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

Research submission guidelines for the South Metropolitan Health Service

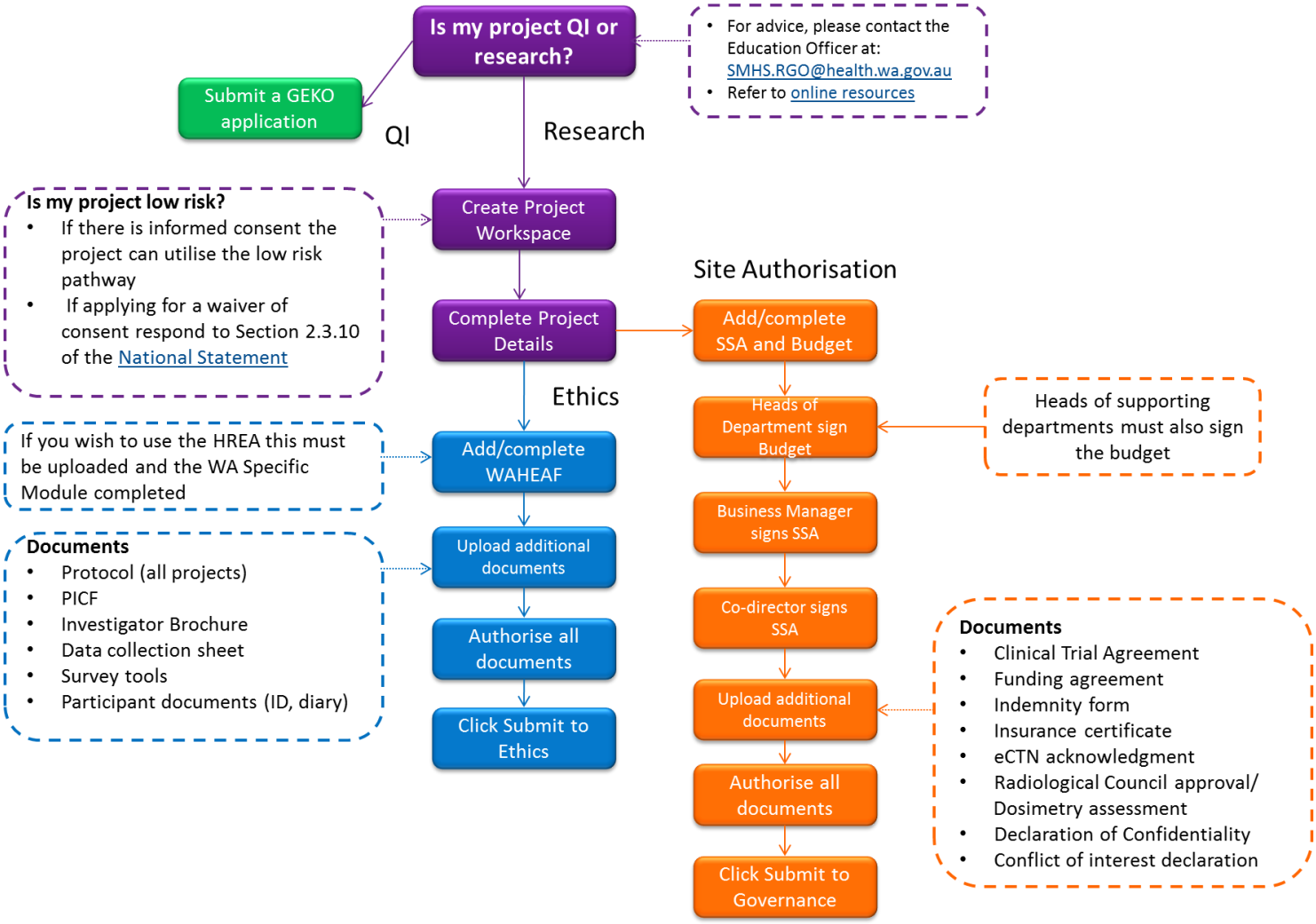
Contents

Introduction

The WA Health Research Governance Framework (policy and standard operating procedures) outlines how single and multi-centre research at WA Health sites is to be conducted. All human research conducted in WA Health must undergo ethical and scientific review by a human research ethics committee (HREC) registered with the National Health and Medical Research Council (NHMRC) and operating in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007 (National Statement). In addition, all research projects must undergo site authorisation at each WA Health site at which it is to be conducted. Both ethics and site approval are required before a project can commence.

These guidelines have been prepared to assist individuals through the process of submitting a research project to the SMHS for ethics review and site authorisation. These guidelines should be read in conjunction with the WA Health Research Governance Framework. Please note that all research must be submitted using the online Research Governance Service (RGS).

Submission Process



1. Is my project QI or research?

Prior to making a submission through RGS, it is important to distinguish quality improvement (QI) activities from research as this will determine the avenue of review and approval required. If a project is classified as research it must be reviewed by a HREC. If a project is QI it is reviewed by the hospital's Safety and Quality Office and managed through the GEKO system.

If you are unsure whether your project is QI or research, please feel free to contact the Education Officer at SMHS.RGO@health.wa.gov.au for clarification.

To assist in determining whether a project is research or QI the following table may be of use:

Points to consider	Research	QI
Purpose	To test a hypothesis OR establish clinical practice standards where none are accepted	To assess or promptly improve a process, program, or system; OR improve performance as judged by accepted/established standards
Starting point	To answer a question or test a hypothesis	To improve performance
Benefits	Designed to contribute to generalisable knowledge and may or may not benefit subjects	Designed to promptly benefit a process, program, or system and may or may not benefit patients
Risks	May place subjects at risk and stated as such	By design, does not increase patient's risk, with exception of possible privacy/confidentiality concerns
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer a research question	Promptly improve a program/process/system
Testing/ Analysis	Statistically prove or disprove a hypothesis	Compare a program/process/system to an established set of standards.

2. Which HREC should I apply to?

WA Health has a system of single ethical review meaning that research reviewed by an accredited HREC at any WA Health site will be recognised by other sites without an additional review.

In addition, some projects require approval from a specialised HREC as outlined below:

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

When submitting a project to the SMHS it is important to be familiar with its Terms of Reference and its meeting dates.

2.1. National Mutual Acceptance

The National Mutual Acceptance of ethical and scientific review for multi-centre human research projects conducted in public health organisations (NMA) is the scheme that enables the single scientific and ethical review of multi-centre human research projects conducted in public health organisations (PHO) across multiple Australian jurisdictions.

Western Australian (WA) public health organisations (WA Health) signed the NMA Memorandum of Understanding on 18 July 2017 and will commence participation on 31 August 2017. Within WA the three accredited HREC's which can act as leads for national projects include SMHS, Sir Charles Gairdner Hospital and Osborne Park Health Care Group and Child and Adolescent Health Service (CAHS).

The NMA aims to:

- enable PHOs of participating jurisdictions to accept a single ethical and scientific review of human research projects (these PHOs are known as Accepting Organisations)
- inform the ongoing development of the national system of single ethical and scientific review of multi-centre research.

If you wish to conduct a project under NMA whether as a lead site or as an accepting site there are differences in the submission and review process for ethics and governance. For more information on NMA and how to apply please refer to RGS and the NMA Guidelines.

3. Low risk research

For low or negligible risk research SMHS is developing an alternate review pathway for these projects. The requirements for submission for low risk research are identical to that of standard risk projects.

Low risk research is considered to be anything which causes no more than discomfort to a participant with discomfort being defined as the experience of having your blood pressure taken.

3.1. Waiver of consent

If a low risk project relies on data collection and does not involve patients directly it may be possible to apply for a waiver of consent. All applications for a waiver of consent must be reviewed by the full HREC meaning that the project will not be reviewed through the low risk review process. When applying for a waiver of consent all sections under Section 2.3.10 of the National Statement must be addressed in the ethics application.

3.2. Impaired capacity

If individuals have impaired capacity they may not be able to consent to participation in research. This is common in research involving emergency, stroke, mental illness and intensive care. Due to the WA Guardianship and Administration Act 1990 research in these populations is limited. This is because next-of kin or person responsible is not able to provide consent to research.

If the project is low risk and involves standard of care or data collection you may be able to apply for a waiver of consent. If the project is standard risk and involves any novel intervention it is unlikely that this research can be conducted in WA unless the patient has the ability to consent prior to the intervention taking place (consent cannot be obtained retrospectively ie. after the intervention has taken place).

4. The application process

4.1. Project Workspace

Once you have registered as a user on RGS the first step is for the Chief Principle Investigator (CPI) to create a project workspace. At this stage of the process you are asked to:

- Nominate the sites at which the study will be conducted
- Include basic information about the project including project type and title
- Select an administering Research Governance Office

After the project workspace is validated you will need to update the project sites under the 'Sites' tab. In addition, you will need to add and invite project members in the 'Members' tab and assign them their appropriate roles.

4.2. Project Details

Following the approval of the project workspace the Project Details section must be completed before the application can progress. In this section information must be provided regarding:

- Project Header (completed/authorise by CPI, CPI Delegate, PI or PI Delegate)
- Ethics Information (completed/ authorised by CPI or CPI Delegate)
- Governance Information (completed/authorised by PI or PI Delegate)
    - Funders (for in-kind support please include the hospital site providing the support and for non-sponsored projects please include the SMHS Executive as they will be the funder of all ethics review and site authorisation fees)
- Investigator Contact Information (completed/authorise by CPI, CPI Delegate, PI or PI Delegate)

4.3. Ethics Application

Step One: Add and Complete the required Forms (Forms and Documents tab)

Step Two: Upload the required documents

Step Three: Authorise all forms and documents

Step Four: Click Submit to Ethics

4.3.1. Forms

The WA Health Ethics Application Form or the WA Specific Module may be completed by any project member. Once complete it must be Authorised by the CPI.

- The **WA Health Ethics Application Form** is embedded in the system and must be completed online. This form can be added in the Forms and Documents section. This is the recommended form for projects in WA.
- If the **Human Research Ethics Application** (HREA) has been completed for a national project this can be uploaded in the Documents section. This is required for all NMA projects. When using this form the **WA Specific Module** must be added and completed in Forms.

4.3.2. Documents

All supporting Documents must be uploaded and Authorised prior to submission. Documents may be Authorised by the CPI or the CPI Delegate. Many document templates can be found online on

the RGS website. Please ensure that all documents include a version and date in the footer and that this information is the same as what is provided when uploading the documents to RGS.

Supporting documents depend on the nature of the project and may include:

- Protocol (compulsory for all projects)
- Participant Information Sheet and Consent Form
- Investigator Brochure
- Data Collection Sheet
- Patient ID Card/Diary
- Survey tools
- Recruitment documents
- Radiation Safety Officer/Radiological Council report/Dosimetry assessment
- NSW Privacy Form/Victorian Module (only for NMA projects with sites in those jurisdictions)

4.3.3. Ionising radiation

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

4.3.4. Validation and review

Once the forms and documents have been received by the HREC office they will be validated. Validation is recognition that the documents have been received. This is not a review. Following validation the project will be assigned to the next available HREC meeting (each meeting is capped at 10 submissions with project accepted on a first come first served basis).

The project will then be reviewed by the HREC and feedback provided in accordance with the Terms of Reference.

4.3.5. Investigator attendance at the HREC meeting

Investigators are invited to attend the HREC meeting at which the project is being reviewed in order to clarify any concerns or issues that were unclear in the submission documents. While not compulsory, investigators are encouraged to attend.

In general, investigators will give a brief description of their proposal at the meeting. The HREC members will then ask the investigator for clarification around the issues they found unclear. The HREC will not indicate to the investigator at the meeting whether the project has been granted approval, this will be conveyed in a letter following the meeting.

4.4. Site Authorisation

In addition to receiving ethical approval from a lead HREC, all research in SMHS is required to obtain site authorisation. Applications for site authorisation may commence at the same time as the ethics application, there is no need to wait until ethics approval is obtained. Site authorisation will be granted following ethics approval and a review by a Research Governance Officer.

Step One: Add and complete the required forms (Forms and Documents tab)

Step Two: Upload required documents

Step Three: Authorise all forms and documents

Step Four: Click Submit to Governance

4.4.1. Forms

The Site Specific Assessment Form and Budget OR the Access Request Form must be completed. Once complete it must be Authorised by the PI.

- The **Site Specific Assessment Form** is embedded in the system and must be completed online. This form can be added in the Forms and Documents section. This can be completed by any project member and must be signed by the Business Manager and Co-Director.
- The **Budget** must be complete by the PI or PI Delegate and record all project support including in-kind funding. This must be signed by the relevant Head of Department and heads of supporting departments.

4.4.2. Documents

All supporting Documents must be uploaded and Authorised prior to submission, templates for many of these documents are available on the RGS website. Supporting documents depend on the nature of the project and may include:

- Clinical Trial Agreement (draft and unsigned)
- Funding agreement
- Indemnity form
- Insurance certificate/ policy wording
- eCTN
- Radiological Council approval/Dosimetry assessment
- Declaration of Confidentiality
- Conflict of interest declaration

5. Schedule of administrative charges

A schedule of fees is provided online on the WA Health website.

For commercially sponsored research, these fees are incurred by the sponsor. The payment will be invoiced directly to the external sponsor by the Research Ethics and Governance Unit, irrespective of whether the research project commences.

Non-commercial trials must still record these fees within the Budget Form on RGS. However, these fees are funded by in-kind support from SMHS Executive and will not be invoiced.

This document can be made available in alternative formats on request.

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