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

Research submission guidelines for the South Metropolitan Health Service

Contents

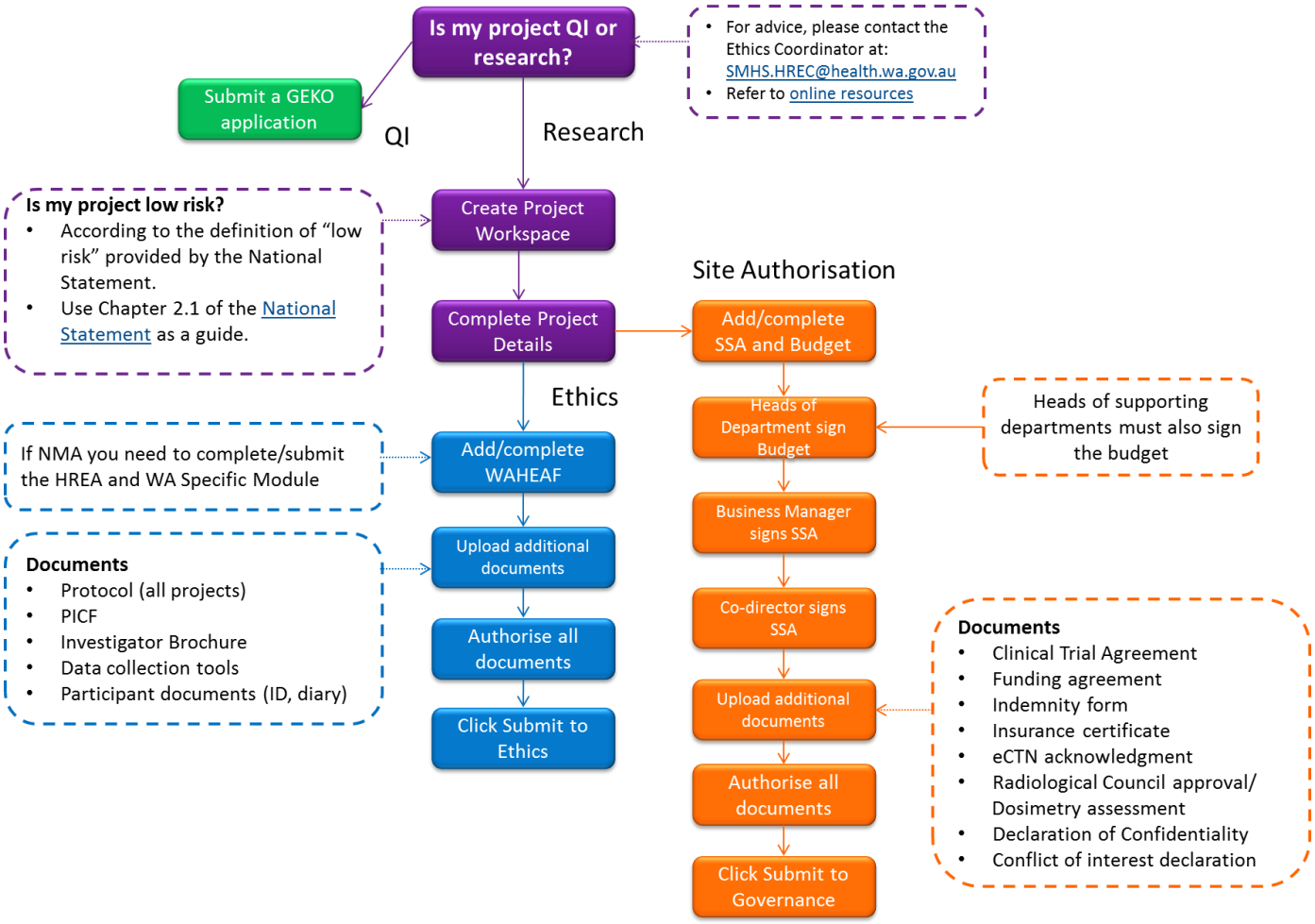
Introduction

The WA Health Research Governance Framework (policy and 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, updated 2018 (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 SMHS for ethics review and site authorisation. These guidelines should be read in conjunction with the WA Health Research Governance Framework and the SMHS Research Governance Policy Please note that all research must be submitted using the online WA Health platform : Research Governance Service (RGS).

The Research Support and Development Unit (RSDU) provides advice and support to researchers within SMHS.

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 Governance, Evidence, Knowledge, Outcomes (GEKO) system.

If you are unsure whether your project is QI or research, please contact the Ethics Coordinator for advice at SMHS.HREC@health.wa.gov.au for clarification.

The table below may assist you to determine whether your project is research or QI. You can also refer to the SMHS QI vs Research Guideline.

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 a registered 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:

- Western Australian Aboriginal Health Ethics Committee (WAAHEC) for health and medical research where Aboriginality is a key determinant or explicitly directed at Aboriginal people
- Coronial Ethics Committee WA for research projects that require access to coronial samples, data or information
- Department of Health WA HREC (DoH) 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 SMHS HREC it is important to be familiar with its Terms of Reference and its meeting dates.

2.1. National Mutual Acceptance

National Mutual Acceptance (NMA) is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. This means that a proposal for a multi-centre human research project conducted across the participating states and territories will be scientifically and ethically reviewed once only by a Public Health Organisation (PHO) HREC that has been certified by the NHMRC. All Australian states and territories are included in the NMA.

Within WA, there are three HRECs that are NHMRC certified and can act as leads for national projects; SMHS, Sir Charles Gairdner Hospital and Osborne Park Health Care Group (SCGHOPHCG) 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. Important Considerations

3.1. Waiver of consent and the opt-out approach

If a research project involves the use of data already collected and does not involve patients directly, it may be possible to qualify for a waiver of consent. Consent waivers are reviewed by HREC on a case-by-case basis and is not a given. 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. A consent waiver cannot be granted for interventional studies.

An opt-out approach to participant recruitment to research may be appropriate when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible. When applying for the opt-out approach all sections under Section 2.3.6 of the National Statement must be addressed in the ethics application.

All applications for a waiver of consent and the opt-out approach must be reviewed by the full HREC meaning that the project cannot be reviewed through the low risk review process. If identifiable information is to be disclosed under a waiver of consent or the opt-out approach a Data Request Form must also be completed and approved by the Data Steward.

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 participants. Part 9E of the *Guardianship and Administration Act 1990* allows the recruitment of people unable to provide consent either with the consent of a Research Decision Maker, or through the Urgent Treatment pathway. For further information on this pathway please refer to RGS. Please contact the RSDU to discuss this pathway further as required. SMHS.HREC@health.wa.gov.au.

3.3. Ionising radiation

Submissions for research involving exposing participants to radiation, even if it is considered standard of care, must include a report from the Radiation Safety Officer. For research that involves participant radiation exposure above standard of care and is greater than 20mSv, 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. The application process

4.1. Project Workspace

Once you have registered as a user on RGS the first step is for the Coordinating Principal 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 approved by the SMHS RGO 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 (Applications tab)

Step Two: Upload the required documents

Step Three: Authorise all forms

Step Four: Click Submit to Ethics

4.3.1. Forms

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

- The **WA Health Ethics Application Form** (WAHEAF) 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 that will only be conducted 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** (WASM) must be added and completed in Forms.

4.3.2. Documents

All supporting documents must be uploaded and submitted via RGS. Multiple 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 (PICF)
- Investigator Brochure (IB)
- Data Collection Sheet
- Patient ID Card/Diary
- Data collection tools (survey/questionnaire, interview questions etc.)
- Recruitment documents (advertisement, flyer, poster, email etc.)
- Radiation Safety Officer/Radiological Council report/Dosimetry assessment
- Victorian Module (only for NMA projects with sites in that jurisdiction)

4.3.3. Validation and ethics review

Once the forms and documents have been received by the RSDU, they will be validated. Validation is recognition that the documents have been received. This is not a review or approval. Following validation, the project will be assigned to the next available HREC meeting (each meeting is capped at 10 submissions with projects accepted on a first come first served basis). The project will then be reviewed by the HREC members and feedback provided in accordance with the Terms of Reference.

4.3.3.1. Low risk research

For low or negligible risk research, SMHS has an established alternate review pathway for these projects. The requirements for submission for low risk research are identical to that of standard risk projects, however these projects will be reviewed out-of-session by a panel of reviewers. This is generally conducted within two weeks of submission. There is no submission closing date for these 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. Please refer to Chapter 2.1 of the National Statement.

4.3.4. 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 (Applications tab)

Step Two: Upload required documents

Step Three: Authorise all forms

Step Four: Click Submit to Governance

4.4.1. Forms

The Site Specific Assessment (SSA) 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 Applications section. This can be completed by any project member and must be signed by the Business Manager and Co-Director.
- The **Budget** must be completed 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.
- The **Access Request Form** is for projects which are only seeking data or patients from the site but where there is no work being conducted on-site. This includes situations where clinicians hand out flyers for a study but are not involved in recruitment.

4.4.2. Documents

All supporting Documents must be uploaded 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:

- Research Agreement (draft and unsigned) (this could include a CTRA, Data Transfer Agreement or Material Transfer Agreement)
- Funding agreement
- Indemnity form
- Insurance certificate/ policy wording
- eCTN – Clinical Trials Notification
- Radiation Safety report / Radiological Council approval
- Student Research and Confidentiality Declaration
- Conflict of interest declaration

5. Schedule of administrative charges

A schedule of fees is provided online on the RSDU webpage.

For commercially sponsored research, these fees are incurred by the sponsor. The payment will be invoiced directly to the external sponsor by the Research Support and Development 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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