agreement can be submitted 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.

203.9 The EMHS 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), or the EMHS General Counsel.

203.10 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 Service Provider (HSP). This avoids the need for each WA HSP to individually review the same external entity's amendments to the standard template.

203.11 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. Alternatively, the external entity may sign the research agreement first and then provide a partially signed copy of the agreement to the RGO to organise signature by the CE/Delegate.

203.12 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 for Clinical Trials

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 EMHS 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 clinical trial.

204.2 For commercially sponsored clinical trials, the Sponsor and/or the Contract Research Organisation (CRO) must provide indemnity to the EMHS institution and members of the Responsible HREC against claims arising from the project on the terms and conditions set out in the relevant Medicines Australia Form of Indemnity for Clinical Trials.

204.3 For non-commercially sponsored clinical trials (i.e., those conducted under a CTRA-CRG) the CRG (non-commercial sponsor) is not required to indemnify EMHS or the HREC.

- 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 non-commercially trial.
- If a CRG offers to provide an indemnity it should be in the form of the Medicines Australia version.

204.4 The version of Medicines Australia (MA) Form of Indemnity for Clinical Trials to be used is the Standard Form of Indemnity - for use where the Indemnified Party (EMHS) is providing premises for the conduct of the Study.

204.5 The second MA Form of Indemnity for Clinical Trials - HREC review only - is not applicable because EMHS does not maintain an HREC.

204.6 The Standard Form of Indemnity will typically be provided to the EMHS site team for submission to the EMHS RGO. The most recent templates are publicly available for download on the RGS documents templates page.

204.7 The details of the indemnity may be included in the research agreement (CTRA) with the sponsor, and the indemnity form must initially be provided in draft format and uploaded to the RGS as a site authorisation application supporting document.

- The indemnifying party (e.g., the Sponsor) must ensure that the correct legal name appears for both 'the Indemnified Party" and "the Sponsor".
- Prior to submitting these documents to the RGO, researchers are to ensure that all project details, including the project number and study title are consistent with the study title and number on the Protocol.
- Other details that are to be confirmed on page 1 include identification of the "the Subjects" and "the Investigator" in paragraph 1.
- Depending on the type of CTRA, a signed Form of Indemnity must be provided to each of the parties to the Agreement.

204.8 Once the RGO has reviewed, the indemnifying party (sponsor) will be asked to provide a signed copy to the RGO to organise signing by the CE/Delegate. This is typically executed at the same time as the CTRA and site authorisation letter.

SOP205: Insurance for research projects

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

- For commercially sponsored clinical trials and other research projects, the party responsible for this is the Sponsor. Details of the insurance must be in Schedule 4 of the research agreement (e.g., CTRA) (See SOP403).
- For non-commercially sponsored clinical trials and research projects, the responsible party is typically EMHS.

205.2 Confirming the insurance arrangements of all parties to a clinical trial or research project is a risk management strategy that trial and project activities are adequately covered by robust insurance provisions. This not only protects the interests of EMHS and the wider WA Health System 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 and clinical trial activities. ICWA protects public institutions under the legal liability cover and provides insurance and risk management advice to its public clients. Where an EMHS-employed researcher initiates a research project or clinical trial – or submission of an externally Sponsored trial/project - the proposal must be reviewed by the RGO, including examination of any external parties' insurances. ICWA provides a support service in scrutiny and advice regarding these insurances, for consideration by the RGO.

205.4 Consideration must be given to clinical trial, product and public liability cover, the availability of legal liability cover (if it is a no-fault policy wording) 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 certificates, and if applicable policies, must be reviewed and approved by the RGO following submission in the RGS as an amendment.

205.5 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.

205.6 In addition of the Certificate of Currency, a copy of the insurance policy wording is often necessary and research staff are encouraged to request this document from the Sponsor. The RGO will assess the insurance information provided against the 13 points of insurance that have been outlined by ICWA as the minimum amount of information that needs to be provided. These are listed in Schedule 4 of the WA versions of the CTRA templates:

- Name and address of the insurer, including its Internet website address.
- Name and address of the insured. If the insurance extends to other parties relevant to the agreement, details must be provided. The Institution needs to be satisfied that the Sponsor is an insured under the policy.
- Policy number.
- Period of insurance.
- Class of insurance.

- Sum insured per event including any sub limits.
- Aggregate sum insured.
- If applicable, any excess of loss/umbrella policy information.
- Deductibles/excesses.
- Whether the policy is constructed on an “occurrence” or “claims made” wording
- Scope of cover: For example, “Legal liability of the insured for death and bodily injury arising from clinical trials, including products liability risks”. There may be a need to quote the operative clause of the policy to capture the correct interpretation.
- Territorial limits of the policy: It is essential that the policy respond to claims lodged and processed in an *Australian jurisdiction*. Notwithstanding that the cover may apply anywhere in the World, if there are any restrictions on claims in an Australian jurisdiction, these must be detailed (if an overseas sponsor is providing insurance, it needs to be clarified that if a claim were to be made that it would not be required to be heard in a court overseas).
- Relevant policy *exclusions and conditions* must be listed and detailed if appropriate: Exclusions relating to contractual liabilities, specific drugs and implements may be important (this is important as the RGO has found examples where the very product being trialled is listed as an exclusion on the insurance policy, rendering the insurance policy provided for that research study as useless, leaving WA Health open to a claim).

205.7 The EMHS RGO will review insurance limits with reference to the risks of the trial/project however the minimum requirements for a sponsor and/or CRO are:

- Public liability insurance for the minimum sum insured of AUD $5,000,000 any one occurrence: and
- Liability insurance covering:
    - clinical trial / product liability (or equivalent) and professional indemnity; and
    - the contractual obligations of the Sponsor and the CRO contained in the Agreement.
        - without limiting the indemnity obligations of the Sponsor and the CRO set out in Schedule 3 of the Agreement.
        - for minimum sum insured of AUD $10,000,000 any one claim and in the aggregate during any one twelve (12) month period of insurance and which does not contain an excess/deductible or self-insured retention amount greater than AUD $25,000 for each claim or series of claims arising out of one originating cause

205.8 If a CRO is acting as a local sponsor it should be either named as an additional insured on the Sponsor’s insurance policy or provide evidence of its company’s policy.

205.9 Any employee of an external institution attending the EMHS site for research purposes (e.g., CRO for site initiation or monitoring visits) should be covered by public liability insurance. Evidence of such insurance should be provided with the submission documentation.

205.10 When the RGO receives information regarding insurance that does not comply with ICWA’s recommendations or is difficult to understand or analyse, ICWA will be contacted for further advice, as might the EMHS General Counsel.

205.11 If a policy has been provided that does not comply with requirements and no further information/documentation is forthcoming from the sponsor/CRO, then the RGO will take the information to the EMSH Executive/Authorising person to decide if the trial/project can proceed based on the insurance provisions provided.

SOP206: Intellectual Property

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

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

206.4 IP questions and issues should be referred to the EMHS Director of Innovation and Research who maintains an IP Register and can provide advice on the potential implications of EMHS-generated IP at all stages of development.

206.5 If there are reasonable grounds to anticipate that IP could be developed during a research project - owned by any party - 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.

206.6 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 2023.

206.7 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.

SECTION 3: SPECIFIC PARTICIPANT GROUPS

SOP301: Groups requiring additional consideration

301.1 Special consideration must be given in terms of research project design, consent process and risk mitigation as per the National Statement Section 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 and Torres Strait Islander peoples
- People in other countries.

301.2 Researchers/Sponsors must design clinical trials and research projects that comply with the specific requirements of the National Statement for the ethical treatment of specific groups and ensure appropriate risk mitigation mechanisms and special considerations are detailed in trial/project protocol and other relevant processes and documents (e.g., PICFs).

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

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

SOP302: Children and young people

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 With respect to the EMHS site governance submission, 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 is the WA Health Central HREC's Mothers and the fetus, Infants, Children, and Adolescents (MICA) meeting. The EMHS RGO will advise the EMHS researcher whose project primarily focusses on children and young people of the most appropriate HREC to review their project.

SOP303: Adults who lack capacity to consent

303.1 The *Guardianship and Administration Amendment (Medical Research) Act 2020* **Part 9E** ('GAA Part 9E') provides two pathways for the participation of adults who do not have the capacity to consent in health and medical research:

- Medical Research with consent of Research Decision-Maker (RDM)
- Urgent Medical Research without consent

303.2 All clinical trials and research projects consenting patients who do not have the capacity to consent in health and medical research must follow the requirements of GAA Part 9E.

- Some trials/projects will have ethical approval and site authorisation to enroll patients only with RDM consent.
- Other trials/projects will also be approved to use the urgent enrolment pathway.

303.3 EMHS is one of the largest users of GAA Part 9E, due to its strong Intensive Care, Trauma and Emergency Medicine research and trial programs, enrolling approximately 50% of participants across WA.

303.4 It is essential that EMHS PIs, and those acting as CPI, on trials and research projects involving recruitment under the GAA Part 9E must familiarise themselves with the requirements of the Act when enrolling patients incapable of providing consent. A WA Health guide to GAA Part 9E and associated document templates are available on the RGS website. EMHS Research Hub staff are available to advise researchers of the requirements during project development.

303.5 The project or trial protocol and associated documents, notably PICFs, must be developed so the recruitment and consent processes are compliant with GAA Part 9E prior to submission for ethical and site governance review.

303.6 For projects reviewed by a non-WA Health HREC under the NMA, the recruitment and consenting process must be clearly and accurately articulated in the WA Specific Module (WASM). The site PI is responsible for ensuring that the information in the WASM (completed in RGS) accurately reflects the requirements of GAA Part 9E and processes at the EMHS site. The PI/PI Delegate is responsible for providing a copy of the completed WASM to the CPI at the lead site for submission to the HREC.

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

303.8 All enrolments completed at EMHS sites must include a correctly completed GAA Medical Research Decision Form ('GAA Form') signed by all key parties to the enrolment, including the Site PI and Independent Medical Practitioner ('IMP').

303.9 Reporting: Completed GAA Forms must be emailed to the EMHS Research Hub as soon as possible after the date of enrolment so it can be reported to the DOH. The EMHS Research Hub will submit the required GAA Medical Research Decision Report ('GAA Report') to the DOH Office of Medical Research and Innovation (OMRI).

303.10 The EMHS Research Hub maintains a record of all EMHS site enrolments reported to the DOH and is responsible for providing OMRI with an annual reconciliation of enrolment records prior to the annual anniversary date when the Minister for Health is required to report GAA Part 9E enrolments to Parliament.

SOP304: Aboriginal and Torres Strait Islander Peoples

1. Research involving Aboriginal and Torres Strait Islander participants 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.

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.

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".

4. EMHS CPIs whose project meets the criteria above must independently submit to WAAHEC (see their website for more information). This specialist HREC review is in addition to the 'Lead' HREC approval sought via an NHMRC-registered HREC, such as the WA Health Central HREC.

5. The EMHS Research Hub can advise if the criteria above apply for a specific project and endeavour to ensure the Lead HREC review and EMHS site governance review run 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, or a Contract Research Organisation, 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, or EMHS General Counsel if required, must negotiate the CDA with the external entity prior to signing by the CE/Delegate. Use of the Standard WA Health CDA template ensures expedited execution and are strongly encouraged. The WA Health CDA template 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)

403.1 External commercially sponsored clinical trials/investigations 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 investigations involving the use of non-pharmaceutical medical technologies, including devices and software.

403.2 Clinical trial/investigation agreements are legally binding contracts between two or more parties that establishes the respective responsibilities and obligations of the parties conducting a clinical trial/investigation. Site 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 WA Health templates for these research agreements can be found on the RGS Documents Template page. These are based on templates from Medicines Australia (representing the pharmaceutical industry) (CTRA) and the Medical Technology Association of Australia (CIRA).

403.4 The WA Health templates for CTRAs and CIRAs must be used as the base templates when negotiating clinical trial agreements with both commercial and non-commercial trial sponsors. 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.

403.5 If a Sponsor or CRG submits a CTRA/CIRA template containing material changes, the RGO will assess those changes against the WA Health templates. 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.

403.6 EMHS staff may receive requests from external sponsors to personally sign a CTRA/CIRA on behalf of the Institution. As for CDAs, EMHS employees must not sign CTRAs/CIRAs as individuals. 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). The PI can acknowledge, by way of signing, their obligations as set out in the terms and conditions of the CTRA..

403.7 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.

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

SOP404: TGA Notification or Approval (CTN/CTA)

404.1 The Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods (medicines and devices) 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 to patients 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. The CTN is a notification of a project taking place with a approval from an HREC and the site, while a CTA involves a direct approval by the TGA by which it evaluates the project in place of an HREC.

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/CTA 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: Registration of Clinical Trials

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. It is the responsibility of the trial Sponsor to register their trial and this 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 Registration also assists health professionals to identify relevant trials for their patients.

405.3 The two trial registries recognised by ICMJE that are most widely used in Australia are:

- Australian New Zealand Clinical Trials Registry
- Clinicaltrials.gov

405.4 In addition to registering a trial as early as possible, and prior to participant enrolment, the CPI/Sponsor should ensure information such as contact details and trial status is current through the life of the trial.

SECTION 5: PROJECT MONITORING

SOP501: Overview of Research Project Monitoring

501.1 All authorised clinical trials and 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 SOP504
- Progress Reports – see SOP505
- Final Reports – see SOP506

501.4 All monitoring submissions for EMHS sites 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 are also used to monitor specific projects and to 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, including not submitting annual progress reports, no reporting safety or breach notices 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 5.4 of the National Statement
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods

SOP502: Safety and Adverse Event Reports

502.1 Sponsors of clinical trials and other interventional research are responsible for ensuring that projects conducted under their auspices are designed, managed and monitored in a way that ensures participants are protected and the trial data generated are both reliable and robust. This is important for both commercial and non-commercial clinical trials, as all trials have the potential to significantly impact on the future clinical care of patients.

502.2 EMHS follows and requires safety reporting in line with the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (2016) and the WA Health Research Governance Policy and Procedure.

502.3 For commercially sponsored clinical trials, the Sponsor is responsible for safety reporting. For Investigator-led, EMHS sponsored clinical trials, the Site PI is responsible for Safety reporting.

502.4 The Sponsor via the CPI and/or PI is responsible for:

- Actively monitoring the ongoing risk/benefit ratio of the clinical trial/interventional research project.
- Ensuring there is appropriate independent oversight of the safety of the clinical trial/project by use of a Data Safety Monitoring Board (DSMB) or independent individuals (e.g., a medical monitor) to review accruing safety data.
- Providing the Lead HREC with an annual safety report, which includes an outline of relevant findings to date, an updated Investigator Brochure (IB) if relevant, a discussion of the implications of the safety data, any measures taken to minimise risk and confirmation that the research project is being adequately monitored (the Executive Summary of a Development Safety Update Report or Data and Safety Monitoring Board report may be used where applicable).

502.5 All safety reports are submitted via RGS using a Safety Report Form under the Monitoring Tab. 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)

502.6 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.

502.7 Serious breaches of the protocol or the Australian Code, that may affect participant safety and/or the reliability of the data, must be reported to:

- The RGO at the site the breach occurred within 72 hours
- The Lead HREC within seven days

502.8 Significant Safety Issues (SSIs) that adversely affect the safety of participants must be reported to:

- RGO at the site the breach occurred within 72 hours
- The Lead HREC within 72 hours

502.9 All local Suspected Unexpected Serious Adverse Reaction (SUSAR) and Unanticipated Serious Adverse Device Effect (USADE) must be reported to the RGO of the site where the issue occurred within 72 hours.

502.10 Where EMHS is the trial Sponsor, the EMHS CPI (acting as Sponsor-Investigator) is responsible for assessing and categorising the safety reports received from Investigators at all participating sites (if there are multiple sites).

502.11 Consistent with national guidelines, researchers are not required to report:

- Adverse events that do not meet the definition of a local SUSAR/USADE.
- SUSAR line listings.
- Hospitalisation, injury or sickness in trial participants not related to the trial (i.e., defined as an adverse event in the protocol).
- Development Safety Update Report (DSUR) or Data Safety Monitoring Board (DSMB) reports, especially where there is no new information materially impacting the trial acceptability or Investigational Product risk/benefit ratio. If the Sponsor requests site acknowledgement, executive summaries may be submitted as an appendix to the Annual Safety Report).

502.12 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.

502.13 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.

Review of safety reports

502.14 On receipt of a safety report the EMHS Research Hub (Research Manager/RGO) will:

- Review the report, including actions taken and recommendations from the researchers.
- Acknowledge receipt of report, and any action taken.
- Where the report is routine or no action is required (such as Annual Safety Report), provide an Acknowledgement Letter via the RGS.

502.15 If the report is of an SSI or Serious Breach requiring local action and escalation for decision making, the EMHS Research Hub will:

- Immediately request additional information, if required for Briefing.
- Brief the EMHS Executive Director of Medical Services, copying in the relevant Hospital Co-Director and HoD.

502.16 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.

502.17 The Briefing may include a recommendation that the Authorising Executive immediately suspend or discontinue site authorisation and, if the report includes notification that the Lead HREC has suspended the ethical approval for the trial/project, a recommendation that the site authorisation must be suspended.

502.18 Notification of the decision made will be conveyed as soon as possible to the CPI/PI/Delegates both outside of and, formally, via RGS, including updating the project's EMHS site approval status.

502.19 Clinical trial-related adverse events (as defined by the trial protocol) may or may not also constitute clinical incidents. All clinical researchers are responsible for ensuring that clinical incidents related to trial or research participation are reported in line with the DOH Clinical Incident Management Policy and their institution's relevant procedures and guidelines.

SOP503: Data and Safety Monitoring

503.1 Sponsors of clinical trials and interventional research must establish a data and safety monitoring plan as a minimum requirement ensure participant safety. The plan should include the following information:

- Procedures to monitor trial progress and safety.
- A plan to assess data quality, timeliness, participant recruitment and retention.
- A plan to assure data accuracy and protocol compliance.
- Definition of specific triggers or stopping rules that will dictate the required follow up actions.
- A procedure for detecting and facilitating reporting severe adverse event (SAE) and/or problems involving risk to participants, in line with SOP502.
- Nominated people to monitor, collect, and report adverse events.
- Details of the Data Safety Monitoring Board (DSMB) members.

503.2 The Data Safety Monitoring Board (DSMB) is considered a critical component to ensure the safe and effective conduct of an interventional trial. It is an independent group of experts which provide their expertise and recommendations to the study investigators, sponsors and the Lead HREC.

503.3 All clinical trials require safety monitoring, but not all trials require monitoring by a formal DSMB that may be external to the trial sponsors and investigators. Investigators/Sponsors developing an appropriate safety and data monitoring process for a future interventional trial should consult the NMHRC guidance.

503.4 Where EMHS is to be the Sponsor, the Investigators must ensure appropriate arrangements are in place to monitor the safety of participants during the trial by implementing a data safety monitoring plan that is clearly described in the protocol and ethics application.

503.5 In the absence of an independent DSMB for an EMHS-sponsored Investigator-initiated single centre trial, it is recommended that the Investigators aggregate, present and discuss trial data and adverse events at a formal Departmental meeting on a regular basis. Where the CPI/PI is also Head of Department it is advisable to have at least one independent clinician at the departmental meeting, including potentially a colleague from another health service.

SOP504: Protocol and Document Amendments

504.1 Changes to a trial or research 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.

504.2 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 EMHS RGO.

504.3 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 for review.

504.4 Additional EMHS sites and new project investigators 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. Addition of a new EMHS site requires completion and submission of a site governance application in RGS (SSA/Budget Form or Access Request Form).

504.5 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.

504.6 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.

504.7 Amendments that are submitted to the HREC and/or EMHS RGO 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.

504.8 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.

504.9 Once the amendment is approved the EMHS Research Hub will issue approval letters via the RGS and, where necessary, via email (e.g., where additional documents such as executed amended agreements) must also be provided.

SOP505: Progress Reports

505.1 EMHS site authorisations do not expire but are contingent upon maintenance of a current ethical approval and receipt of at least annual progress reports.

505.2 Once site authorisation has been granted by EMHS the Site PI is required to submit, as a minimum, an annual progress report for each EMHS site/s via the RGS.

505.3 When finalising EMHS site authorisations, the reviewing RGO will endeavour to align the site progress report due date with the Lead 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.

505.4 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

505.5 The RGS sends automatic email reminders to the CPI and PI, and their delegates, 4 weeks prior to progress report due dates.

505.6 Progress reports submitted for EMHS sites (to the 'EMHS RGO') are processed by the EMHS Research Hud. 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.

505.7 Receipt of site reports is acknowledged via an RGS letter, and a summary of information is added to the internal EMHS Research Hub Project Tracker.

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

505.9 The Research Hub tracks pending and overdue progress reports for EMHS sites using its Project Tracker and data extracted from the RGS via PowerBI.

505.10 When a progress report becomes overdue, the Research Hub 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 Hub 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 Research Manager will contact the responsible person and 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).

505.11 If the decision is made by the Executive Director to suspend the ethical or site approval, a letter to this effect will be sent to the CPI/PI via RGS. The processes in SOP507 will be followed.

SOP506: Site Final Reports

506.1 Once a clinical trial or research project has been completed, the Site PI must submit a *Site Final Report* to the EMHS RGO (EMHS Research Hub) via the RGS. Once all sites have reviewed and acknowledged their respective site final reports and changed their site status in the RGS to 'closed', the CPI can submit a *Project Final Report* to Lead HREC (if this is a WA Health HREC).

506.2 The RGS Site 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.

506.3 Site Final Reports submitted for EMHS sites (to the 'EMHS RGO') are processed by the Research Hub. 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.

506.4 Receipt of Site Final Reports is acknowledged via an RGS letter, and a summary of information is added to the internal EMHS Research Hub Project Tracker with the project status updated to 'closed'.

506.5 For NMA HREC-approved trials and projects, where the HREC is an interstate HREC, once all WA Health Site Final Reports have been approved and the site status' updated to 'closed', the RGO will update the HREC approval status to 'closed'. Reporting to the Lead HREC by the external CPI is outside of RGS.

506.6 Preparation of final reports is prompted by the researchers themselves when they determine that they have completed the project, or the Sponsor formally closes the site. However, there are situations where the EMHS Research Hub may become aware of likely closure due to:

- Overdue site progress reports.
- Prior progress reports indicating the project was pending closure.
- Site Final Reports have been submitted for non-EMHS sites but not for EMHS sites.
- Communication from another RGO.

506.7 When a Site Final Report is overdue, the Research Hub 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, 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 EMHS Research Manager will again phone the responsible person and offer support to ensure the final report is submitted.

SOP507: Suspension or Early Termination of a Project

507.1 All Clinical trials and research approved by EMHS must continue to meet the standards described in the National Statement and terms required of the EMHS site authorisation. Projects may be suspended or terminated early by the Sponsor, CPI, HREC or EMHS CE/Delegate for any reason, including issues that are identified as part of the monitoring or audit processes.

507.2 If the HREC or EMHS CE/Delegate suspends or terminates a project early, 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. The notifications must be made by the party initiating the suspension/early termination.

507.3 If the CPI suspends the project, this decision must be communicated to the HREC and EMHS RGO via an amendment or safety report in the RGS, depending on the circumstances of suspension.

507.4 If the EMHS CE/Delegate suspend approval/authorisation for a project, the CPI/PI will be notified in writing of the reasons for this decision and any actions and conditions required to reactivate the project (if applicable).

507.5 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 (if applicable) must also be explained.

507.6 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.

SOP508: Project Completion

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

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

509.2 The purpose of clinical trial and research project monitoring is to oversee the progress of a trial, to protect the rights and well-being of trial participants and to give reassurance that the trial protocol and procedures are being followed, that legal/governance requirements are being complied with, and that the critical data collected are reliable.

509.3 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 (GCP) for clinical trials in Australia, project-specific ethical and site conditions, and to identify any practical, logistical or resourcing issues that might be hindering project progress of trials and research projects undertaken with EMHS.

509.4 The audit program complements routine minimum monitoring of active research projects as described in SOP501. Mechanisms for monitoring of trials and research include:

- Review of annual progress and final reports
- Review of individual safety reports
- Review of annual safety summaries
- Review of sponsor notifications
- Sponsor site monitoring visits
- Monitoring reactive to complaints or incidents.

509.5 In the context of the wide sources of information contributing to the monitoring of trials and research, 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.
- Raise awareness of the requirements of and promote researcher accountability.
- Inform research education planning and review of research policies and procedures.
- Ensure that the conduct of research does not compromise the integrity of the results.

509.6 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.

509.7 Depending on availability of staff, the EMHS Research Hub will audit 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).

509.8 Audits will be conducted by an RGO, Ethics Coordinator or Research Manager on a rotational basis, based on workload and availability.

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

EMHS Research Audit Program Guide

509.10 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

509.11 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.

509.12 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.

509.13 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 and/or the EMHS Executive Director of Medical 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.

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

509.15 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

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 EMHS 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 or a waiver of consent is granted by the HREC.

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 EMHS RGOs must ensure that site-specific requirements for consent are met, including reviewing the HREC-approved 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 EMHS 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 Lead HREC via the NMA scheme (See SOP103), as state-specific legislative requirements differ.

SOP602: Waiver of Consent

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, EMHS 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 WA Health Service Provider (HSP) 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.

602.7 Researchers accessing patient data under a waiver of consent, or where data us being accessed where an opt-out approach to enrolment of participants has been approved by the HREC, are required to seek approval from the relevant data custodian through completion of a Data Request Form and Checklist (DRF).

602.8 Review of the completed DRF will form part of the site governance review by the EMHS RGO. The reviewing RGO will approach the data custodian(s) on behalf of the researcher to obtain their approval. Researchers must clearly outline to the RGO the data sources that will be accessed so that the appropriate data custodian can be identified.

SOP603: Opt-Out Approach

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 via a clear and established mechanism.

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 Provide (HSP) 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.

603.7 Researchers accessing patient data where an opt-out approach to enrolment of participants has been approved by the HREC, are required to seek approval from the relevant data custodian through completion of a Data Request Form and Checklist (DRF). This is because, legally, the opt-out approach does not meet criteria for consent and so the governance process mirrors that of a waiver of consent (i.e., where there is no consent).

603.8 Review of the completed DRF will form part of the site governance review by the EMHS RGO. The reviewing RGO will approach the data custodian on behalf of the research to obtain their approval. Researchers must clearly outline to the RGO the data sources that will be accessed so that the appropriate data custodian can be identified.

SECTION 7: DATA AND PRIVACY

SOP701: Principles

701.1 Protecting participants and the responsible handling of their information is extremely important in clinical trials and other health and medical research. Confidentiality and privacy processes must be implemented for all trials and research projects conducted within the WA Health System and EMHS.

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 Custodian, or from the Data Steward if a researcher on the project is the Data Custodian. 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 Researchers and EMHS 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 Custodians/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 Custodians/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

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 dataset is responsible for determining the type of information being disclosed.

SOP703: Department of Health Data Collections and Linkage

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 WA Health Central 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 Director General (or delegate)
- Be monitored by the WA Health Central 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. They will then be followed long-term using the Department of Health data collections. These projects will generally require WA Health HREC approval and both EMHS and DOH site authorisations.

SOP704: Information Security, Retention and Disposal

704.1 Researchers must ensure research information, including clinical trial data, 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 EMHS 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 EMHS 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 EMHS RGO 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

705.1 An information breach occurs when information that an entity holds is subject to unauthorised access, use or disclosure, or is lost, damaged or destroyed. An information breach may be caused by malicious action (by an external or insider party), human error, or a failure in information handling or security systems. It can involve different types of information and give rise to a range of actual or potential harms to the individuals and WA health entities whose information is compromised.

705.2 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.

705.3 If the information breach is also identified as an adverse event, the breach must also be handled with the generation of a Safety Report Form via RGS and notification of the HREC and EMHS RGO.

SECTION 8: BIOBANKS

SOP801: Establishment and governance of biobanks

801.1 HRECs and the EMHS RGO must ensure that all research projects and clinical trials 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, the EMHS RGO 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

901.1 WA Health Staff: All WA Health System employees, including investigators/research team members employed by EMHS and EMHS Research Hub staff are subject to the Information Management Policy Framework 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* within the RGS workspace. 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

1001.1 This SOP is written in accordance with Section 5.6 of the National Statement, the Australian Code (2018) and the WA Health Managing Conflicts of Interest Policy.

1001.2 All researchers conducting research under the auspices of EMHS have an obligation to disclose and manage actual, potential or perceived conflicts of interest.

1001.3 A conflict of interest in research is *"a situation in which financial or other personal considerations may compromise or have the appearance of compromising a researcher's professional judgment in conducting or reporting research"*. Even the perception that a conflict of interest exists can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in research.

1001.4 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).

1001.5 To manage their responsibilities under the Code, EMHS researchers must:

- Comply with WA Health processes for managing conflicts of interest to identify, disclose, record, manage and regularly review/update any actual, perceived or potential conflicts of interest.
- Meet any additional Conflict of Interest requirements of external bodies relevant to their research or role, such as funding bodies, conference organisers and publishers.
- For clinical trials, include the nature of the sponsorship and the relationships between the Sponsor, trial participants and the researcher in any disclosures.

1001.6 EMHS researchers who have 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.

1001.7 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 project.

1001.8 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.

1001.9 Where an investigator/team member declares a conflict this will be reviewed by the RGO in accordance with the WA Health Research Governance Framework, the WA Health Managing Conflicts of Interest Policy and the EMHS Integrity & Ethics Information on Conflicts of Interest. The RGO 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.

1001.10 The RGO 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.

1001.11 When finalised, the action/s to be taken will be documented by the RGO and acknowledged by the Investigator/team member and submitted to the EMHS Executive Director of Medical Services who is the Authorised Person to approve the agreed management plan.

1001.12 The research must not be authorised until the conflict of interest is addressed to the satisfaction of the CE/Delegate.

1001.13 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 Executive Director of Medical Services.

SOP1002: Hospital Administrator Conflicts of Interest

1002.1 This SOP is written in accordance with the WA Health Managing Conflicts of Interest Policy.

1002.2 Hospital Administrators (including Executives, Divisional Co-Directors and Operations Managers, Heads of Department and members of the EMHS Research Hub, notably RGOs) have an obligation to disclose and manage actual, potential or perceived conflicts of interest related to their roles supporting, reviewing, authorising and monitoring of research and clinical trials conducted within EMHS.

1002.3 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).

1002.4 Even the perception that a conflict of interest exists can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in the authorisation and monitoring of research and clinical trials.

1003.1 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 – Divisional Co-Director).

1003.2 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, authorisation or monitoring, they must as soon as practicable declare the interest remove themselves from consideration of the project-related task.

1003.3 When a Hospital Administrator declares a conflict of interest and must withdraw from consideration of the project, the RGO will arrange can assist in arranging an alternative signatory based on discussion with all parties, including the researchers, relevant Heads of Department and Divisional Co-Directors.

SECTION 11: COMPLAINT MANAGEMENT

SOP1101: Complaints about the Conduct of a Research Project

1101.1 This SOP is written in accordance with:

- Section 5.7 of the National Statement
- 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 Framework
- The WA Health Complaints Management Policy (3 February 2020)

1101.2 EMHS 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 or clinical trial 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 clinical trials and 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 Lead HREC's Terms of Reference, noting that the reviewing HREC may be any WA Health HREC or NMA-certified HREC.

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 EMHS Executive Director of Medical Services

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 Research Governance Review

1102.1 This SOP is written in accordance with:

- Sections 5.7 and 5.8 of the National Statement
- The Australian Code (2018)
- WA Health Research Governance Framework
- The WA Health Complaints Management Policy (3 February 2020)

1102.2 Concerns or complaints about EMHS site governance reviews must be sent by the EMHS Site 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.

1103.1 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.

1103.2 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 governance review was conducted in accordance with WA Health policy, was fair, unbiased and timely.

1103.3 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. The complainant will be informed in writing of the outcomes of the review within 7 calendar days of finalisation of the review.

1103.4 If the complainant is not satisfied with the outcome, the complaint will be escalated to the EMHS Director Innovation and Research for review.

1103.5 The Director Innovation and Research 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 Director Innovation and Research will determine if the research governance review was conducted in accordance with WA Health policy, was fair, unbiased and timely.

1103.6 Where the previous determination by the Research Manager is upheld and no further investigation is to occur and, the Director Innovation and Research will inform the PI and the Research Manager. The Director Innovation and Research may also make additional determinations and recommend internal actions arising from the review.

1103.7 If a further investigation is conducted, the Director Innovation and Research will notify the PI and Research Manager of the outcome and any arising recommendations.

1103.8 This further investigation must take no longer than 30 calendar days from the date of escalation, unless exceptional circumstances exist.

1103.9 Where a resolution cannot be achieved following Director Innovation and Research review, the ADCS may arrange for an external party to conduct an independent review.

1103.10 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

1201.1 The EMHS Research Hub invests significant time reviewing proposed clinical trials and research projects to ensure they are safe, feasible, compliant with relevant NHMRC, WA Health and EMHS policies and WA law, and adequately funded and resourced to be seen to completion. This review is provided in-kind if there is no external funding or competitive grant funding provided for the project. If the project or trial is commercially funded or initiated, then review fees will typically be charged. If the project is not commercially funded project but has significant external funding, the level of in-kind support may vary.

1201.2 New applications for clinical trials and research projects that are sponsored by external commercial organisations (e.g. pharmaceutical companies or other commercial entities) attract a review fee.

1201.3 Commercial support may be financial or in-kind (e.g., provision of drugs or devices) support for an EMHS-initiated and Sponsored trial. Fees for in-kind support by commercial agencies may be waived for such projects if the following conditions are included in a WA Health approved clinical trial agreement:

- The IP arising from the project is not restricted by the commercial agency.
- The data arising from the project is not provided to the commercial agency for marketing or publicity purposes.
- The researcher retains full publication rights.

1201.4 Additional fees are charged for amendments, particularly those of a substantial nature requiring detailed review by an RGO and for which review and approval by the authorising executive.

1201.5 Applications by individual investigators for non-sponsored or for grant funded applications do not attract a review fee.

1201.6 Competitive research grant-funded projects do not attract a fee.

1201.7 Fees are published on the EMHS website.

1201.8 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.

1201.9 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. A recommendation on changes will made to the EMHS Director, Innovation and Research.

SOP1202: Invoicing for Ethics and Governance Reviews

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 EMHS Research Hub Administrative Officer will flag these reviews when 'validating' new research governance submissions and amendments in RGS and record them on an Excel *Invoicing Tracker.*

1202.3 On completion of governance reviews for either new projects or amendments, 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 Administrative Officer to ensure billable reviews are not missed.

1202.4 At regular intervals aligned with Area Executive Group (AEG) research activity reporting, the EMHS Research Manager will take steps to audit the preceding period's reviews (new authorisations and billable amendments) by reconciling the information in the *Invoicing Tracker* with the Executive Director signing record and RGS authorisations data to ensure no billable reviews are missed.

1202.5 The Research Hub Administrative Officer will prepare s60 Debtor Advice Forms for all billable reviews and email these to EMHS Accounts Receivable. They will also 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.*

1202.6 The Administrative Officer will monitor to the *Invoicing Tracker* to 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.