Government of Western Australia
North Metropolitan Health Service
Mental Health, Public Health and Dental Services

Standard Operating Procedure for the Approval of Research

RESEACH ETHICS AND GOVERNANCE OFFICE

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Contents

ABBREVIATIONS LIST

APRA	Australian Prudential Regulation Authority
CA	Confidentiality Agreement
CDRA	Clinical Data Registry Agreement
CDT	Clinical Drug Trial
CI	Coordinating Investigator
CIRA	Clinical Investigation Research Agreement
CRG	Collaborative Research Group
CRO	Clinical Research Organisation
CTN	Clinical Trial Notification
CTRA	Clinical Trial Research Agreement
DoC	Delegate of Chair
ED	Executive Director
EO	Executive Officer
EU ASR	European Union Annual Safety Report
FMF	Financial Management Form
HREC	Human Research Ethics Committee
ICMJE	International Committee of Medical Journal Editors
IP	Intellectual Property
LLS	Legal and Legislative Services, Department of Health
MA	Medicines Australia
National Statement	National Statement on Ethical Conduct in Human Research (2004)
NHMRC	National Health and Medical Research Council
NMHS-MH	North Metropolitan Health Service – Mental Health
NMHS-MHPHDS	North Metropolitan Health Service – Mental Health, Public Health and Dental Services
PI	Principal Investigator
Researcher	Can be the site investigator, co-ordinating or principal investigator
REGO	Research Ethics and Governance Office
RGO	Research Governance Officer
RGS	Research Governance Service
SAE	Serious Adverse Event
SAP	Scientific Advisory Panel
SAR	Serious Adverse Reaction
SADR	Serious Adverse Drug Reaction
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration

INTRODUCTION

The North Metropolitan Health Service Mental Health, Public Health & Dental Services (NMHS-MHPHDS) Research Governance Framework is a two-tiered system of review, approval and monitoring of research made up of:

- Ethical and Scientific review/approval (Human Research Ethics Committee) and
- Research Governance review/approval (Governance Officer).

Both of these research review processes are accountable to the Executive Director (ED), North Metropolitan Health Service Mental Health, Public Health & Dental Services and as outlined the WA Health Research Governance Policy and Procedures 2012.

The ethical and scientific review /approval process is conducted by the North Metropolitan Health Service-Mental Health (NMHS-MH) Human Research Ethics Committee (HREC).The North Metropolitan Health Service-Mental Health (NMHS-MH) Human Research Ethics Committee (HREC) was established in 2005. This HREC reviews all research undertaken within NMHS-MH involving human participants.

The primary role of the HREC is to protect the welfare and the rights of participants in research. It is part of a national system of ethics committees established by the National Health and Medical Research Council (NHMRC) to assess research projects involving humans. The NMHS-MH HREC assesses all submissions against the guidelines developed by the NHMRC. The "National Statement on Ethical Conduct in Human Research" can be downloaded from the NHMRC website at: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018 .

The NMHS-MH HREC operates in accordance with the WA Health Research Governance Framework (external link), which governs the scientific, ethical and site governance review and approval and the conduct and monitoring of human research within WA public health organisations.

The policy and procedures apply to WA Health employees and non-WA Health employees (including clinical and non-clinical university academics) who propose to undertake, manage, review and govern human research involving patients, their tissue or data accessed through WA Health.

The NMHS-MH HREC also operates under terms of reference based on the National Statement. A copy of the NMHS-MH HREC Terms of Reference can be obtained from the Research Ethics and Governance Office (REGO).

Research governance is a framework through which the NMHS-MH is accountable for the scientific quality, ethical acceptability, regulatory and professional governance standards of the research it sponsors or permits at sites under its jurisdiction. It is a governance and risk management activity that facilitates standards of research practice, and allows for a more detailed and site specific review of research applications.

The Research Ethics and Governance Office (REGO) provide an independent systematic evaluation of research applications, which ensures safety, accountability and minimised risk, for the participants, the researcher and the NMHS-MHPHDS. It involves financial, contractual and intellectual property (IP) management, and enables the NMHS-MHPHDS to consider whether the research may be supported at specific NMHS-MHPHDS sites, utilising site specific assessments.

The Research Ethics Governance Office (REGO) coordinates and monitors the ethics/scientific and governance review processes for human research projects undertaken within the NMHS-MHPHDS.

These Standard Operating Procedures (SOPs) outline the process and procedures involved in the review, approval and monitoring of research within sites under the control of NMHS-MHPHDS and should be read in conjunction with the WA Research Governance Policy and Procedure (http://www.health.wa.gov.au/CircularsNew/attachments/724.pdf)

DEFINING HUMAN RESEARCH

The National Statement on Ethical Conduct in Human Research defines human research as investigations conducted with or about people, on their data or tissue, to gain knowledge and understanding on particular subjects. Research excludes routine testing, routine analysis of materials and development of teaching materials that do not embody original research.

Human research must be conducted based on the values set out in the National Statement: respect for human beings, research merit and integrity, justice and beneficence.

All human research projects undertaken within NMHS-MHPHDS have to undergo both ethics and governance review. The ethics review focuses on the ethical aspects of the design, review and conduct of the project and the governance review focuses on the compliance with legal/ institutional obligations.

To determine if a project qualifies as research, see **Table 1: Quality Improvement/ Clinical Audit or Research?** below**.**

DEFINING QUALITY IMPROVEMENT/ CLINICAL AUDIT

Quality Improvement and similar activities are viewed as integral aspects of the evaluation of service delivery and are essential for improving standards of health care and the quality of professional practice and service delivery in many other fields of endeavour, including teaching and learning activities.

Quality Improvement (QI) or Audit projects to be undertaken by NMHS-MHPHDS employees may not require ethical or governance review. If a project meets the criteria for submission as "Quality Improvement" (see Table 1: Quality Improvement/ Clinical Audit or Research? below), then it should be registered with the Safety, Quality and Performance Unit (email NMAHSMentalHealth.OSH@health.wa.gov.au). Further information can be found on the NMHS-MHPHDS website: https://mhphds-healthpoint.hdwa.health.wa.gov.au/directory/Safety%20and%20Health/Pages/default.aspx

Data from such studies cannot be published in most scientific journals without either a HREC review or a HREC exemption letter. Therefore, the QI investigators who wish to publish their findings need to apply to the NMHS-MH HREC for review or an exemption letter.

In order to be considered for ethical review, the Principal Investigator (PI) needs to submit a NMHS-MH QI Proposal Form (available on the REGO website www.nmahsmh.health.wa.gov.au/ethics/index.cfm).

For more information, please contact the REGO (nmahsmhrego@health.wa.gov.au)

Prior to requesting the exemption from ethical review from the HREC, the investigator should also provide the HREC with proof of approval to conduct their QI Activity provided to them by their Line Manager and relevant SQRM Committee.

To amend an already approved QI project, the Principal Investigator (PI) needs to provide the HREC with a 'tracked changes' copy of the amended application as well as a 'clean copy'. Prior to submission to the HREC, the Principal Investigator must obtain approval to amend the application from the Safety, Quality and Performance Unit. Proof of approval needs to be submitted to the HREC.

Table 1: Quality Improvement/ Clinical Audit or Research?

1. Ethics Consideration		Yes	No
1	Does the proposed project pose any risks for patients beyond those of their routine care? *(risks include physical risks e.g. pain or discomfort; psychological risks e.g. embarrassment, guilt or fear; and social risks e.g. discrimination or stigmatisation)*	☐	☐
2	Does the proposed project involve any clinically significant departure from the routine clinical care provided to the patients?	☐	☐
3	Will there be testing of non-standard (innovative) protocols or equipment? *(if what you are using has been used elsewhere for a similar purpose then this is not innovative)*	☐	☐
4	Does the proposed project impose a burden on patients beyond that experienced in their routine care? *(e.g. persistent phone calls, additional hospital visits or lengthy questionnaires)*	☐	☐
5	Will information be gathered (about the participant) go beyond that which is collected routinely? *(information may include bio-specimens or additional investigations)*	☐	☐
6	Will the participants' personal information be used for a purpose other than the purpose for which it was collected?	☐	☐
7	Does the proposed project risk breach the confidentiality of any individual's personal information, beyond that experienced in the provision of routine care?	☐	☐
8	Does the activity potentially infringe the privacy or professional reputation of participants, providers or our organisation?	☐	☐
9	Is the proposed project to be conducted by a person who does not normally have access to the patient's records for clinical care or a directly related secondary purpose?	☐	☐
10	Will data or analysis from this activity be used for other purposes? *(this includes but is not limited to, inclusion in academic thesis and similar reports)*	☐	☐
11	Will there be randomisation or the use of control groups or placebos?	☐	☐
12	Will there be comparison of cohorts? Are you splitting your group and comparing the subgroups with each other? Will one of the subgroups be treated differently?	☐	☐
13	Will there be targeted analysis of data involving minority / vulnerable groups; whose data is to be separated out of the data collected or analysed as part of the main QA/ evaluation? *(this includes but is not limited to ethnicity and other similar variables)*	☐	☐
14	Will the participation or non-participation adversely affect participants' normal health care delivery program or, for the evaluation of teaching activities, will the assessment of the student (e.g. grades received) be affected by participation or non-participation?	☐	☐
15	Do you intend to publish this activity in the future and therefore require an Ethics approval number? (This document can be used as your application for HREC exemption)	☐	☐

If the answer to all the questions (apart from Q15) is "No", your project is a quality improvement (QI) project. Your project should be submitted for approval via the usual Safety, Quality & Performance (SQP) process.

If the answer to the last question is 'Yes', the researcher should request a publication exempt letter from the NMHS-MH HREC.

DEFINING CASE REPORTS/ CASE STUDIES

If an activity or study can be described as a *Case Report or Case Study* rather than *Human Research*, then the activity or study may be exempt from formal ethics review.

In general, the review of medical records for publication of "case reports" of typically three or fewer patients is NOT considered human-subject research and does NOT typically require HREC review and approval.

It should be noted that teaching, and soliciting colleagues' advice on clinical care of a specific patient or groups of patients during presentation of a case at internal NMHS-MHPHDS conferences DOES NOT require HREC or SQRM review. Generalized commentary by a clinician on the outcome of their clinical care of patients in accepted venues for discussion of clinical management is also not considered research requiring HREC review if there is no prospective research plan, or no formal, systematic and prospective collection of information.

Process for Approval of Case Studies, Quality Improvement, Audit, and Teaching & Learning studies

The NMHS-MH Research Ethics and Governance Office (REGO) has established procedures to facilitate approval of Case Study, Quality Improvement, Audit, and Teaching & Learning studies, intended to educate, monitor, evaluate or improve existing teaching, health care delivery service, or other activities.

There is also a separate process for submissions of low and negligible risk research applications (see **SOP303**)

These procedures are written in accordance with Chapter 5.1 of the National Statement on Ethical Conduct in Human Research. For guidance, the author should refer to the National Statement to determine if their activity may be exempt, in particular:

- Chapter 2.1 – Low and Negligible risk research, and
- Chapter 5.1 – Oversight and review of ethical review procedures (5.1.10 – 5.1.17); Research involving no more than low risk (5.1.18 – 5.1.21); Research that can be exempted from review (5.1.22 – 5.1.23)

The forms for requesting ethics review exemption for QI, Case studies are available on the REGO website: www.nmahsmh.health.wa.gov.au/ethics/index.cfm

REGISTRATION OF CLINICAL TRIALS

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

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

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

- a unique identifying number;
- a statement of the intervention and comparison studied;
- a statement of the study hypothesis;

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

To be eligible for publication, trials must register at or before the onset of participant enrolment and this requirement applies to any clinical trial commencing enrolment after 1 July 2005.

Registries recognised by ICMJE include:

Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/Default.aspx

Clinicaltrials.gov: www.clinicaltrials.gov

International Standard Randomised Controlled Trial Number [ISRCTN] Register: http://isrctn.org/

Netherlands Trial Register: http://www.trialregister.nl/trialreg/index.asp

UMIN [Japanese] Clinical Trials Registry: https://www.umin.ac.jp/ctr/index.htm

OTHER REQUIRED APPROVALS

Research involving certain groups or types of data may require approval from other entities prior to being able to commence. In WA these may include the following:

Aboriginal or Torres Strait Islander Peoples

Research that specifically (i.e. other than coincidently) involves Aboriginal or Torres Strait Islander participants should also be submitted to the WA Aboriginal Health Information and Ethics Committee (WAAHIEC). Research should be submitted to WAAHIEC 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 has an impact on one or more Indigenous communities; and
- Indigenous health funds are a source of funding.

Information about this committee and necessary forms can be obtained from: https://www.ahcwa.org.au/ethics

WA Health Data Collections

Research that requires access to WA Health data collections and/or involve data linkage should also be submitted to the Department of Health WA HREC. Information about this committee and necessary forms can be obtained from: https://ww2.health.wa.gov.au/Articles/A_E/Department-of-Health-Human-Research-Ethics-Committee

REFERENCE DOCUMENTS

Researchers should be familiar with the following information provided on the Research Governance Service (RGS) website: https://rgs.health.wa.gov.au/Pages/Research-Governance-Framework.aspx

and the following key documents, before preparing a submission:

- WA Health Research Governance Policy and Procedure 2012
  http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=12923

- WA Health Research Governance and Single Ethical Review Standard Operating Procedures 2013
  https://ww2.health.wa.gov.au/About-us/Policy-frameworks/Research/Mandatory-requirements/WA-Health-Research-Governance-and-Single-Ethical-Review-Standard-Operating-Procedures

- WA Health National Mutual Acceptance Guidelines 2017
  https://rgs.health.wa.gov.au/Documents/WA%20Health%20NMA%20Guidelines.pdf

- National Statement on Ethical Conduct in Human Research
  https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

- Australian Code for the Responsible Conduct of Research
  https://www.nhmrc.gov.au/sites/default/files/documents/attachments/grant%20documents/The-australian-code-for-the-responsible-conduct-of-research-2018.pdf

- Australian Clinical Trial Handbook
  https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf

SECTION 1: RESEARCH AUTHORISATION

SOP101: Research Authorisation within NMHS-MH

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

Applicable to: All researchers wishing to undertake research within NMHS-MH

Version: 1.6 dated April 2020

Due for Review: June 2022

101.1 All research involving humans to be carried out within sites under the control of NMHS-MH require NMHS-MH approval and must undergo ethical (including scientific) and governance review. Both review processes may occur concurrently and the REGO Executive Officer (EO) will attempt to ensure well-coordinated concurrent processes to avoid duplication wherever possible. Such research may involve patients, staff, data, samples or information. See Diagram 101.1 for schematic representation of approval process.

101.2 Research that requires NMHS-MH approval must be submitted using the Research Governance Service (RGS) portal developed by the WA Health Research Unit: https://rgs.health.wa.gov.au/Pages/Home.aspx

101.3 The REGO will endeavour to review and make a recommendation within 60 calendar days from the day the application was received. This time frame incorporates a "stop clock" capability when additional input is required from the investigator or sponsor before consideration can continue.

101.4 A copy of REGO Terms of Approval outlining researchers' responsibilities and obligations will be sent to the Principal Investigator (PI) via RGS. These responsibilities must be abided by to prevent withdrawal of approval, as stated in the SOP603 – Withdrawal or Termination of Approval by the NMHS-MH HREC.

101.5 In accordance with the WA Health Research Governance Policy and Procedure 2012, the ethics approval applies for a maximum of three (3) years, with option for five (5), if justified. The HREC has the capacity to set a shorter approval period, contingent on the complexity and risk of the project.

101.6 If the research is to continue beyond the given expiry date, the PI must apply via the Research Governance Service (RGS) for an extension of approval to the REGO. The request should outline the reasons for the extension and provide justification as to why it should be granted.

101.7 The HREC approval for an ethics extension is limited to one period of three (3) years. The HREC has the capacity to set a shorter ethics extension period, contingent on the complexity and risk of the project.

101.8 The research should not continue beyond the expiry date without an extension being granted.

101.9 The HREC Chair and Research Governance Officer (RGO), or delegates, are the delegated authority by the NMHS-MH Executive Director (ED) to grant extensions to the approval period.

101.10 Projects that request support from NMHS-MH in the form of access to participants, their tissue or data and do not involve conducting research at any facilities, locations or services under the control of NMHS-MH do not require approval from the NMHS-MH HREC, but must demonstrate that another HREC has approved the project.

101.11 In addition to ethical and scientific review, research undertaken at sites under the control of NMHS-MH or accessing NMHS-MH participants or data, must also undergo NMHS-MH governance review, prior to research authorisation being granted. This review can occur concurrently with the ethical and scientific review and will involve either a site specific assessment (SSA) or access request review. However, site approval cannot be granted without proof that the project has valid ethics approval. Please refer to Section 2 – Research Governance Review, for information regarding the governance review process and the documentation requirements for submissions.

101.12 NMHS-MH authorisation to commence research will be granted only after the outcome of the ethical and governance reviews is received and reviewed by the NMHS-MH Executive Director (ED) or delegate authorised to grant institutional approval.

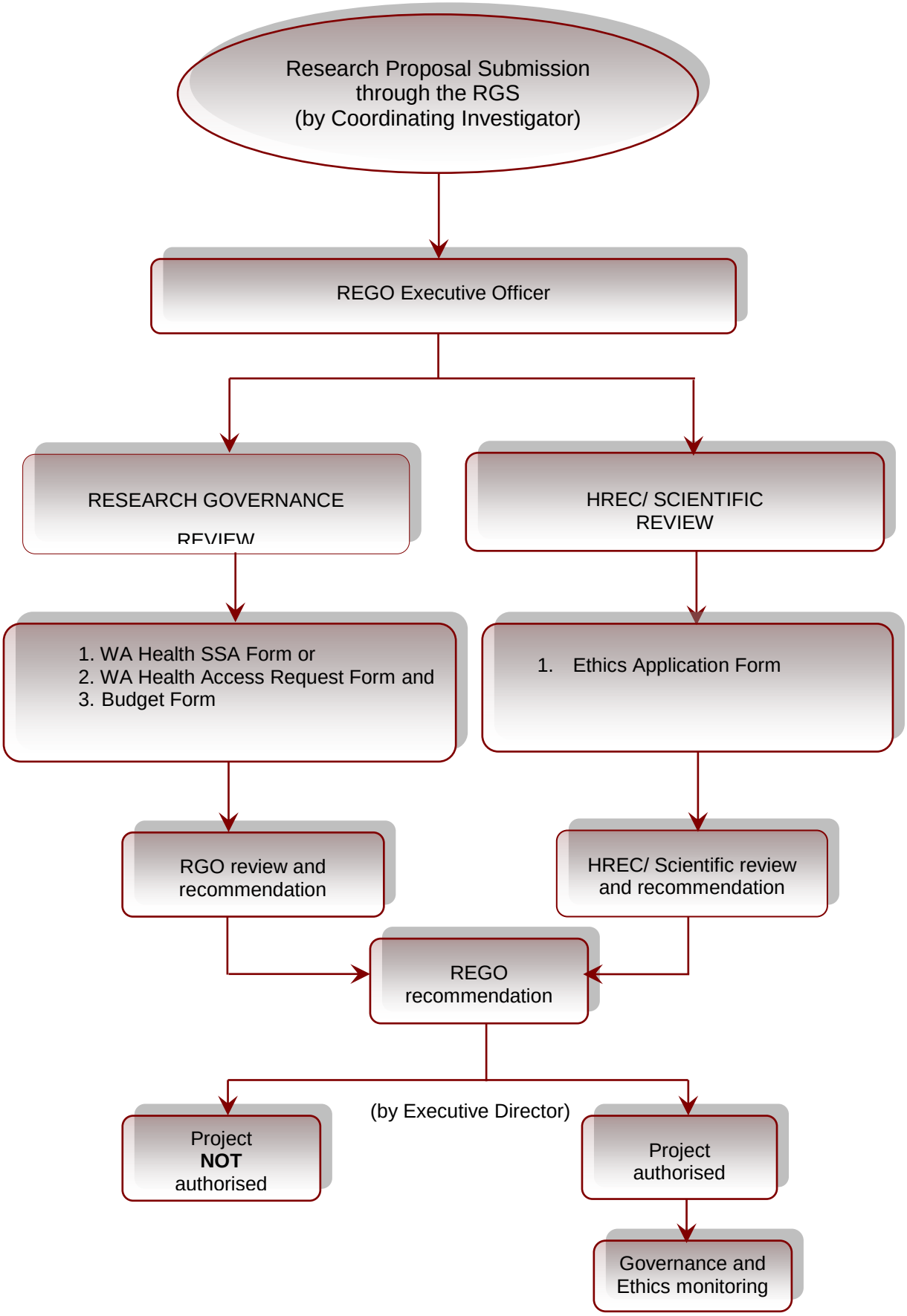
101.13 Once the project has been authorised by the ED, the nominated researcher will be notified in writing through RGS that the research may commence.

101.14 All research approved by the NMHS-MH will need to submit annual and final reports to the REGO. The PI will be alerted via the RGS, one month prior to the deadline of the annual/final report.

101.15 There will be no direct communication with HREC members either from sponsors or investigators. All correspondence will be undertaken via the Executive Officer (EO).

101.16 The Executive Officer (EO) will manage the RGS for the approval and monitoring of all current research activities conducted in NMHS-MH. The EO will submit, on an annual basis, to the NMHS-MH Executive Director or Delegate a report listing all the research proposals submitted and authorised to be carried out within NMHS-MH.

Diagram 101.1: NMHS-MH HREC and Research Governance Submission and Approval Pathways



SOP102: Application Submission Process

Function: To provide an outline of the process of application submission

Applicable to: All researchers wishing to undertake research within NMHS-MH

Version: 1.6 dated June 2020

Due for Review: June 2022

102.1 All research ethics submissions must be made online through the Research Governance Service (RGS; external site).

102.2 The submission cut-off day is always the same each month and is generally approximately one week before the HREC meeting.

102.3 A schedule of submission and HREC meeting dates can be found on the REGO website: http://www.nmahsmh.health.wa.gov.au/ethics/index.cfm and under the Meeting Calendar tab on the RGS website.

102.4 Researchers are encouraged to contact the REGO for advice before submitting an application.

SECTION 2: RESEARCH GOVERNANCE REVIEW

SOP201: Research Governance Application and Review Process

Function: Outlines the processes of a research governance application and review for site specific assessment (SSA) by the Governance Officer

Applicable to: Researchers and study coordinators

Version: 1.6 dated June 2020

Due for Review: June 2022

201.1 The governance review process is conducted through the RGS.

201.2 In accordance with the WA Health Research Governance Policy Framework, human research projects cannot commence at a NMHS-MHPHDS site until the Coordinating Investigator (CI) has received written notification of authorisation by the NMHS-MH Executive Director (ED) or their delegate; refer to SOP101 – Research Authorisation within NMHS-MH.

In addition to a HREC review/recommendation, all research projects conducted within the NMHS-MH must also undergo a research governance review/recommendation by the Research Governance Officer (RGO), before the ED grants authorisation. The HREC and research governance review processes will occur separately and concurrently.

201.3 Prior to submitting the research project documentation through the RGS, the REGO is available to provide advice on the appropriate governance documentation and fees, both to researchers and to external parties. All communication with sponsors is undertaken by the EO. There will be no communication with sponsors by HREC members.

201.4 Researchers should begin negotiations with relevant NMHS-MHPHDS personnel responsible for resources and services as early as possible to ensure financial and resourcing implications are identified and documented on the Site Specific Assessment (SSA) Form or Budget/ Finance Management Form for Clinical Drug Trials (CDTs) as relevant. Please refer to SOP203 – Financial Governance

201.5 If the research is sponsored, the initial budget should be negotiated by the Principal Investigator (PI) and Sponsor.

201.6 If the project is a clinical trial, investigators are required to submit documentation on insurance, indemnity and financial arrangements and a copy of the Clinical Trial Agreement at the earliest possible opportunity, as review of contractual documentation can be a lengthy process.

201.7 Discussions pertaining to the research governance processes should commence and run parallel to the HREC review cycle. To ensure appropriate timelines are met for the review and approval of a research governance application, it should be submitted to the RGO at the time of submission to the HREC i.e. it is not necessary to await the HREC outcome before submitting a site authorisation application.

201.8 Ongoing communications between the REGO and the PI and other members of the study team will usually occur via RGS and email. Researchers are, however, encouraged to contact the REGO via telephone or come to the REGO at any stage to

discuss the application process or particular issues with their research study to facilitate communication. The REGO will aim to maintain regular communications with researchers through the submission process until approval.

201.9 The Research Governance Officer (RGO) will discuss aspects of the application with relevant personnel from the site, sponsors and the reviewing HREC as required.

201.10 When the HREC has given its recommendation for the study, the RGO will complete his/her assessment and will make a recommendation to the NMHS-MH Executive Director or Delegate regarding authorisation of the project and indicate whether authorization is recommended, not recommended, or dependent on changes requested by the HREC committee, in the RGS.

201.11 The Research Governance Officer (RGO) will provide reasons for the decision if authorisation is not recommended or requires consideration by the ED or Delegate.

201.12 **Governance Review Forms**

The governance review is carried out using one of the following forms:

1. **WA Health Site Specific Assessment Form (SSA Form) –** this form is submitted via RGS and must be used for single-centre and multi-centre human research projects, conducted within the NMHS-MH jurisdiction, that require a full ethics review. For more information, please see SOP 202 – Site Specific Assessment Forms
2. **WA Health Access Request Form –** this form is submitted via RGS and can be used when a research project involves access to participants, access to their data, or distribution of leaflets, posters, handouts, letters of invitation, surveys, or questionnaires but not through direct contact with potential participants, and does not involve processing or analysis of the participants' data or collation and analysis of responses at any NMHS-MH sites.

201.13 **HREC Application Forms**

1. **Human Research Ethics Application (HREA) Form –** this form can be used for intra-jurisdictional (within WA) or interjurisdictional (outside WA) single or multi-site research. It requires researchers to provide information regarding the study pertaining to staff involvement, finances, and other sites' involvement. The study team is required to outline their intention to comply with matters pertaining to patient privacy and confidentiality, gaining informed consent, professional safety, data transfer and storage and other matters of significance for a research study. This form is currently not available in the RGS. To facilitate its submission to the NMHS-MH HREC the HREA Form must be completed externally (https://hrea.gov.au/) and uploaded to the RGS as a PDF supporting document.

   The HREA Form must be submitted in conjunction with the **WA Specific Module (WASM)**, which makes provisions for WA specific ethics aspects which are not covered by the HREA. The WASM is generated by the RGS and submitted as a form.

   All the other supporting documents for an ethics application (e.g. Protocol, Participant Information Sheet and Consent Form, questionnaires, posters, letters, etc.) must be completed externally and uploaded to the RGS as PDF documents.

2. **WA Health Ethics Application Form –** this form is automatically generated by the RGS and is submitted for research projects conducted within WA Health only.

   Templates for all WA Health Governance and Ethics forms can be found on the RGS website: https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx

201.14 All researchers are required to be aware of and compliant with relevant research laws, policies and codes of conduct, namely:

- GCP Guidelines: https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
- National Statement on Ethical Conduct in Human Research 2007 (Updated 2018): https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
- Australian Code for the Responsible Conduct of Research: https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
- WA Health site policies

201.15 **Research Protocol**

The research protocol is a document describing the objectives, design, methodology, organisation and statistical rationale of the project. The research protocol is reviewed by the RGO in detail. This is to ensure that the research activities described in the protocol are adequately communicated in the study documents. For example, if patients are to undergo CT scans or X-rays, then the RGO needs to check that the participants have been advised in the Patient Information Sheet and Consent Form, and that the Departments who provide those services have signed the SSA Form.

A Research Protocol Template is available via the RGS:
https://rgs.health.wa.gov.au/pages/Document-Templates.aspx

SOP202: Financial Governance

Function: To describe the process for financial review and approval of site specific assessments (SSAs) by the Research Governance Officer (RGO)

Applicable to: Researchers and Study Coordinators

Version: 1.6 dated June 2020

Due for Review June 2022

202.1 **Budget Form**

As part of the site authorisation process, the PI is required to complete the Budget Form in the RGS to document funding and costs related to the research project. The PI must ensure all NMHS-MH fees are included in the budget.

202.2 In clinical trials, the budgets are often supplied by sponsors in the Clinical Trial Research Agreement (CTRA) with a pre-determined payment amount and schedule, but are usually open to negotiation. The PI is required to negotiate the Payment Schedule with the sponsor to cover trial costs; based on the costs quoted on the Financial Management Form (FMF). Upon the parties' acceptance, this budget is then documented in the FMF and CTRA.

202.3 **Supporting Departments**

Researchers should begin negotiations with relevant NMHS-MH personnel responsible for resources that will be required for the study (e.g. Heads of Service/Directors or delegate/s and relevant Finance and Business Officers) as early as possible.

If a research application utilises the services of a supporting site/service, even if it is considered 'standard of care' by the researcher, the researcher should still contact the Head of Service/Director to discuss the research requirements and obtain sign-off. These sites/services should be remunerated for all services applied to Clinical Trial subjects, whether they are determined routine or not i.e. all request forms should include Clinical Trial details.

The SSA Form ensures that the Principal Investigator, Head of Service/Director, Finance Officer and Heads of Supporting Sites/Services under whose auspices the research is taking place have all signed to show they understand the financial, personnel, logistical and other resource implications a particular research study will have upon their departments.

All the Head of Service/Director, Finance Officer and Heads of Supporting Sites/Services of the supporting departments will have to sign the SSA via the RGS.

202.4 **NMHS-MH Pharmacy Service**

Clinical trials involving drugs will attract Pharmacy Fees. The NMHS-MH Pharmacy Service can either charge their fees as part of the CTRA or deal directly with the Sponsor using a separate Pharmacy Financial Agreement. In the latter, no Pharmacy Fees are documented in the payment schedule but will be documented in an appendix to the CTRA and invoiced to the Sponsor independently. This Pharmacy Financial Agreement is reviewed by the RGO as it will form an Appendix to the CTRA and be signed by the ED or delegate.

202.5 **Fees**

Applications for studies that are fully or significantly sponsored by external commercial agencies (e.g. pharmaceutical companies or other commercial bodies) attract a submission fee. Fees are payable on submission. Additional fees may be charged for amendments, particularly those of a substantive nature. See Table 202.1. Fees do not include GST.

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

Table 202.1

	Research Governance Review	Scientific & Ethical Review	Total
New application	$3,500	$3,500	$7,000
Substantial Amendments*	$600	$600	$1,200
Administrative Amendments (Refer to SOP502)	No Fee	No Fee	No Fee

*i.e. Major changes to the project documentation

SOP203: Clinical Trials Notification (CTN) and Clinical Trials Exemption (CTX) Schemes

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

Applicable to: Researchers and Study Coordinators

Version: 1.6 dated June 2020

Due for Review: June 2022

203.1 The Therapeutic Goods Administration (TGA) is the organisation in Australia that is responsible for the regulation of therapeutic goods such as prescription medicines and surgical devices. The TGA administers two schemes under which clinical trials involving therapeutic goods may be conducted: **The Clinical Trial Notification (CTN) Scheme** and the **Clinical Trial Exemption (CTX) Scheme**.
A notification or application to the TGA is required for all clinical investigations of the use of a product in Australia, where that use involves:

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

The CTN Scheme is a **notification** process. For clinical trials being conducted under this scheme, all material relating to the proposed trial is submitted directly to the HREC. The HREC and the scientific subcommittee are responsible for assessing the scientific validity of the clinical trial, including approving the protocol and ethical acceptability of the trial process. The HREC and the site must both sign the relevant pages of the CTN form when they approve the trial. The TGA is notified of the clinical trial through submission of the CTN form. A trial being conducted under the CTN scheme cannot commence until the CTN form has been submitted to the TGA with the appropriate fee.

The CTX Scheme is an **approval** process. Unlike the CTN scheme, rather than the trial material being submitted to the HREC, it is submitted directly to the TGA for evaluation, along with a fee. The trial documentation is also reviewed by the NMHS-MH HREC. A CTX trial cannot be commenced until written approval for the use of the investigational product has been received from the TGA. **Any researchers considering conducting a trial under the CTX scheme should contact the NMHS-MH HREC Chair in the first instance. From this point on, the SOP will refer to the CTN scheme only as this is the most appropriate scheme for most research studies conducted within NMHS-MH sites and services.**

More information on CTN and CTX Schemes can be found on the TGA website https://www.tga.gov.au/clinical-trials.

203.2 The CTN form is formally called “Notification of Intent to Supply Unapproved Therapeutic Goods under the Clinical Trial Notification (CTN) Scheme” and can be downloaded from the TGA website https://www.tga.gov.au/clinical-trials. Before the CTN form can be lodged with the TGA, it needs to be signed by the Principal Investigator (PI) and submitted as part of the research application to the RGO for review and completion.

For commercial studies, the commercial sponsor should provide the PI with an original CTN for all participating sites. It is then the Sponsor’s responsibility to lodge the CTN form with the TGA once the appropriate signatures from the site have been obtained.

For researcher initiated studies, the researcher will be required to obtain the form, ensure it is completed and lodge it with the TGA themselves.

Researchers who are unsure if they require a CTN, or for information about completing the form and the costs associated with lodging a CTN, can contact the TGA directly: 1800 020 653.

203.3 For the purposes of the CTN form, the Sponsor of the clinical trial must be an Australian entity i.e. it must have a registered ABN.

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

- The Sponsor name on the CTN corresponds with the Sponsor name on all the other vital documents (p.3). For commercially sponsored trials, the commercial sponsor is usually the last to sign (p.6);
- The title of the study and protocol numbers are correct (p.3);
- The medicine details correspond with those in the protocol and all medicines and placebo have been included and dosages printed correctly (p.4);
- Any unregistered devices being utilised in the study are included in Device details (p.5);
- Ideally the PI will have signed prior to submission. If approving for other sites, each individual site must ensure that the PI signs Section 2 (p.7);
- If the site is acting as the Sponsor for a local Investigator, then the site will also need to sign as the 'Sponsor' (p.6);
- Official HREC name and address and other pertinent details. This will be NMHS-MH HREC (p.8);
- Approving authority name and address are correct. This will be NMHS-MH Executive Director or Delegate for all trials conducted within NMHS-MH (p.9).

203.5 Upon HREC approval and RGO endorsement of the clinical trial to the NMHS-MH Executive Director (ED) or approved Delegate, the CTN will be signed by the Chair/DoC of HREC and the site/service's authorised signatory. This will occur when all other approval documentation is signed by the ED or Delegate, NMHS-MH.

203.6 The REGO will keep a copy of the CTN within the trial file.

203.7 The CTN is returned to the PI with the other signed and approved documents. Then the PI will either submit the CTN to the TGA with the relevant fee (researcher initiated trial) or will return it to the Sponsor to sign and submit (sponsored trial).

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

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

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

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

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

SOP204: Research Study Agreements

Function: Outlines the function and review process for the Research Study Agreements

Applicable to: Researchers and Study Coordinators

Version: 1.6 dated June 2020

Due for Review: June 2022

204.1 When considering whether a Research Study Agreement is required, there are two options available:

- NMHS-MH internal research projects – the research project is solely NMHS-MH based and funded; and does not involve funding or the provision of a product/drug from an external party. In this case no research study agreement is required.
- NMHS-MH research projects involving External Parties – the research project involves an arrangement between NMHS-MH and an external party for provision of a product or funding. In this case there is a requirement to have a Research Study Agreement (i.e. Clinical Trial Research Agreement, Material Transfer, Financial or Equipment Agreement).

204.2 All research involving NMHS-MH staff, subjects or resources conducted with an external sponsoring entity should be the subject of a written research contract. The type of research activity undertaken will dictate the type of research contract required.

204.3 For samples of Research Study Agreements and to download the appropriate form, please visit the RGS website:

https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

204.4 WA Health standard clinical trial, registry and confidentiality agreement templates must be used wherever possible to facilitate review and are available from the RGS website https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

204.5 Each clinical registry conducted in NMHS-MH must be governed by a Clinical Data Registry Agreement (CDRA). It is mandatory that the Standard CDRA is used for all sponsored clinical registries. Review and amendments are the same as for the CTRA processes outlined in SOP 206 – Clinical Trial Research Agreement.

204.6 These contracts must be reviewed by the RGO under the direction of WA Health Legal and Legislative Services advice prior to authorisation by the Executive Director or Delegate, who should be satisfied with the proposed contract before they sign.

SOP205: Declaration of Confidentiality and Confidentiality Agreements

Function: Outlines the function and review process for Declarations of Confidentiality and Confidentiality Agreements

Applicable to: Researchers and Study Coordinators

Version: 1.6 dated June 2020

Due for Review: June 2022

205.1 **Non-Clinical Trials**

The WA Health Declaration of Confidentiality must be completed via RGS by all research personnel (including students) who are not employees of WA Health, who will be:

- conducting a research project within WA Health; or
- accessing WA Health participants, their tissue or data

205.2 **Clinical Trials**

If a Confidentiality Agreement (CA) is required at the outset of clinical trial discussions, the RGO can be contacted for advice.

205.3 Confidentiality Agreements (CA) between a Sponsor and a Site/PI at the commencement of a trial, involve legal liability and possible risk of litigation to those parties to the agreement. CA can contain multifaceted legal issues which without legal advice may be undefined. If signed by the PI, the PI will become solely accountable, as they do not necessarily have the legal delegation to bind or sign agreements on behalf of NMHS-MH. It is highly recommended that all these agreements are approved by NMHS-MH RGO. The PI should seek advice from the RGO.

205.4 WA Health recommends that NMHS-MH staff do not sign any CA as under their employment agreements they are required to keep work-related matters confidential. Before any CAs are signed it is recommended putting to the entity requesting the agreement the following:

"It is not standard practice for public sector employees to sign confidentiality agreements. The State Solicitor's Office of Western Australia recommends that they do not do so. Public sector employees are required by the Public Sector Management Act 1994 to keep information obtained in the course of their employment confidential. Under section 81 of the Criminal Code of Western Australia, unauthorised disclosure of information is a criminal offence punishable by up to 3 years imprisonment. Accordingly confidential information provided to a public sector employee is more than adequately protected by law."

205.5 If a CA is still required, it is highly recommended that the Confidentiality Agreement Template, available on the RGS website: https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx is used to reduce the legal time required to review each Sponsor's individual CA. This template should be sent to the Sponsor by the PI during the initial correspondence regarding a trial.

205.6 The RGO will negotiate and process the agreements for the Executive Director or Delegate to sign on behalf of NMHS-MH, which will last for 5 years. The RGO will maintain a record of the CA executed with external parties and (if these are not trial specific) are available to cover all future trials for the 5 year period. A copy of this may be forwarded to involved interested parties.

SOP206: Clinical Trial Research Agreements (CTRA)

Function: Outlines the function and review process for the CTRA

Applicable to: Researchers and Study Coordinators

Version: 1.6 dated June 2020

Due for Review: June 2022

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

206.2 **Commercial Clinical Trials**

In commercial clinical trials the Sponsor or Contract Research Organisation (CRO) is a Company or Organisation that takes responsibility for the initiation, management, indemnity and financing of a clinical trial and endorses the CTN or CTX form. The study protocol has been developed by the commercial entity, and it retains ownership of the product, study material and intellectual property (IP). Consequently, the risks and liabilities associated with the trial must be borne primarily by the Sponsor/CRO and they must provide Indemnity and Insurance. For such trials, it is important that the CTRA reflects the responsibilities of the Sponsor, CRO, Institution and PI; covering the management, financing, IP, publication, insurance and indemnity issues comprehensively.

206.3 **Non-Commercial Clinical Trials**

Non-Commercial clinical trials are Investigator-Initiated and can be unsponsored, sponsored, grants or part of a Collaborative Research Group (CRG). The PI, CRG or the site is the primary author and custodian of the trial Protocol and is responsible for the initiation, management, financing and intellectual property of the trial. Although these studies are not sponsored by a commercial entity, industry or a non-commercial organisation may provide some funding or product support for the trial. There is a clear benefit in continuing these arrangements, particularly where such trials offer patients a treatment that would not otherwise be available.

In the case of non-commercial NMHS-MH trials, the intellectual property, risk and indemnity typically rests with NMHS-MH. In the case of a CRG clinical trial it is generally accepted practice that the study material and IP is owned by the CRG and the expectation is that the hospital will assume the liabilities of the clinical trial. Indemnity and Insurance for these trials may be provided by RiskCover on behalf of NMHS-MH, if the risk is deemed acceptable.

206.4 The TGA supports a National Standards based, system-wide approach to the clinical trial agreements and indemnities. Standard CTRA have been formulated by Medicines Australia (MA) and the Department of Health Legal & Legislative Services (LLS) for use in all clinical trials involving external parties. WA Health including NMHS-MH is required to use CTRAs approved by the Legal & Legislative Services (LLS) branch of the WA Department of Health.

The REGO advises that WA Health template agreements should be used. These template agreements can be found on the RGS website:

https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

206.5 Prior to submitting a research application for approval, a commercial Sponsor, Contract Research Organisation (CRO) or CRG should contact the REGO for advice on the most appropriate CTRA form.

206.6 Parties entering into a CTRA must be legal entities; therefore the CTRA must identify and define their legal title (including ACN/ABN), registered address and business name. It is a requirement (due to the CTN, refer to SOP 203.3) that the external parties, e.g. Sponsor or CRO, be incorporated within Australia, or use a subsidiary that is incorporated within Australia.
NMHS-MH is not a legal entity in itself but part of the North Metropolitan Health Service. The site's legal name varies slightly depending on whether the legal document (CTRA, Indemnity and CTN/CTX Forms) applies to all hospitals within NMHS-MH or individual sites:

Where there is one or more (but not all) of the public hospitals comprised in the NMHS-MH, the legal name is:

"*The Minister for Health is incorporated as the North Metropolitan Health Services – Mental Health under section 7 of the Hospitals and Health Services Act 1927 (WA), with responsibility for [Insert name of relevant Hospital(s)] and has delegated all the powers and duties as such to the Chief Executive Officer of the Metropolitan Health Service, known as the Director General of Health. "*

Where all hospitals comprised in NMHS-MH are involved the legal name is:

"The Minister for Health is incorporated as the North Metropolitan Health Services – Mental Health under section 7 of the Hospitals and Health Services Act 1927 (WA) and has delegated all the powers and duties as such to the Chief Executive Officer of the Metropolitan Health Service, known as the Director General of Health."

(NB: The address and ABN of the party needs to follow the legal title on Indemnity Forms.)

All legal documents should have the following execution clause:

"*Signed by [insert name], [Executive Director] for and on behalf of the Director General of Health as delegate of the NMHS-MH."*

206.7 The CTRA recognises the PI's responsibility for the conduct of the study, but the PI does not have the legal authority to be a party to, or amend a CTRA. The CTRA is a legal document between the site and the Sponsor/CRG. All legal agreements must be signed by the appointed representative of the Minister for Health, including Amendments, CTN/CTX, Pharmacy and Imaging Agreements and Indemnity Forms.

206.8 The PI can acknowledge, by way of signing, their obligations as set out in the terms and conditions of the CTRA. It is important that the Investigator reads the CTRA and is aware of their own and their staff's obligations.

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

- the NMHS-MH site's legal name (must be used as the party to the CTRA);
- the title of the trial;

- the Sponsor legal name and that the same entity corresponds with the name on the indemnity, CTN and other vital documents; and
- all other details, contained in the schedules are correct, including:

Trial Details, Payment Schedule, Medicines Australia Form of Indemnity for Clinical Trials, Insurance Certificate of Currency and Policy Details, Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Trial, Study Protocol Identification, Special Conditions.

This does not apply to a non-commercial CTRA.

206.10 The RGO will review the submitted CTRA to ensure consistency with WA Health approved agreements and Legal and Legislative Services (LLS) guidelines. Where a Sponsor or CRG submits, without amendment, a current version of an approved CTRA, that document can be accepted by the RGO unless the RGO determines that LLS's advice is required.

206.11 It is recognised that there will be instances where the standard CTRA may require modification in relation to different clinical trials and different Sponsors requirements. If changes have been made, the RGO will advise the Sponsor/CRG whether the proposed amendments are acceptable.

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

206.13 If a Sponsor or CRG submits a CTRA containing material changes, the RGO will need to assess the effect of those changes on the integrity of the CTRA using the LLS guidelines. If these changes are outside the scope of the guidelines the RGO must seek legal advice from LLS.

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

206.15 The RGO will arrange for sign-off of the CTRA with the other documents, once RGO requirements have been met and HREC approval of the trial has been obtained.

206.16 Once signed (with other approval documentation) by the Executive Director or Delegate, the CTRA and Indemnity Form (where relevant) will be uploaded to RGS along with the other project documents.

SOP207: Medicines Australia Form of Indemnity for Clinical Trials

Function: Outlines the function and review process for the Indemnity Form

Applicable to: Researchers and Study Coordinators

Version: 1.6 dated June 2020

Due for Review: June 2022

207.1 In all clinical trials, NMHS-MH must ensure that it does not assume liabilities attached to an external entity. Care must be taken in providing indemnity to a third party as such an action may void NMHS-MH's indemnity cover with RiskCover.

207.2 In non-commercial trials a risk assessment must be made by the RGO if indemnity is to be provided by NMHS-MH. In most non-commercial trials, NMHS-MH (as delegate for the Minister for Health) assumes the risk of that trial and covers its employees and the participants. Should a civil claim arise as a consequence of the trial, the State Government's indemnity arrangements mean that RiskCover (which manages the self-insurance arrangements for WA Health), will generally be relied upon to meet the costs of responding to that claim.

The RiskCover Fund does not extend to parties who are involved in Clinical Trials outside the Public Sector, thus all trial participants and staff must be patients or employees of NMHS-MH to be covered.

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

207.3 In all commercial trials conducted under the following CTRA, the Sponsor and/or the CRO must provide indemnity to the site and members of the Responsible HREC against claims arising from the research on the terms and conditions set out in the relevant Medicines Australia Form of Indemnity for Clinical Trials:

1. CTRA - Medicines Australia (MA) Standard Form (Form A)
2. CTRA - Medicines Australia Form - Contract Research Organisation acting as the Local Sponsor (Form D)
3. CIRA – Medical Technology Association Standard Clinical Investigation Research Agreement (MTAA CIRA).

Non NMHS-MH parties may seek to be indemnified by a commercial sponsor. Where a third party, such as a research institute, wishes to be indemnified by the commercial sponsor, a separate Form of Indemnity should be used for each party indemnified.

207.4 The MA Standard Form of Indemnity does not cover liabilities that arise from the negligent conduct of the PI or the Institution. Should an allegation be made, NMHS-MH employees are indemnified under a WA Government policy that covers employees acting in good faith and in accordance with the terms of their employment. RiskCover is likely to be relied upon in the event that the site or its employees act negligently.

207.5 Where the Sponsor is an overseas entity and party to the CTRA, the indemnity may be provided by the Sponsor or by the CRO. If the overseas company is not party to the agreement, the CRO must provide the indemnity; it cannot provide indemnity as an agent of the overseas company. The indemnity provided must be backed up by an

acceptable Insurance Policy.

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

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

For the majority of studies, the Standard Form of Indemnity will be submitted, which can be downloaded from the RGS website:

https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx#clinical-trial-top

207.7 The MA Indemnity Form provides a written assurance that the Guidelines for Compensation for Injury Resulting from Participation in A Company-Sponsored Trial will be adhered to, without legal commitment, in the event of injury caused to a Subject attributable to participation in the trial in question". This Compensation Guidelines favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by participation in Clinical Trials.

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

For the site, the correct information for the indemnified party should be the legal name as stipulated in SOP 206.7 with the addition of the wording below following the name of the NMHS-MH site:

XXXX Hospital, ABN YY YYY YY, of (insert address)

The signatory should remain the same as SOP 206.7

Note that the ABN (Australian Business Number) and address are included as part of the legal name.

Researchers are advised to check http://www.abr.business.gov.au/(41py2yburl5wwzgrlcxulj45)/main.aspx for the correct entity names and ABN of the other parties.

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

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

207.9 Following submission to REGO, the Form of Indemnity will be checked to verify that the details for each party are correct, that "the Subjects' and "the Principal Investigator" have been identified in paragraph 1, and that none of the wording has been altered, deleted or inadvertently omitted when completing the document details. If a CRO is providing the indemnity the wording 'Sponsor' should be changed to 'CRO' to match the parties' title in the CTRA.

207.10 Any proposed changes to the wording of the Form of Indemnity by any party to the study, aside from those required above, must be made separate to this document. Generally this is done in Schedule 3 of the respective CTRA. If the indemnifying party makes any changes to the text of the Form of Indemnity, RGO will need to have these reviewed by WA Health LLS.

207.11 Once the Form of Indemnity is finalised, it will be included as part of the documents submitted for site sign-off. At that time, they will be signed and dated by the authorised NMHS-MH signatory (acting as a delegate of the Minister for Health), and then uploaded to RGS.

SOP208: Insurance

Function: Outlines the review process by the Research Ethics and Governance Office (REGO) of insurance provisions provided for a research project.

Applicable to: Researchers and Study Coordinators

Version: 1.6 dated June 2020

Due for Review: June 2022

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

208.2 RiskCover manages the WA Government's self-insurance arrangements, which incorporate the WA Health system, including research activities. RiskCover protects public sites under the legal liability cover and also provides insurance and risk management advice to its public clients. Where a research study is to be undertaken within NMHS-MH, the study proposal must pass certain scrutinies by REGO, including examination of the external parties' insurances. RiskCover provides a support service in scrutiny and advice regarding these insurances and the REGO operates under its guidelines.

208.3 In Commercially Sponsored Trials it is important to ensure the insurance held by a Sponsor will actually cover the liability of the insured (Sponsor) for injury or death, plus damage to property, as a result of the Sponsor's performance under the CTRA. Scrutiny of the insurance by the RGO therefore becomes important because if the insurance does not have veracity, then the integrity of the clinical trial collapses.

208.4 The Clinical Trial Research Agreement (CTRA) stipulates which insurance requirements must be met. The site will review insurance limits with reference to the risks of the study, however, the minimum requirements for a sponsor and/or CRO are:

(1) product liability insurance for a minimum sum insured of AUD $10,000,000 and also in the aggregate;

(2) public liability insurance for the minimum sum insured of AUD $5,000,000; and

(3) liability insurance covering:

- the contractual obligations of the Sponsor contained in this Agreement;
- the negligence of the Sponsor in the conduct of the Trial;

for a minimum sum insured of AUD $10,000,000 and also in the aggregate.

208.5 Where insurance is required, an insurance certificate of currency, as a minimum, should be provided with the submission paperwork. For insurance companies based in Australia [and listed on the Australian Prudential Regulation Authority's (APRA) list of acceptable insurers], the certificate of currency is usually an acceptable evidence of cover.

208.6 If the insurance company is not APRA approved a full copy of the insurance policy wording is required by RiskCover to assess the veracity of the policy. Research staff are required to access this document from the Sponsor. Although the insurance industry uses common terms to describe the various classes of insurance, the actual policies

offered by insurers within each class can vary significantly and the wording of the overseas policies may not always be clear. If the Sponsor is unable to provide the policy, wording information must be provided to address the following 12 points required by RiskCover as the minimum requirements to assess the veracity of the policy.

208.7 The RGO will assess the insurance information provided against the 12 points of insurance that have been outlined by RiskCover as the minimum amount of information that needs to be provided. These are listed in the WA CTRA's in Schedule 4 and are as follows:

1. Name and address of the insurer, including its Internet website address.
2. Name and address of the insured. If the insurance extends to other parties relevant to the agreement, details should be provided. The site needs to be satisfied that the Sponsor is actually insured under the policy.
3. Policy number.
4. Period of insurance.
5. Class of insurance.
6. Sum insured per event including any sub limits.
7. Aggregate sum insured.
8. If applicable, any excess of loss/umbrella policy information.
9. Deductibles/excesses.
10. Whether the policy is constructed on an "occurrence" or "claims made" wording.
11. Scope of cover. For example, "Legal liability of the insured for death and bodily injury arising from clinical trials, including products liability risks". There may be a need to quote the operative clause of the policy to capture the correct interpretation.
12. Territorial limits of the policy. It is essential that the policy respond to claims lodged and processed in an Australian jurisdiction. Notwithstanding that the cover may apply anywhere in the World, if there are any restrictions on claims in an Australian jurisdiction, these must be detailed (If an overseas sponsor is providing insurance, it needs to be clarified that if a claim were to be made that it would not be required to be heard in a court overseas).

Relevant policy exclusions and conditions should be listed and detailed if appropriate. (Exclusions relating to contractual liabilities, specific drugs and implements may be important as examples have been found in the past where the very product being trialled is listed as exclusion on the insurance policy, rendering the insurance policy provided for that research study invalid, thus leaving WA Health open to any claims arising from the trial).

208.8 Where the 12 points of insurance information have not been provided, the GO will contact the Sponsor/CRO to provide the balance of information. Once this information is received by the REGO and deemed to be in order, then the insurance can be approved.

208.9 The REGO will contact RiskCover for further advice if the insurance does not comply with RiskCover's recommendations or is difficult to analyse.

208.10 After consultation with RiskCover, if the insurance does not comply with requirements, the RGO will consult with the NMHS-MH Executive Director to decide if the trial can proceed based on the insurance provisions provided.

SOP209: Intellectual Property

Function: Outlines the process for the protection and management of Intellectual Property in research within NMHS-MH

Applicable to: All staff involved in research within NMHS-MH

Version: 1.6 dated June 2020

Due for Review: June 2022

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

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

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

The following reference documents provide further guidance in this area:

- Intellectual Property Management in the WA Department of Health: http://www.health.wa.gov.au/IP
- WA Government Intellectual Property Policy and Best Practice Guidelines: https://www.commerce.wa.gov.au/sites/default/files/atoms/files/wa_govt_ip_policy_and_best_practice_guidelines.pdf
- National Principles of Intellectual Property Management for Publicly Funded Research: https://www.arc.gov.au/policies-strategies/policy/national-principles-intellectual-property-management-publicly-funded-research

209.2 **IP Management and Ownership**

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

When a NMHS-MH employee is involved in a research study that has been approved by the NMHS-MH, the NMHS-MH supports this project by providing indemnity and insurance. If there are reasonable grounds to anticipate that significant IP could be developed in the

study, the employee will be requested to acknowledge the ownership of this IP by the State of Western Australia, represented by WA Health/NMHS-MH.

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

209.3 **IP in Collaborative Research Studies**

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

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

209.5 **Publications**

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

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

Unless IP assignment is required by the publisher, any publication, whether in print or electronic form, arising from WA Health activities should carry the copyright disclaimer available on the Department of Health IP Management website: http://ww2.health.wa.gov.au/Articles/F_I/Intellectual-Property .

209.6 Any queries in relation to IP matters in WA Health/NMHS-MH should be directed in the first instance to REGO. If required these may be then referred to the IP Coordinator within the Department of Health: http://ww2.health.wa.gov.au/Articles/F_I/Intellectual-Property

209.7 NMHS-MH employees should seek authorisation for publication for Professional or Scientific Papers from the NMHS-MH delegated authority.

SOP210: Complaints Regarding the Conduct of Research

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

Applicable to: All participants, research and other interested persons

Version: 1.6 dated June 2020

Due for Review: June 2022

210.1 The Executive Officer (EO) is the nominated person to whom complaints from research participants, researchers or other interested persons about the conduct of approved research projects may be made in the first instance.

210.2 The EO is responsible for obtaining in writing the grounds of the concern or complaint and shall notify the RGO and HREC Chair as soon as possible after a complaint is received.

210.3 The REGO will send a letter of acknowledgement to the complainant and a letter of notification to the Principal Investigator (PI) within 5 working days, outlining the complaint and the process that the REGO will follow for investigating the complaint, as set out below.

210.4 The EO and/or the HREC Chair will instigate an investigation of the complaint and its validity and make a recommendation to the project's PI on the appropriate course of action. This investigation and response shall take no longer than 30 working days from the time of notification of the complaint or concern, unless exceptional circumstances exist. If the complaint is substantiated, action may include:

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

In addition, the NMHS-MH delegated authority for the site where the research is being undertaken will be informed of the outcome of the investigation and the recommended course of action.

210.5 The complainant shall be informed of the outcomes of the EO/HREC Chair investigation. If the complainant is not satisfied with the outcome of the EO/ Chair investigation, then they can request the REGO to refer the complaint to the Executive Director (ED) of NMHS-MH or Delegate.

210.6 The NMHS-MH ED or Delegate will determine whether there is to be a further investigation of the complaint. If it is decided there is to be a further investigation, then the ED/Delegate will convene a suitable panel to review the complaint, ensuring that both the complainant and the project PI are afforded the opportunity to make submissions. Where no further investigation is to occur, the ED/Delegate will inform the complainant and the REGO in writing of this outcome.

210.7 Where the complaint concerns a matter other than the conduct of a research project (i.e. HREC review process), the EO shall refer the complaint to the NMHS-MH Stakeholder Liaison Officer who will investigate the complaint and its validity, and make a recommendation to the REGO and HREC Chair on the appropriate course of action.

SOP211: Conflict of Interest - Researcher

Function: To describe the process of managing a conflict of interest identified within a research project reviewed by the NMHS-MH

Applicable to: The NMHS-MH REGO

Version: 1.6 dated June 2020

Due for Review: June 2022

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

211.2 When conducting research projects within the WA Health, all WA Health employees acting as site researchers are required to declare any conflict of interest via RGS.

211.3 Where a researcher has indicated a conflict of interest, the process undertaken by the researcher to address this conflict will be reviewed by the REGO. If the REGO determines the process is inadequate, a letter will be sent to the researcher outlining its concerns and asking for these to be addressed.

211.4 Where a conflict of interest fora researcher in a research application under review is identified by the NMHS-MH REGO (i.e. a conflict not already addressed in the *RGS*), the subject of that conflict will be notified in writing by the REGO. The letter will state the nature of the conflict. The researcher will be given the opportunity to respond and amend the planned research to remove the conflict if necessary.

211.5 The RGO will review the researcher's response and evaluate whether the researcher has adequately addressed its concerns. If the REGO still believes that a conflict exists, the researcher may be asked to attend the HREC meeting to discuss these issues.

211.6 The research will not be given HREC and/or governance approval until any conflict of interest is addressed.

211.7 Conflicts of interests are managed in accordance with the *WA Health Managing Conflict of Interest Policy and Guidelines 2010.*

http://www.health.wa.gov.au/circularsnew/attachments/452.pdf

http://www.health.wa.gov.au/circularsnew/attachments/453.pdf

SECTION 3: ETHICAL AND SCIENTIFIC REVIEW

SOP301: Submission of Research for Single Site Review and Multicentre Research with No Recognised Prior Review Applications

Function: To describe the requirements when submitting a research application to the NMHS-MH HREC for single site review or a multicentre research application that has not been reviewed by another NHMRC certified or WA Health HREC.

Applicable to: All researchers submitting research applications to the NMHS-MH HREC that require full HREC review

Version: 1.6 dated June 2020

Due for Review June 2022

301.1 The NMHS-MH HREC will review the ethical and scientific integrity of the standard single site research and multicentre research with no recognised prior review applications in the same manner. These reviews are conducted via RGS.

301.2 All research projects conducted within NMSH-MHPHDS are reviewed by the NMHS-MH HREC.

301.3 The documentation requirements for such reviews are:

- WA Health Ethics Application Form or NEAF + WA Specific Module;
- Participant Information sheet and Consent Form (including those for additional sub-studies);
- Questionnaires, diaries, ID cards and any other documentation;
- Evidence of recognised scientific merit, peer review or a proposal of sufficient detail to determine scientific merit, literature review, aims, hypotheses and methods, including description of participants and data analysis.
- Any other documents pertaining to the project.

The research cannot proceed at any NMHS-MH site until institutional approval is given (dependent on both ethical and governance review) by the ED or Delegate.

301.4 If the research involves access to participant records or samples without the consent of the participant, a waiver of consent is required. The Researcher will have to address the points outlined in Section 2.3.10 of the National Statement.

If the research involves access to participant records or data from a Commonwealth agency or private organisation (e.g. GP or private hospital) without the consent of the participant, Section 95 or Section 95A of the Privacy Act is applicable. A document addressing the privacy issues outlined in the applicable guideline should be included with the application.

Guidelines regarding these sections of the Act can be found on the NHMRC website, at: http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e26.pdf and http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e43.pdf

301.5 Complete applications should be submitted to the NMHS-MH HREC via RGS by the submission cut-off date. The submission cut-off dates are available on the REGO website http://www.nmahsmh.health.wa.gov.au/ethics/index.cfm

or via the RGS Meeting Calendar https://rgs.health.wa.gov.au/Pages/Meeting-Calendar.aspx

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

301.7 Templates of the required forms necessary for submitting research applications are available on the RGS website, or click the link below:

https://rgs.health.wa.gov.au/pages/Document-Templates.aspx

301.8 Projects involving clinical drug trials (CDTs) must be submitted to the Drug and Therapeutics Committee, NMHS-MH Pharmacy Department, Graylands Hospital, (please contact the Chief Pharmacist on 08 6159 6678) for review and approval, prior to submission to the NMHS-MH REGO. A copy of the approval letter needs to be submitted to the HREC.

301.9 NMHS-MH REGO will charge a submission fee for research projects sponsored by a commercial company (e.g. Pharmaceutical company). The appropriate submission fees for ethics review and governance review need to be paid before the project can receive ethics and governance approvals. For further information regarding fees please refer to SOP202.5– Fees.

SOP302: Submission of Multicentre Research with Recognised Prior Review Applications

Function: To describe the procedure for the submission of multicentre research application that has been reviewed by another WA Health (Reciprocal) or NHMRC certified HREC

Applicable to: All researchers submitting multicentre research applications to NMHS-MH that have been approved by another WA Health or NHMRC certified HREC

Version: 1.6 dated June 2020

Due for Review: June 2022

302.1 Under the WA Health Single Ethical Review scheme, the NMHS-MH HREC accepts the ethical and scientific review undertaken by a Lead WA Health HREC as sufficient review for the purposes of the multi-centre projects conducted at sites under the NMHS-MH control.

302.2 Under the National Mutual Acceptance (NMA) scheme, the NMHS-MH HREC accepts the ethical and scientific review undertaken by a NHMRC Certified Lead HREC participating in the NMA (a list of these HRECs can be found on the NHMRC website) as sufficient review for the purposes of the multi-centre projects conducted at sites under the NMHS-MH control.

302.3 If the prior review is accepted, then an original copy of all documents should be provided for the NMHS-MH HREC office file via RGS.

302.4 The Coordinating Investigator (CI), through the Principal Investigator (PI), is required to submit via RGS, as part of the governance review, a copy of the following as evidence of ethics approval:

- ;
- The Lead HREC approval letter/form;
- Project protocol;
- Participant Information sheet and consent forms (including those for additional sub-studies) customised to be applicable to NMHS-MH;
- Questionnaires, diaries, ID cards and any other documentation;
- Conflict of interest form for the Principal Investigator and each Associate Investigator;
- Any other documents pertaining to the application

302.5 The Research Ethics and Governance Office (REGO) will screen the submitted application to ensure that it has been correctly submitted and includes the appropriate site-specific documentation. If the application documentation is not submitted correctly then the application will not be eligible for review in that submission cycle. Once the necessary corrections have been made, the review process can commence.

302.6 It should be noted that the REGO will continue to review all research proposals occurring within the NMHS-MH regardless of which HREC provides approval. Research sponsored by a commercial company (e.g. Pharmaceutical company) will be charged a submission

fee. The appropriate submission fee needs to be paid before the project can receive institutional approval to commence at sites under the NMHS-MH jurisdiction. For further information regarding fees please refer to SOP 202.5– Fees.

302.7 All correspondence from the NMHS-MH will be sent to the Principal Investigator (PI) who will be responsible for forwarding it to the CI.

SOP303: Submission of Low and Negligible Risk Research Applications

Function: To describe the procedure for the submission of low and negligible risk research application.

Applicable to: All researchers submitting low and negligible risk research applications to NMHS-MH HREC.

Version: 1.6 dated June 2020

Due for Review: June 2022

303.1 Low risk research is defined in Section 2.1.6 of the National Statement as "research in which the only foreseeable risk is one of discomfort". If the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

Negligible risk research is defined in Section 201.7 of the National Statement as "research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience." If the risk, even if unlikely, is more serious than inconvenience, the research is not negligible risk.

Further information about low and negligible risk research can be found in Sections 2.1 and 5.1 of the National Statement.

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf

303.2 Low and negligible risk is not available for proposals involving:

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

unless research on collections of non-identifiable data satisfies the conditions for exemption from full review . For more details, please see the National Statement, paragraphs 5.1.22 and 5.1.23

303.3 Projects that meet the NHMRC criteria for low risk and negligible risk, as defined in SOP 303.1, are eligible for exemption from full review by the whole HREC.

303.4 Eligible projects can be submitted at any time via RGS and are reviewed out of session by a reviewing panel consisting of at least two of the following: a member of the Scientific Advisory Panel (SAP; to assess risk and the scientific merit of the project), the HREC Chair, and Executive Officer (to assess the risk and the ethical aspects of the project).

303.5 The reviewing panel has the discretion to refer the project to full HREC for review if they consider that the research poses more than low risk or negligible risk.

303.6 Any research project in which consent is not being obtained and/or where a waiver of consent or an opt-out approach is requested, even if it otherwise meets the criteria of low risk, is not eligible for review out of session as only a full HREC can provide that approval.

303.7 If the research involves access to participant records or samples without the consent of the participant, a waiver of consent is required. A letter addressing the points outlined in Section 2.3.10 of the National Statement should be included with the application.

If the research involves access to participant records or data from a Commonwealth agency or private organisation (e.g. GP or private hospital) without the consent of the participant, Section 95, Section 95A or Section 95AA of the Privacy Act 1988 (the Act) is applicable. A document addressing the privacy issues outlined in the applicable guideline should be included with the application.

Guidelines regarding these sections of the Act can be found on the NHMRC website at:

- https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988 https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988 and
- https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95aa-privacy-act-1988-cth

303.8 All low risk and negligible risk research projects reviewed and approved out of session, are presented to the full HREC for endorsement, at the following meeting.

303.9 It should be noted that the RGO also considers and reviews all low risk and negligible risk research applications. The review is conducted via RGS.

SOP304: Application for a Waiver of Consent

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

Applicable to: All researchers whose research does not obtain consent for the use of information/data or samples

Version: 1.6 dated June 2020

Due for Review: June 2022

304.1 Only the NMHS-MH HREC may grant approval for a waiver of consent for research undertaken within the NMHS-MH.

304.2 Researchers wishing to apply for a waiver of consent must first ensure that their research meets the criteria set out in section 2.3.10 of the National Statement. The researcher should address all points (a-i) under this Section in their application.

304.3 Researchers should also be aware that the National Statement recommends (under Section 4.4.14) that, where consent was not obtained due to the participant's inability to provide it at the time of inclusion in the research, as soon as reasonably practicable the participant should be informed and given the option to formally consent or withdraw from the research without any reduction in quality of care.

304.4 The HREC will decide on granting a waiver of consent at its regular meeting.

304.5 Researchers applying for waiver of consent that is granted by the HREC will receive notification of this in the REGO letter that accompanies the Institutional approval for the research.

304.6 Researchers who are not successful in applying for a waiver of consent will be notified in writing via RGS of the HREC decision and be provided with the reasons. The researcher can request that they attend the next HREC meeting to discuss the matter.

SOP305: Ethics Approval Period

Function: To describe the length of the ethics approval period for research projects conducted within the NMHS-MH

Applicable to: All researchers submitting research applications to the NMHS-MH HREC that require full HREC review

Version: 1.6 dated June 2020

Due for Review: June 2022

305.1 In accordance with the WA Health Research Governance Policy and Procedure 2012, the ethics approval applies for a maximum of three (3) years, with option for five (5), if justified. The HREC has the capacity to set a shorter approval period, contingent on the complexity and risk of the project.

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

305.3 The initial approval is for a period of one year and thereafter for future periods of one year at a time, subject to the receipt of satisfactory progress/annual reports via RGS.

305.4 If no satisfactory progress/annual reports are received by the due date, the NMHS-MH HREC has the right to suspend or terminate the ethics approval.

305.5 If the NMHS-MH HREC has suspended or terminated the ethics approval, the project must cease immediately.

305.6 At the end of the ethics approval period the data collection for the project must cease.

305.7 To continue a project beyond the initial three (3) years ethics approval period, the CPI is entitled to request an extension of the ethics approval. Extension of the ethics approval period is limited to one period of two (2) years.

305.8 For a research project to continue beyond the five years ethics approval period, the project must be resubmitted to the NMHS-MH HREC for review and approval.

305.9 Projects that have reached the maximum ethics approval **and** completed the data collection **and** ceased all contact with participants, but for which data analysis is still ongoing for the purpose of publication writing, do not require resubmission to the HREC as long as only de-identified data are being used for data analysis, and that there are no arising ethical issues.

The continuation or renewal of ethical approval can be requested by the CPI via an amendment in RGS, under limited circumstances and at the discretion of the NMHS-MH HREC. Conditions are that the project remains aligned with the latest statutory regulation in Commonwealth and State and Territory laws, National Statement in Ethical Conduct in Human Research, and institutional and governance policies. Examples of such approvals may include (but are not limited to) requests for data retention periods for the purpose of publication. Annual reports are still required to be submitted until the closure of the project.

SECTION 4: HUMAN RESEARCH ETHICS COMMITTEE MEETINGS

SOP401: Submission and Meeting Schedule

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

Applicable to: All researchers submitting research applications or substantive amendments to the NMHS-MH HREC

Version: 1.6 dated June 2020

Due for Review: June 2022

401.1 Currently, the NMHS-MH HREC meets monthly, except for January when there is no meeting. The next year's submission and meeting schedule is approved by the NMHS-MH HREC at the November meeting of the current year.

401.2 All members of the HREC and SAP will receive a copy of the submission and meeting schedule.

401.3 The current cut-off submission day is approximatively one week before the HREC meeting. However the dates may change annually.

401.4 The schedule of submission cut-off and meeting dates can be found on the NMHS-MH website at: http://www.nmahsmh.health.wa.gov.au/ethics/index.cfm or via RGS Meeting Calendar https://rgs.health.wa.gov.au/Pages/Meeting-Calendar.aspx

SOP402: Meetings: Agenda, Minutes and Distribution of Papers

Function: To describe the process by which the NMHS-MH HREC Agenda is formulated and circulated to the committee members

Applicable to: All applications submitted for review by the NMHS-MH HREC

Version: 1.6 dated June 2020

Due for Review: June 2022

402.1 Currently meetings of the NMHS-MH HREC are held in the Seminar Room 1, Gascoyne House, Graylands Campus and commence at 5.00 pm on the first Wednesday of each month. There is no meeting in January.

402.2 The Executive Officer (EO) will review and validate via RGS all correctly completed applications received by the relevant submission date. The EO will then compile the agenda and invite the HREC members via RGS to review the documentation seven (7) days prior to the meeting date.

402.3 Meetings require a quorum to commence. In the absence of a quorum, a meeting may still be held (an inquorate meeting) but any decisions made will be subject to ratification at the next full meeting of the committee.

402.4 Core members (according to the *National Statement S5.1.29*) are required to be present at all meetings.

402.5 Members unable to attend a meeting are to notify the EO as soon as possible to ensure their apologies can be tendered at the meeting.

402.6 Members unable to attend have to submit written comments in lieu of attendance which are provided to other members prior to or at the meeting.

402.7 Committee members will identify any conflict of interest they have with any research being reviewed at the meeting, before or during the meeting. They must verbally declare that interest to the committee at the meeting and this is to be recorded in the minutes of the meeting. The minutes will document the conflict of interest and what action was taken.

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

- where minor scientific or ethical issues are identified during the HREC review, the researcher will be notified in writing via RGS and asked to make the necessary changes and submit the revised documents to the REGO. These will be reviewed and approved by the Chair or the Delegate of the Chair (DoC), as appropriate.
- where substantial scientific or ethical issues are identified, the researcher will be notified in writing by the Chair or DoC and requested to resubmit their application with the required changes having been made and outlined in a covering letter to the next scheduled HREC meeting.

402.9 The DoC can be empowered by the HREC to review and approve changes requested by the committee. If the DoC identifies further issues with the submitted changes, they can either request further amendments or refer the application back to the HREC for

consideration.

402.10 At the discretion of the HREC Chair, researchers may attend a meeting to resolve any issue(s) that cannot be addressed effectively in correspondence. The researcher will be present to discuss the application but will be required to leave prior to any decisions being made. Please see SOP405: Researcher Attendance at HREC Meetings

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

402.12 If no scientific or ethical issues are identified during the HREC review, the committee will grant ethics approval and recommend the study for institutional approval.

402.13 The Executive Officer (EO) is responsible for creating the meeting agenda in the RGS at least seven days prior to the meeting date.

The order of agenda papers is as follows:

- Agenda
- Minutes of previous meeting
- Resubmissions
- New applications
- Amendments
- Other Business
- Correspondence
- Monitoring Reports

402.14 Any member not receiving an invitation via RGS to review the meeting documentation within this time frame will contact the EO.

402.15 If a member is unable to attend a meeting, they are required to submit written comments for consideration by the HREC during the meeting. These comments can be submitted via RGS or can be emailed to both the HREC Chair and/or EO prior to the meeting. It is the EO's responsibility to circulate these comments to all committee members attending the meeting.

402.16 It is the responsibility of the Executive Officer to prepare the draft minutes of the committee meeting. These minutes will be reviewed by the Chair to ensure they accurately reflect both the discussion at the meeting and the decisions made by the committee.

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

- research application registration number;
- title of project;
- date of approval or conditional approval;
- terms and conditions, if any, of approval of the project;
- any clarifications or amendments requested by the Committee

402.18 The Minutes of the meeting will record if a member was not present and whether the absent member provided written comments.

402.19 The minutes will be circulated as part of the paperwork for the next committee meeting for ratification.

402.20 The EO is responsible for making changes to the minutes requested by the Committee members as part of the ratification process.

SOP403: Conflicts of Interest of HREC Members

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

Applicable to: The NMHS-MH HREC and its subcommittees

Version: 1.6 dated June 2020

Due for Review: June 2022

403.1 All committee members are required to sign a conflict of interest declaration upon the commencement of their term.

403.2 If a HREC member identifies a conflict of interest they have before or during a meeting, they must verbally declare that interest to the committee at the meeting and this is to be recorded in the minutes of the meeting. Conflicts of interest will be managed in accordance with the WA Department of Health "Managing Conflict of Interest Guidelines". A copy of these Guidelines can be seen here :

http://www.health.wa.gov.au/circularsnew/attachments/452.pdf

403.3 At the time when the project is reviewed, the member may remain in the room to answer questions regarding the study protocol but must leave and will not participate in any decision-making associated with the research application with which they have an identified conflict of interest. The member must not be informed of the committee's decision at the time of the meeting but be advised in the normal manner as for any study.

403.4 The committee member's absence and return to the meeting pertaining to a conflict of interest will be noted in the minutes and documented in the Conflict of Interest Register by the Executive Officer. Any further investigation or procedures associated with the management of the conflict of interest will also be documented in the Register.

403.5 Scientific experts invited to meetings to assist in the review of research will also be subject to the same requirements and must declare any known conflict of interest.

SOP404: HREC External Expert Reviewers

Function: To assist the NMHS-MH HREC with the scientific and/or ethical review of research applications

Applicable to: All researchers submitting research applications to the HREC

Version: 1.6 dated June 2020

Due for Review: June 2022

404.1 The HREC may access expert reviewer(s) to assess the scientific content or ethical issues arising from an application submitted for approval. Such reviewers may be specialists in ethics, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups. Such reviewers may be outside the HREC membership.

404.2 Any expert reviewer is bound by the same confidentiality requirements as HREC members.

404.3 Any expert reviewer should declare any conflict of interest they may have. Such conflicts will be managed as per the process outlined in SOP 403 – Conflict of Interest of HREC Members.

404.4 Expert reviewers may provide a written report and/or attend meetings, as requested by the HREC.

404.5 Expert reviewers attending HREC meetings will only be present for discussion of the particular application(s) for which their expertise is requested but will be required to leave prior to any decision being made.

404.6 The attendance of the expert reviewer and the substance of his/her advice at the meeting should be recorded in the Minutes.

404.7 A committee member may nominate an expert. If the HREC does not know of an expert in the research field, the EO will investigate and report to the Chair of the committee. The Chair will decide who to approach for the review. The EO will contact the potential expert and request they review the research project.

404.8 If the potential expert declines, the EO sources another expert as outlined above.

404.9 If the potential reviewer accepts, they will be provided with access to the following:

- A copy of the research application
- A review form
- A Confidentiality Agreement Form to complete

404.10 The EO will nominate a date for the review to be submitted. This review will be included in the resubmission paperwork to the committee.

404.11 The signed Confidentiality Agreement will be kept with the original paperwork of the research project in the REGO.

SOP405: Researcher Attendance at HREC Meetings

Function: To describe the process for researchers attending NMHS-MH HREC meetings

Applicable to: Researchers invited to attend HREC Meetings

Version: 1.6 dated June 2020

Due for Review: June 2022

405.1 This SOP is written in accordance with section 5.2.18 of the National Statement.

405.2 When written or telephone communication between researchers and the HREC or REGO is unable to resolve issues with a research application or; where the HREC or the subcommittees require more information from a researcher to be able to make a decision regarding an application, a researcher may be invited to attend a HREC meeting.

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

405.4 Once the committee has had its questions answered the researcher is requested to leave the meeting. The HREC committee will then deliberate and make its decision and proceed with the rest of the meeting.

405.5 The invited researcher is notified of the outcome of the meeting in the same manner as any researcher whose application is reviewed at that meeting.

405.6 The researcher's attendance at the meeting will be documented in the Minutes.

SOP406: Resubmission to HREC

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

Applicable to: All researchers resubmitting a research application to the HREC or either of its subcommittees

Version: 1.6 dated June 2020

Due for Review: June 2022

406.1 This SOP is written in accordance with sections 5.2.14 to 5.2.16 of the *National Statement*, regarding communication with researchers.

406.2 If a research application has been reviewed by the NMHS-MH HREC or one of its subcommittees and has not been granted approval, a letter from the REGO will be sent to the researcher via RGS notifying them of the HREC decision. This letter will outline the issues that the committee identified during its review and encourage the researcher to resubmit the application with the changes made.

406.3 Once received by the HREC, the resubmitted application will be included on the agenda for the next meeting and distributed to the committee members with the rest of the meeting documentation.

406.4 Resubmitted applications are the first applications reviewed at any HREC meeting.

406.5 The HREC will review the resubmission and ensure the requested changes or issues have been addressed.

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

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

406.8 If the HREC approves the resubmission, then the application can progress through the remainder of the approval process as usual.

406.9 If the HREC has not recommended the resubmitted application receive approval, then the process outlined above is repeated. This will continue until the HREC approves the application, rejects the application or the researcher withdraws the application.

SOP407: Delegate of the HREC Chair

Function: To describe the role of the Delegate of the Chair (DoC) of the NMHS-MH HREC in the review and approval process.

Applicable to: All researchers submitting research, amendments or reports to the NMHS-MH HREC

Version: 1.6 dated June 2020

Due for Review: June 2022

407.1 The NMHS-MH HREC may meet physically up to 11 times a year and have unlimited ad hoc meetings, and due to the work associated with the ongoing administration of research approval, the HREC may delegate certain duties to the position of DoC.

407.2 The DoC must be employed by NMHS-MH and have suitable experience to undertake the duties required.

407.3 The Delegate of the Chair will:

- sign correspondence on behalf of the Chair
- assist in the review of low risk applications
- review responses to HREC queries
- approve studies, with clearance from the HREC

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

407.5 The DoC is able to review and approve the administrative requirements necessary for the ongoing approval of research conducted within NMHS-MH.

407.6 The DoC has the discretionary power to recommend requested changes and amendments to applications that have a full HREC review or review by relevant staff with particular expertise.

407.7 The DoC is not a full member of the HREC and does not have the right to vote on its deliberations.

SECTION 5: AMENDMENTS

SOP501: Types of Amendments

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

Applicable to: Researchers wishing to amend their research

Version: 1.6 dated June 2020

Due for Review: June 2022

501.1 All amendments to research approved by the NMHS-MH must be submitted to the REGO for review and approval via the RGS.

Amendments can only be made to a research project once the research has received its initial approval from the NMHS-MH.

501.2 Amendments are categorised as either Substantial or Administrative.

501.3 An administrative amendment is defined as:

- corrections of typographical or grammatical mistakes;
- changes in specimen handling or specimen analysis procedures;
- changes in co-investigators;
- changes in sponsor personnel;
- changes in drug descriptors (adopting new approved name, for example, not a change in drug identity); and
- inclusion of a new document (e.g. advertisement or poster)

For the process of review for administrative amendments, please refer to SOP502.

501.4 A substantial amendment is defined as any change to the protocol that lies outside the definition of an "Administrative Amendment". For the process of review for Substantial Amendments, please refer to SOP502.

501.5 Only substantial amendments to research studies being undertaken within NMHS-MH will require a site specific review by the RGO.

SOP502: Submitting Ethics and Governance Amendments

Function: To describe the process for the submission and approval of the ethics and governance amendments by the REGO

Applicable to: Researchers submitting ethics and governance amendments to the NMHS-MH REGO

Version: 1.6 dated June 2020

Due for Review: June 2022

502.1 Ethics and Governance amendments are to be submitted via the Monitoring section in RGS. All amendments must comprise the following:

- WA Health Ethics/Governance Amendment Form
- Amended document (clean copy)
- Amended document with track changes

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

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

502.4 The NMHS-MH HREC approves ethics amendments only if the NMHS-MH HREC is the approving HREC ("lead HREC) of that project.

502.5 In cases where the substantive amendment warrants a change to site specific documentation, these documents must be submitted to the NMHS-MH Research Governance Officer (RGO) within the REGO.

502.6 All ethics administrative amendments are reviewed by the Delegate of the Chair (DoC) on behalf of the HREC. The DoC has the power to approve all ethics administrative amendments. All ethics administrative amendments approved by the DoC are tabled at the next HREC meeting.

502.7 The DoC has the capacity to refer any ethics administrative amendment to the Chair or HREC for review.

502.8 Once the amendment is approved, the REGO will then issue an approval letter. An amendment is considered approved from the date the letter is signed. Researchers cannot implement an amendment until the approval letter is received from the NMHS-MH REGO.

SECTION 6: MONITORING

SOP601: Annual and Final Reporting to the NMHS-MH REGO

Function: To describe the requirement for researchers to submit annual reports to the NMHS-MH HREC and the reporting of research activity within NMHS-MH

Applicable to: All researchers who have had research approved by the NMHS-MH

Version: 1.6 dated June 2020

Due for Review: June 2022

601.1 This SOP is written in accordance with section 5.5.5 of the National Statement and the NMHS-MH REGO Terms of Approval.

601.2 "Annual/final report" in this section refers to both ethics annual report and governance annual/final report, unless otherwise specified.

601.3 Once approval for a research study has been granted by the NMHS-MH, the researcher is required to submit annual reports on the progress of the approved research and a final report at the conclusion of the project.

601.4 The annual and final reports must be returned by the due date to the NMHS-MH REGO, as a monitoring submission, via RGS.

601.5 **Annual reports**

Annual reports are due on the anniversary of the date that the research was granted approval. The RGS will send an automatic email to the researcher one (1) month prior to the due date, as a reminder.

The annual report should provide information on the progress to date, maintenance and security of records, compliance with the approved proposal, and compliance with any conditions of approval.

Also, the annual report should include, but is not limited to:

- Publications;
- Adverse events (SAE's, SUSAR, SAR, SADR) and any changes arising from these events;
- Staffing changes;
- Findings;
- Slower or better than expected recruitment or results; and
- Whether the project is progressing as expected.

Failing to submit annual reports may lead to suspension of approval for the research.
For clarity of process, annual reports should be submitted separately to any amendments or other requests.

Annual reports will be reviewed by the RGO/DoC. Additional information can be requested if required. The DoC has the capacity to refer any ethics annual report to the Chair or HREC for review. Once the report review is complete a letter is sent to the researcher via RGS acknowledging acceptance of the report.

601.6 **Final reports**

A final report is only to be submitted to the REGO once all involvement with the research has been or is being finalised. A report should not be listed as final in the case of recruitment completion or at the close of any other than the final stage of the project.

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

The final report should include but is not limited to:

- Publications arising as a result of the research;
- Adverse events (SAE's, SUSAR, SAR, SADR) and any changes arising from these events;
- Staffing changes;
- Findings;
- Slower or better than expected recruitment or results;
- Whether the project has progressed as expected; and
- Whether the aims of the research have been met.

When a final report has been received by the REGO, it will be reviewed by the RGO/HREC Chair or DoC. The DoC has the capacity to refer any ethics final report to the Chair or HREC for review. Once the report review is complete, a letter is sent to the researcher via RGS stating that the research project is closed and no further work can be undertaken.

601.7 The Annual/Final Reports are listed in the HREC meeting agenda and minutes.

SOP602: Discontinuation of a Research Project

Function: To describe the procedures governing the discontinuation of a research project granted approval by the NMHS-MH.

Applicable to: All research that has NMHS-MH approval where termination occurs.

Version: 1.6 dated June 2020

Due for Review: June 2022

602.1 This SOP is written in accordance with section 5.5.7 of the National Statement.

602.2 The Principal Investigator (PI) will inform the REGO of a research project which is:

a) abandoned – has never commenced;

b) prematurely terminated – commenced at the site but terminated on ethical, safety, financial or other grounds;

c) suspended – commenced at the site but temporarily stopped for any reason. The suspension applies to certain aspects of the project such as recruitment or the entire project; or

d) completed.

A monitoring submission form will be forwarded to the REGO via RGS.

602.3 Where the research project is abandoned, prematurely terminated or suspended, the PI will promptly inform the reviewing HREC and will notify the research participants in writing.

602.4 The PI will demonstrate that the issues relating to suspension have been adequately addressed, and that the suspending authority has granted the permission to recommence before restarting the suspended procedure.

602.5 When notifying the HREC of the suspension or termination of research by researchers or a sponsor, it is required that the PI provides the HREC with the reasons for the decision (as outlined in the Terms of Approval). Such notification should be sent to the REGO as a monitoring submission, via RGS.

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

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

602.7 If a suspended project is to be recommenced, the researcher is required to notify the REGO via monitoring submission in RGS and receive written notification from the HREC and RGO that this is acceptable, prior to restarting research within the NMHS-MH.

602.8 The initial notification of research termination/suspension and the request to recommence such research will be forwarded to the HREC for consideration.

602.9 At the completion of a research project, the PI is responsible for notifying the REGO of the actual start date and end date of the trial, total number of patients recruited and the amount of trial payments received.

SOP603: Withdrawal or Termination of Approval by the NMHS-MH

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

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

Version: 1.6 dated June 2020

Due for Review: June 2022

603.1 This SOP is written in accordance with sections 5.5.10 and 5.5.11 of the National Statement.

603.2 All research granted approval by the NMHS-MH must continue to meet the standards described in the National Statement as well as the terms of approval set down by the NMHS-MH REGO.

603.3 If research does not meet these requirements as stated above, then the REGO may recommend withdrawal or suspension of the approval of a research project to the NMHS-MH Executive Director.

603.4 NMHS-MH reserves the right to withdraw or suspend institutional approval of any previously approved research project without recommendation from the REGO.

603.5 NMHS-MH may withdraw approval for research in accordance with Section 5.5.9 of the National Statement. The researcher will be notified in writing by NMHS-MH that approval has been withdrawn including the reasons for this decision.

603.6 If approval is withdrawn from a research project, the PI must immediately suspend the research, should make arrangements to meet the needs of the participants in the research, and inform them in writing about the suspension of the research.

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

603.8 Where research is suspended, researchers will be given the opportunity to assure NMHS-MH that the conditions set out in 5.5.10(c) of the National Statement have been met when they wish to recommence the research. These will be reviewed by the RGO and HREC Chair and a recommendation made to the NMHS-MH Executive Director as to whether the research should recommence.

603.9 If the case for recommencement of the research is accepted by the NMHS-MH Executive Director, the researcher will be notified in writing via RGS that the research can resume.

603.10 If the case for recommencement of the research is not accepted by the NMHS-MH Executive Director, the withdrawal of approval will stand and the research will remain suspended or closed.

SOP604: Adverse Event Reporting

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

Applicable to: All researchers conducting research approved by NMHS-MH

Version: 1.6 dated June 2020

Due for Review: June 2022

604.1 The REGO does not require sponsors or researchers to submit individual reports of Serious Adverse Events (SAEs) that do not occur within a NMHS-MH catchment area. The REGO has adopted the reporting requirements outlined in the National Health and Medical Research Council (NHMRC) policy and Australian Health Ethics Committee (AHEC) Position Statement November 2016:

https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

604.2 Reporting Requirements are summarised in the Table 604.1 below and can also be reported (if a NMHS-MH patient or consumer) as per the Department of Health *Clinical Incident Management Policy*

https://ww2.health.wa.gov.au/About-us/Policy-frameworks/Clinical-Governance-Safety-and-Quality/Mandatory-requirements/Clinical-Incident-Management-Policy

604.3 Prior to submission to the HREC, researchers are required to review adverse event reports, Suspected Unexpected Serious Adverse Reaction (SUSAR) reports and other safety reports, and indicate whether any action will be taken as a result of the event. Such indication should be included with the report submitted.

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

604.5 Protocol deviations should be reported in a prompt manner and include what action, if any, is taken to correct the deviation.

604.6 Protocol violations should be reported in a prompt manner and include what action, if any, is taken to resolve the violations.

604.7 All types of adverse events required to be submitted to the REGO should be sent to NMHS-MH REGO as a monitoring submission via RGS.

These notifications will be reviewed by the RGO and HREC Chair or DoC.

604.8 The Chair/DoC has the discretion to send any of the above reports to the HREC for review. The matter will be taken to the next meeting or be dealt with out of session if the matter is urgent. The Chair will then recommend a course of action to the REGO which will be conveyed to the Principal Investigator.

604.9 Where no action is required, the REGO will acknowledge any of the above reports via RGS.

Table 604.1

Adverse Event Report Requirements

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

SOP605: Record Keeping

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

Applicable to: The Research Ethics and Governance Office (REGO)

Version: 1.6 dated June 2020

Due for Review: June 2022

605.1 **Research Records**

All records of research proposals received and reviewed are maintained in accordance with the National Statement 5.2.25 - 5.2.29 and the WA Department of Health Retention and Disposal Schedule for Administrative and Functional Records 2007.

605.2 Principal Investigators (PIs) are responsible for ensuring the security of all project data, including confidential material, hard copies and electronic data.

605.3 Human research material must be retained in accordance with the PI's employing institution retention and disposal schedule.

605.4 NMHS-MH REGO will keep a register of all research applications received before September 2017 on a Research Governance Database. All records pertaining to research applications received after September 2017 are located within the RGS.

605.5 **Confidentiality**

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

605.6 Only those staff members listed as being part of the research can request access to project specific correspondence. Researchers removing or adding additional staff members to the research team are required to submit notification of this to the HREC via RGS.

605.7 **Archiving**

The REGO retains and archives records in accordance with the Department of Health current Record Keeping Plan Retention and Disposal Schedule for Administrative and Functional Records.

All active project files approved before September 2017 are kept in the Executive Officer's office until a final report is received. Once a final report is received, the database is updated to indicate the project is closed and the files will be archived.

SOP606: Research Governance Monitoring

Function: To describe the process for the governance monitoring of the conduct of approved research

Applicable to: The Research Governance Officer and Executive Officer

Version: 1.6 dated June 2020

Due for Review: June 2022

606.1 The National Statement refers to monitoring as the process of verifying that the conduct of the research conforms to the approved proposal. The monitoring role of the NMHS-MH is part of its research governance.

606.2 Institutional responsibilities for monitoring the conduct of approved research are outlined in the NHMRC National Statement and the "Framework for Monitoring: Guidance for national Approach to Single Ethical Review 2012"

606.3 Research governance measures established by the NMHS-MH incorporate components including:

- registration of a research project on an approved database;
- conduct of the project in accordance with the approved protocol, including project design, recruitment, consent, safety monitoring and reporting;
- special conditions of approval for site authorisation;
- changes to the protocol, including amendments with resource implications;
- compliance with policy, conformance with contracts and agreements;
- financial management;
- quality control, including record keeping and data integrity and management;
- management of complaints/misconduct or conflict of interest;
- reporting, including progress, safety and annual reporting;
- project closure, including administrative processes, safety updates, final reporting;
- communication of individual research result;
- publication of outcomes

606.4 The monitor of research related responsibilities of the REGO include:

- monitoring the conduct of research within NMHS-MH through review of annual and final progress reports submitted by the CI;
- monitoring special conditions imposed in the conduct of research;
- conducting or coordinating audits of research projects when required;
- reviewing and managing amendment documentation related to authorised research projects that have implications for the site (e.g. resourcing);
- processing complaints relating to the conduct of research
- receipt and investigation of allegations of research misconduct;
- review of required reports and receipt and investigation of conflict of interest allegations;
- completion of requirements for project closure;
- review of annual and final reports for the publication of research outcomes

Version 2.0 date 07 June 2020
Revision by Camelia Zota – Executive Officer NMHS MH REGO
Approved by Dr Viki Pascu – Director of Clinical Services NMHS MH

This document can be made available in alternative formats on request for a person with a disability.