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

NMHS-MH RESEARCH ETHICS AND GOVERNANCE OFFICE (REGO)

Working with us

nmhs.health.wa.gov.au

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Contents

REGO - What do we do?

1. We co-ordinate the ethic/scientific and governance review processes for human research projects undertaken within the North Metropolitan Health Service – Mental Health (NMHS-MH).

   Our research governance framework is a two-tiered system of review, approval and monitoring of research, made up of:

   - Ethical and Scientific Review – undertaken by the Human Research Ethics Committee; and
   - Research Governance Review – undertaken by the Research Governance Officer.

2. We monitor the conduct of authorised research projects.
3. We manage complaints, misconduct or conflict of interest related to the conduct of authorised research projects.

What we can do:

Provide expert advice to investigators seeking to undertake research within the NMHS-MH, in accordance with National, State and local policies.

Submitting your initial application

Before you submit your application, you have to decide whether your project is a quality improvement or research project. To make this decision, please consult Table 1 on page 7.

Once prepared, the application must be submitted by 11:30 pm on the submission day of the appropriate month to NMHS MH HREC via Research Governance Service (RGS) website:

Also see the RGS website for more information: https://rgs.health.wa.gov.au/Pages/Home.aspx .

Submitting amendments for your project

Please note that the above mentioned submission deadlines apply to amendments as well as initial applications.

For assistance with your application please contact:

Camelia Zota

REGO Executive Officer

Tel: +61 8 61596502

Email: Camelia.Zota@health.wa.gov.au

NMHS-MH specific requirements

Participant Information and Consent Forms (PICF)

Project PICF's will be reviewed using the NHMRC standardised participant information and consent templates. Copies of these templates can be found on the RGS website https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx .

Jurisdiction-specific (see below) and study-specific information should be added as necessary and sections that are not applicable to the specific research project may be removed as needed.

1. NMHS MH Logo is at the top and on the first page of both the Information Sheet and Consent Form.
2. The NMHS-MH REGO contact details need to be within both the information and consent forms that are provided to participants. The following text needs to appear on the last page of both forms:

   "Approval to conduct this research has been provided by the Human Research Ethics Committees of the North Metropolitan Mental Health Service Research Ethics and Governance Office (NHMS MH REGO) in accordance with their ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the NMHS MH REGO Executive Officer on (08) 6159 6502 or NMAHSMHREGO@health.wa.gov.au. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project."

3. Projects / researchers who propose to access to the NMHS MH medical records of consented participants are required to inform their participants (in writing) at the time of consent. **The following text is the NHMRC preferred language for the project information sheet.**

   "Information about you may be obtained from your health records held at this and other health organisations for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project." **With this associated point in the consent form.** *I understand what data is being collected and agree to the interviewer reviewing my case notes.*

   Alternatively you could seek the participant's permission to access their medical records.

   "I agree that researchers can access my medical records (name the institution?) for the purpose of this study" YES / NO

   Projects / researchers who propose to store their data in a databank or for it to be used for future research are required to inform participants (in writing) at the time of consent and ask them to consent to this use of their information. Suggested language for the consent form:

   I agree that data gathered as part of this study can be used in future research projects that have ethics approval from a registered HREC, as long as my name or any identifying information is not made available to these projects.
   YES / NO

4. Researchers intending on publishing or presenting the results of their study (in any format) should have this item in their consent form.

   I agree that research data gathered for the study may be published as long as my name, or any identifying data, is not used in any publication.

Consenting NMHS-MH patients

1. All project PICF's require NMHS MH HREC & REGO approval prior to implementation.
2. Projects / researchers are required to approach each patient's treating psychiatrist (or NMHS-MH case manager) prior to their assent, in order to verify the individuals capacity to give informed consent for their specific study. Please note that this does not absolve researchers of their own responsibilities for ensuring consent is informed.

   The NMHS MH Research Ethics & Governance Office does not require researchers to obtain "written" confirmation from the nominated NMHS MH staff member as the exact procedures for confirming capacity to give informed consent is at the discretion of the Chief Investigator.

Existing NMHS MH research projects use a combination of face-to-face, telephone or email to contact an individual's psychiatrist. No matter the method, all researchers are advised to keep a record of these communications as research projects files are subject to institutional monitoring.

3. Researchers are required to send a note/email to the consultant psychiatrist/case manager informing about their patient's engagement in their project and recommending that this note/email be placed in the patient's case notes.
The NMHS MH REGO recommends the following wording for this note/email:

"Dear _____,

Your patient (insert patient's name) has consented to participate in (insert Chief Investigator/ student's name) project entitled (insert project name).

The North Metropolitan Health Service Mental Health has recommended that we inform the treating team every time one of their patients agrees to participate in research project. If you would like more information about this project please see the attached Information Sheet.

We suggest that you place a copy of this email into (insert patient's name) patient file in order to inform additional clinical team members. This note/e-mail has been sent to you because (insert patient's name) has stated that you are his/her Case Manager / Psychiatrist. If you are no longer (insert patient's name) case manager / psychiatrist, please contact me on (insert phone number) or e-mail (insert email address) and I will endeavor to contact the correct person."

Accessing previously collected data

NMHS MH databases – Please provide a copy (blank) of the consent form which NMHS MH service users have signed giving permission for their de-identified data to be used for research purposes.

Project Data – Please provide a copy (blank) of the consent form which participants have signed giving permission for their de-identified "research" data to be used for "future" or "additional" research purposes.

Clinical Trials

All clinical trials must be registered in a publicly accessible database before recruitment of the first participant. Recognized registers include, but are not limited to:

- Australian New Zealand Clinical Trial Registry
- Clinical Trials.gov.au
- International Standard Randomised Controlled Trail Number (ISRCTN) Register

Investigators conducting clinical trials must provide information to the REGO, on the SSA Form and on the Ethics Application Form that the trail has been/will be registered on a recognised clinical trial registry (including the name and the reference number, if available).

All clinical trials involving WA Health personnel, participants or resources conducted with an external sponsoring entity, must be the subject of a written agreement. The type of research activity undertaken will determine the type of contractual arrangement required. Templates for such agreements and information on Insurance and Indemnity are available on the Research Governance Service website.
https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx

Clinical Drug Trials

Projects involving clinical drug trials must be submitted to the Drug and Therapeutics Committee, NMHS-MH Pharmacy Department, Graylands Hospital, (please contact the Chief Pharmacist on 6159 6681) 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 with the initial application.

Site Specific Assessment Form (SSA)

Is the tool utilised by the Research Governance Officer in assessing new proposals to ensure that the proposed research can be adequately conducted at and supported by the NMHS-MH.

It is the applicant's responsibility to ensure that all sections within the SSA are completed.

For new projects, the SSA is submitted via RGS, as part of the governance review https://rgs.health.wa.gov.au/Pages/Home.aspx

Declaration of Confidentiality – A Declaration of Confidentiality must be completed via RGS/Declarations tab by all research personnel (including students) who are not employees of WA Health, who will be conducting a research project within NMHS-MH or accessing NMHS-MH participants, their tissue or data.

Conflict of Interest – A Conflict of Interest declaration must be submitted via RGS/Declarations tab by any researcher that has a conflict of interest to declare in relation to the research project they are involved in.

Resource and Budget Information (Budget Form) – Costs which are covered by NMHS MH (e.g. in kind) or will be re-couped from an external sponsoring agency must be confirmed by a NMHS-MH Business Manager.

Researchers need to provide Heads of Supporting Departments or their Delegates with the following information (minimum) which will be forwarded to the relevant Business Manager.

1. Specific Staff Members Name and hours of involvement (average per participant)
2. Total number of patients (if you need to recruit 80 to get 40 then quote 80)
3. Start date and End date for the project
4. NMHS-MH office / equipment being used and hours of use (per participant)

For all DoH employees involved in research projects, 24% should be added to their hourly rate.

All students should have supervisors added to the Budget Form.

The SSA must be signed electronically, via RGS by the Head of any department (or delegate) providing support or services (including access to participants) to a research project.

Within the NMHS-MH, the signatories of this section of the SSA Form, endorsing the department's support for research projects conducted within their jurisdiction are as follows:

1. Co-Director of Adult Impatient Services;
2. Co-Director of Adult Community Services;
3. Co-Director of Mental Health Specialties (State Forensic Services, Youth Service, Older Adult Services, WAEDOCS, CCI, NSU);
4. Director Nursing
5. Director Aboriginal Health;
6. Director Public Health;
7. General Manager Dental Health

Standard Application

All new projects are submitted to the NMHS MH HREC VIA RGS, https://rgs.health.wa.gov.au/Pages/Home.aspx. The WA Health Ethics Form is inbuilt in the RGS, and all the other relevant project documents are submitted as attachments. If the researcher wishes to use the HREA instead of the WA Health Ethics Form, this will have to be submitted as an attachment. The HREA must be accompanied by the WA Health Specific Module which is in-built in the RGS.

Please note:

*Submissions involving clinical drug trials must be submitted to the Director Pharmacy Services, NMHS-MH Pharmacy Department, Graylands Hospital, (please contact the Chief Pharmacist at 6159 6681) for review and approval, prior to submission to the NMHS-MH REGO.

* Projects that have not had prior scientific peer review need to submit a Research Proposal (with literature review, hypothesis to be tested, aims and methods, including data analysis) which will be reviewed by the SAP.

Quality Improvement or Research? (Quality Improvement Checklist)

Table 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 the participants normal health care delivery program or, for the evaluation of teaching activities, that the assessment of the student (e.g. grades received) will not 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 Questions 1-15 is “No”, your project is a quality improvement project. Your project should be submitted for approval via the usual Safety, Quality and Performance (SQP) process. For more information please contact the NMHS-MH Quality Improvement Coordinator at NMHSMHSQandP@health.wa.gov.au

If the answer to Question 15 is “Yes”, the researchers should complete an application for a publication exemption letter from the NMHS-MH HREC.

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.

Please note, projects applying for HREC exemption must provide evidence that their project has been authorised and registered using the NMHS-MH SQP projects.

In order to be considered for ethical review, or prior to requesting an exempt letter from the HREC the Principal Investigator needs to submit a NMHS-MH HREC Application for Ethics Review Exemption Form for QI/Case Studies to the REGO by email at NMAHSMHREGO@health.wa.gov.au or by mail at:

NMHS-MH REGO
Executive Officer
Gascoyne House, Graylands Campus
Locked Bag No. 1
PO CLAREMONT WA 6910

The form is available on the REGO website: http://www.nmahsmh.health.wa.gov.au/ethics/index.cfm

To amend an already approved QI project, the Principal Investigator needs to provide the HREC with a track change 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.

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 MH 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, no formal, systematic and prospective collection of information.

As a result, the NMHS MH Research Ethics and Governance Office (REGO) has established procedures to facilitate approval of negligible risk (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.

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)

If your project is a QI study or a Case Study/Case Report, it should be submitted for approval to the NMHN MH Safety, Quality and Performance Unit.

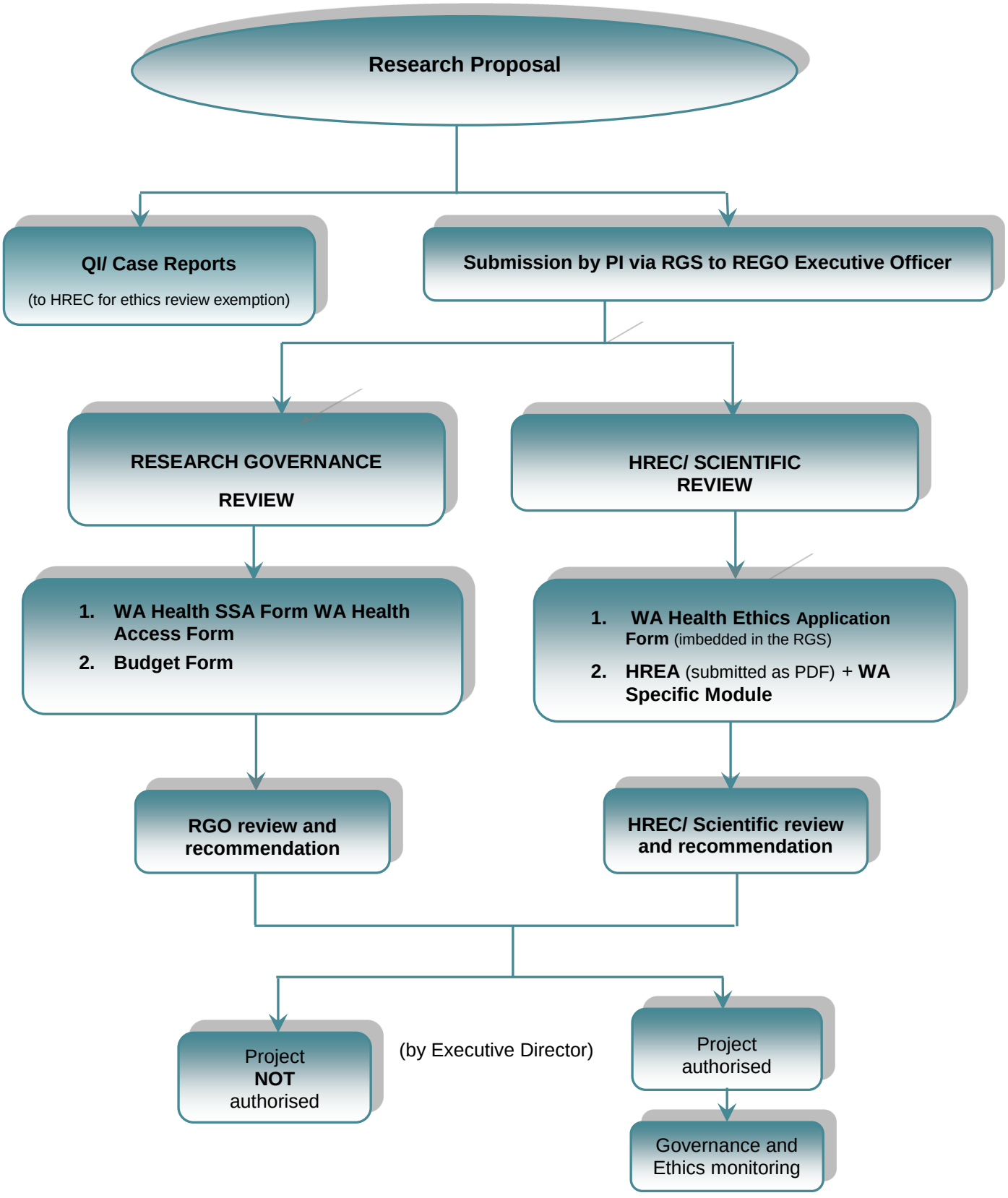
For more information please contact the NMHS-MH Quality Improvement Coordinator at NMHSMHSQandP@health.wa.gov.au

In order to be considered for ethical review, or prior to requesting an exempt letter from the HREC the Principal Investigator needs to submit a NMHS-MH HREC Application for Ethics Review Exemption Form for QI/Case Studies to the REGO by email at NMAHSMHREGO@health.wa.gov.au

The form is available on the REGO website: http://www.nmahsmh.health.wa.gov.au/ethics/index.cfm

NMHS-MH HREC and RG Submission and Approval Pathways

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



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