Government of **Western Australia**
North Metropolitan Health Service
Women and Newborn Health Service

Standard Operating Procedures

The process of ethical approval and monitoring for research within the Women and Newborn Health Service

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CONTENTS

Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CPI	Coordinating Principal Investigator
CTN	Clinical Trial Notification
HREC	Human Research Ethics Committee
KEMH	King Edward Memorial Hospital
National Statement	The National Statement on Ethical Conduct in Human Research (2007) updated 2018
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
RGO	Research Governance Officer
REGO	Research Ethics & Governance Office
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SASC	Scientific Advisory Sub Committee
SER	Single Ethical Review
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SSI	Significant Safety Issue
SUSAR	Suspected Unexpected Serious Adverse Reaction
WAHEAF	WA Health Ethics Application Form
WNHS	Women and Newborn Health Service

1. Purpose

The purpose of these Standard Operating Procedures (SOPs) is to serve as a guide to the process of ethical review for research involving human participants within the Women and Newborn Health Service. These SOPs outline the responsibilities and functions of the various stakeholders involved in the scientific and ethical review of research. This document is not intended to cover the SOPs pertaining to research governance review; the SOPs for the process of research governance review within the Women and Newborn Health Service are available in a separate Standard Operating Procedures.

2. Overview

To be properly governed, research must be conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation, regulations and institutional policy. Research governance also incorporates credentialing of researchers and managing institutional risk.

The WA Health Research Governance Policy and Procedures (OD 0411/12) and WA Health Research Governance and Single Ethical Review Standard Operating Procedures (0446/13) were implemented to ensure that all human research conducted within WA Health meets the highest ethical, scientific, regulatory and professional governance standards. It also aims to ensure that research complies with relevant national and state legislation, guidelines and codes of conduct. The policy articulates the framework through which research is reviewed, approved, conducted and monitored within WA Health.

3. Alternative review mechanisms for non-research projects or specific negligible risk research

All research projects (other than those described in 3.2) that are conducted at a WA Health site, or use WA Health data, samples, or resources, require full ethical and scientific review by a Lead WA Health HREC.

Projects that are considered non-research activity (e.g., quality improvement activities) or negligible risk research (e.g., some service-related research) may be exempt from full ethical and scientific review outlined in this document. See Section 3.2 below.

3.1. Non-research activity

Examples of non-research projects may include quality improvement/quality assurance activities and case reports/series.

3.1.1 Quality improvement/quality assurance activities are typically reviewed via the Governance Evidence Knowledge and Outcomes (GEKO) pathway, provided certain criteria are met. Please visit the GEKO intranet page for more information on eligibility for the GEKO pathway. GEKO applications that are flagged for publication will also require review by the HREC; see section 17 for more information.

3.1.2 Case reports/series do not ordinarily require review or approval by either an HREC or GEKO Committee, yet specific advice must be sought from the HREC Office when patient consent cannot be obtained or there are other outstanding circumstances. HREC oversight may be requested at the discretion of the REGO Director. See section 13 for more information about case reports.

3.2. Negligible risk research

Service-related research (e.g., information provision) that is conducted by WNHS staff and is negligible risk may infrequently be deemed appropriate for review and approval via the GEKO pathway, following an assessment by the HREC that a full ethical review is not necessary.

3.2.1 The expression 'negligible risk research', according to the National Statement, describes research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience.

3.2.2 GEKO applications that are considered negligible risk research by the Performance, Review and Audit Coordinator must be reviewed and recommended for the GEKO pathway by the HREC. The GEKO application must include a completed Project Outline (available on the GEKO intranet page) with "no" selected for all items on the included checklist (page two). Please see section 17 for more information or contact the HREC Office and/or the Performance Review and Audit Coordinator to determine if your research project may be eligible for review by the GEKO pathway.

4. Ethics and governance review in parallel

In line with the WA health Research Governance Policy and Procedures (OD 0411/12), WNHS has a system of review which includes two separate, parallel arms:

- Scientific and ethical review
- Governance site authorisation review

Approval by both a lead HREC (ethics approval) and the Director of Clinical Services (site authorisation) is necessary before research can commence. Applications for ethics and governance review may be submitted simultaneously and doing so will help to prevent delays in the review process. However, a letter of ethics approval from an appropriate HREC must be provided before Governance review and recommendation can be completed and site authorisation granted.

Figure 1 summarises the parallel ethics and governance review process for local, single site projects. The schematic is intended as a guide only. For multicentre or more complex projects, please see sections 3.1 and 16, and contact the Research Ethics and Governance Office.

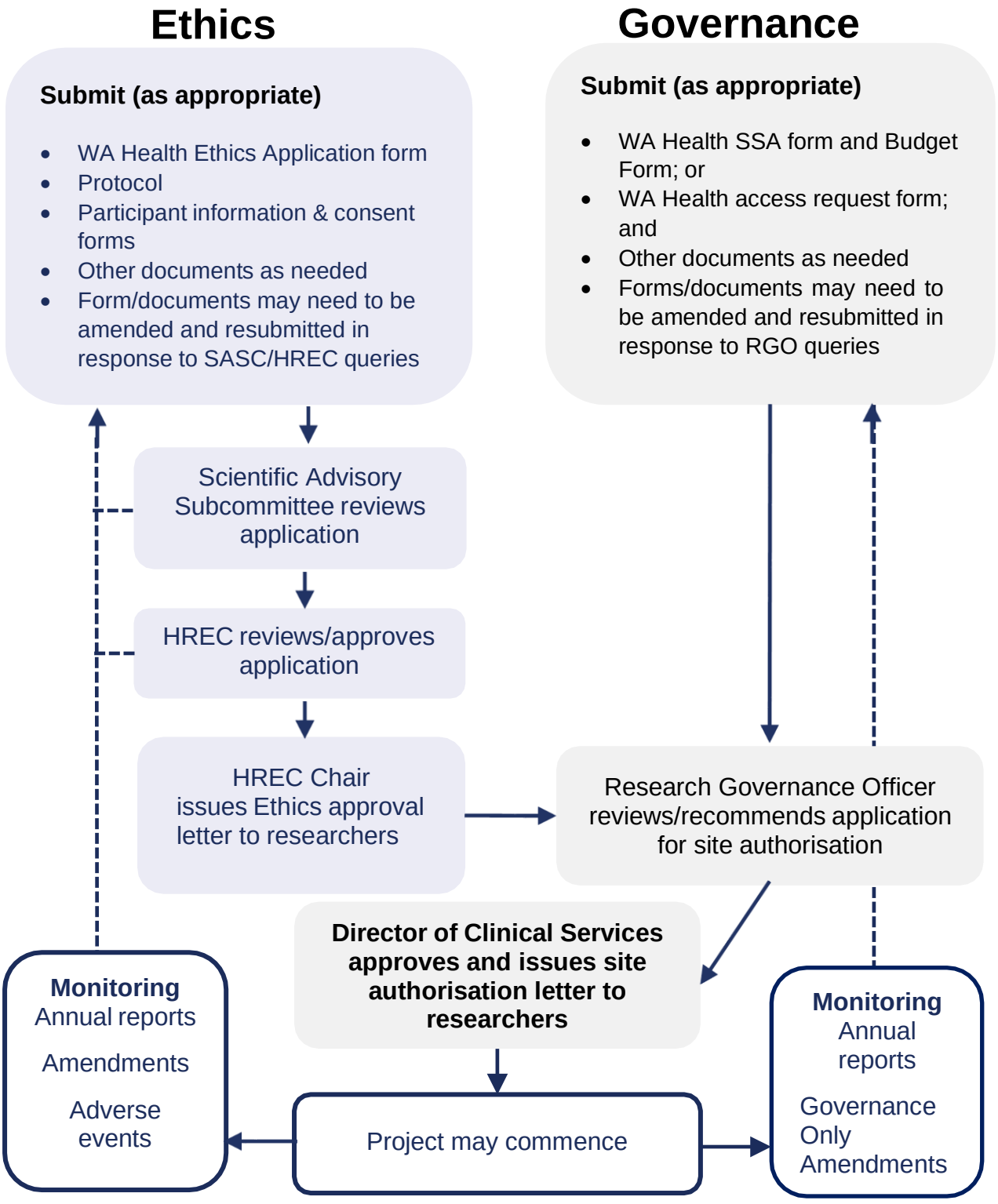

Figure 1. Parallel ethics and governance review process for local, single site projects.

4.1 Scientific and ethical review

Scientific and ethical review of human research enables WA Health to ensure that a proposed research project complies with appropriate ethical and scientific standards through an effective and efficient system of review.

Applications are first reviewed by the SASC to determine if the project is scientifically valid, feasible and rigorous. If queries are raised by the SASC, investigators will respond and/or resubmit their application for SASC review (see section 5.2. Subcommittee). Only once an application is recommended by SASC will it move forward to be reviewed by the HREC.

If the HREC approves the project, investigators will be issued with a letter of ethics approval. However, this letter constitutes **ethics approval only** and site authorisation is required before research may commence at the site.

4.1.1 Under the WA Health Single Ethical Review scheme, all multi-centre research projects at sites under the control of WA Health or involving participants, their tissue or data accessed through WA Health, must be ethically and scientifically reviewed only once, by a Lead WA Health HREC. The exception is those projects that require additional specialist HREC review; see section 4.1.3. for more information. WA Health sites must accept 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 their control.

4.1.2 Under the National Mutual Acceptance (NMA) scheme, all multi-centre research projects being conducted at public health organisations within the participating jurisdictions must be ethically and scientifically reviewed only once by an NHMRC certified Lead HREC participating in the NMA. The exception is those research projects that require additional specialist review. Further information about the NMA scheme can be found in section 16.

4.1.3 Some projects may require review by a specialist HREC. The specialist HRECs within WA Health include:

- The Western Australian Aboriginal Health Ethics Committee (WAAHEC) for health and medical research projects where Aboriginality is a key determinant or are explicitly directed at Aboriginal people. Where WAAHEC approval is required, an application must be submitted to the WAAHEC (external to the RGS) ***before*** the WNHS HREC will consider the ethics application submitted via the RGS.
- The Coronial Ethics Committee WA for research projects that require access to coronial samples, data or information. Submission to the Coronial Ethics Committee is external to the RGS.
- The Department of Health (DoH) WA HREC for all research projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage. Submission to the DoH WA HREC occurs via the RGS. If *only* Department of Health Data Collections will be accessed, i.e. no site data will be accessed directly and

no research activity will take place at a site, the DoH WA HREC **may act as the Lead WA Health HREC** and WNHS (or other) HREC review is not required.

4.1.4 WA Health sites must accept the ethical and scientific review undertaken by a Lead WA Health HREC or an NHMRC certified Lead HREC as sufficient review for the purposes of the multi-centre projects conducted at sites under their control.

4.1.5 Research conducted at non-WA Health sites (e.g., universities and research institutes) may require separate ethical review at that institution, unless the institution has a pre-existing agreement with WA Health. External researchers are advised that their institutional Research Ethics Office may need to be provided with their WNHS Ethics approval documentation to receive reciprocal approval prior to commencing.

4.1.6 Refer to the RGS information on multi-centre research (https://rgs.health.wa.gov.au/Pages/Multi-centre-Research.aspx) or contact the relevant Ethics and Governance Offices for more information.

4.2 Governance review

Research governance ensures the principles, requirements and standards of research are implemented. It addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management, monitoring arrangements, and promotes good research culture and practice. The governance application consists of either an SSA form and Budget form or an Access Request (AR) form. Governance review at WNHS is conducted by the Research Governance Officer and assesses aspects of proposed research which may have legal or financial implications for the institution, including resource utilisation, budgets, contracts, insurance policies and indemnities. The Research Governance Officer may request that the investigators amend existing documentation, submit additional documentation, and/or respond to queries regarding their governance application. Once the Research Governance Officer is satisfied that all requirements have been met, they will provide their recommendation for site authorisation to the WNHS Director of Clinical Services. The institution retains the right not to authorise the commencement of a research project, regardless of the outcome of the governance office or HREC review. Applicants have the right to appeal this decision directly with the WNHS Executive Office.

4.3 Authorisation to commence research

To commence research at King Edward Memorial Hospital (KEMH), investigators must receive a letter from the WNHS Director of Clinical Services notifying that KEMH site authorisation has been granted. To commence research at other WA Health sites, investigators must receive a letter from the respective Executive that site authorisation has been granted. Site authorisation will not be granted at any site until ethics approval has been granted by an appropriate lead HREC.

4.4 Centralised review and the Research Governance Service

The review process is centralised using the Research Governance Service (RGS), an interactive, secure web-portal that assists Western Australian Public Health Organisations in managing the ethics and governance processes for human research projects. Whether research is intra jurisdictional (within WA) or inter jurisdictional (across Australia), all applications involving WA Health sites must be made via RGS.

5. Application for ethical review

5.1 Submitting an Ethics application

5.1.1 Investigators are responsible for registering a project on the RGS, including providing the title and the coordinating principal investigator's (CPI) name, and obtaining a project reference number (PRN). The PRN is a unique number allocated to each research project and should be referenced in all correspondence related to the project.

5.1.2 The RGS platform does not allow partially completed applications to be submitted. Information about members, sites, and project details (excluding

section three) must be complete before a WA Health Ethics Application form or WA Specific Module can be generated or submitted. Section three of project details must also be complete before an SSA, AR or Budget form can be generated.

5.1.3. The CPI is responsible for inviting team members to the project on RGS. If project members are not already registered as an RGS user, they will need to complete the registration process on RGS and receive approval from an RGS Administrator before they can be invited to a project. User registration approval may take up to 1-2 working days. Non-WA Health employees will also be required to provide a WA Health referee.

5.1.4 As a minimum, a protocol must be submitted with the WA Health Ethics Application form. In addition, the following documents should be provided as required:

- Participant Information and Consent Form/s
- Recruitment documents (letters, emails, posters, advertisements)
- Questionnaires, surveys, interview outlines
- Other participant documents, e.g., diaries
- Investigator brochure
- Other relevant HREC approvals.

Templates for the Participant Information and Consent Form/s are available on the WNHS Research Ethics and Governance website (https://www.kemh.health.wa.gov.au/Research/Research-ethics-and-governance).

5.1.5 If a proposed project involves a medical/interventional product or device, the CPI is responsible for contacting the KEMH Product Evaluation and Standardisation Committee (PESC) prior to submitting their ethics application to enquire whether the product or device has been reviewed by a PESC at KEMH or any other WA Health Service Provider. If the product or device has been previously reviewed by a PESC, the committee's recommendation should be uploaded as a document on RGS and submitted with their ethics application. If the product or device has not been previously reviewed by a PESC, the investigator should state this clearly on their WA Health Ethics Application Form (or Western Australian Specific Module for projects approved under the NMA scheme).

5.1.6 The HREC office is responsible for:

- Responding to research queries regarding an ethics application and providing advice as appropriate.
- Updating researchers on the status of their ethics application as it progresses through the review process (refer to sections 6 and 7).
- Validating applications and adding them to the agenda of the next SASC meeting (refer to section 6.2).

5.1.7 The application closing deadline for an HREC meeting is the date of the preceding HREC meeting and late applications are not accepted. Each application will first be reviewed by the SASC and will not be submitted to the next HREC meeting until the SASC have recommended the application for ethical review. Please see section 5 for more information about the SASC possible review outcomes. The HREC and SASC meeting schedule for the current year is on the WNHS Research Ethics and Governance website (https://www.kemh.health.wa.gov.au/Research/Research-ethics-and-governance).

5.1.8 If an investigator or any member of the research team is not a WA Health employee, they are required to complete a Confidentiality Declaration within RGS. If any project team member is a student, the student must be under direct supervision and submit via the RGS a Student Confidentiality Declaration.

5.2 Resubmission

5.2.1 The HREC and subcommittees reserve the right to request the resubmission of an application if substantial queries are raised during the review. Concerns and issues to be addressed are outlined in writing to the applicant(s) following the meeting.

5.2.2 The HREC office is responsible for:

- Notifying the investigator within five working days of the committee's decision.
- Offering support and advice to the investigator regarding the HREC/SASC queries.

5.2.3 Investigators are responsible for responding to all queries within a timely fashion, including the resubmission of all amended documents (tracked and final versions) via RGS. If a response is not received within a maximum of four months, the ethics application may be withdrawn and a new ethics application will need to be submitted.

5.2.4 Once resubmitted the proposal will be reviewed at the next available meeting. If the HREC identifies any complex issues that may require face-to-face discussion, the applicant will be invited to attend the next meeting by the Chair of the HREC.

6. Committees

6.1 Administration

The WNHS Research Ethics and Governance Office will provide administrative support to the HREC and SASC. This support includes:

- Maintain responsibility for all communication with investigators, unless otherwise agreed by the Chair.

- Organise meetings of the HREC and the SASC via the RGS agenda.
- Maintain an up-to-date calendar for HREC and SASC meetings, available from the KEMH Research Ethics and governance website.
- Maintain up-to-date membership details and distribution lists.
- Attend to all meeting documentation.
- Arrange training opportunities for HREC members.
- Record the minutes of HREC and SASC meetings and upload them to RGS for ratification at the next meeting.
- Circulate the minutes to HREC and SASC members no more than five working days of the meeting.
- Provide timely updates and communication with committee members.
- Provide reports in line with institutional requirements.
- Maintain records in line with institutional and state requirements.
- Attend to review and approval of out of session amendments and have the delegated authority to sign all amendment approval letters, on behalf of the HREC Chair.

6.2 Subcommittee (SASC) meetings

6.2.1 SASC meetings will be scheduled one week following the application closing deadline. The SASC meeting is held monthly (excluding January), typically one week after the HREC meeting. The meeting is conducted in accordance with the relevant subsections of the HREC Terms of Reference.

6.2.2 The SASC's primary role is to assess the scientific validity, feasibility, and rigour of proposed projects. If queries are raised by the SASC, investigators will respond and/or resubmit their application for SASC review. Only once an application has been recommended by SASC will it move forward to be reviewed by the HREC.

6.2.3 The decisions available to the committee include:

- Recommended to proceed to the HREC for review.
- Recommended to proceed to the HREC for review 'subject to'. Investigators will be asked to provide a response and/or resubmit their application with changes prior to HREC review. The SASC Chair will determine, in consultation with other SASC members, whether changes/responses have satisfied the SASC concerns.
- Resubmit to SASC - these applications must be revised in accordance with the concerns of the SASC and resubmitted to the next SASC meeting for review.

6.2.4 If SASC has raised any queries regarding the application, or if the application requires resubmission, the investigator will be notified within five working days of the meeting.

6.3 HREC meetings

6.3.1 HREC meetings will be held in the first week of each month (excluding January) and will be conducted in accordance with its Terms of Reference 2021.

6.3.2 The HREC's primary role is to protect the rights of individual participants in research and the primary responsibility of each committee member is to decide independently whether, in his/her opinion, the conduct of each research project submitted to the HREC will protect participants.

To do this the HREC shall satisfy itself that:

- The project conforms to the National Statement.
- The project complies with the WA Health Research Governance Policy and Procedures 2012 and the WA Health Research Governance and Single Ethical Review Standard Operating Procedures.
- Persons invited to participate will be provided with enough information, at their level of comprehension, to enable them to make an informed decision as to whether to participate in the study.
- Appropriate procedures relating to obtaining informed consent are observed.
- The privacy of persons participating in research projects involving the collection, storage, disclosure, or other use of personal information is protected.
- Procedures for the handling of complaints from research participants are advertised and clearly outlined (e.g., in the participant information form).
- Where members of the committee have a conflict of interest with items on the agenda, they will declare the conflict and will take no part in the formal discussion and approval of the agenda item. They may, however, provide advice and information pertinent to the agenda item to the committee if requested by the membership.

6.3.3 The HREC will additionally take into consideration feedback from the SASC following their assessment of the application's scientific, clinical and safety aspects.

6.3.4 Quorum requirements, consistent with the National Statement, are outlined in the WNHS HREC Terms of Reference and must be met before a decision is made.

The decisions available to the committee include:

- Approval granted.
- Approved granted 'subject to'. These proposals may be resolved out of session, subject to written approval by the HREC Chair.
- Approval not granted. These applications must be revised and resubmitted to the HREC for review.

6.3.5. If the HREC has raised any queried regarding the proposal, or if the proposal requires resubmission, the investigator will be notified within five working days of the meeting.

6.4 Researcher attendance at HREC meetings

6.4.1 When written, electronic or telephone communication between researchers and the HREC is unable to resolve issues with a research application, or where the HREC requires a face-to-face interactive discussion with an investigator to be able to make a decision regarding an application, an investigator may be invited to attend a HREC meeting.

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

6.4.3 Once the committee has had its questions answered the investigator will be requested to leave the meeting room before the committee makes their deliberations and proceeds with the rest of the meeting.

6.4.4 The invited investigator will be notified of the outcome of the meeting in the usual manner.

6.5 Minutes

6.5.1 Minutes of each meeting will be recorded by the administrator and provided to the committee for ratification.

6.5.2 Minutes of the meeting will provide a record of:

- The studies considered
- Any queries raised
- Committee decisions
- Members' attendance

6.5.3 Following ratification of the minutes at the next meeting of the HREC, a copy of the approved minutes is to be uploaded to the RGS.

6.6 The Delegate of the Chair

The HREC Deputy Chair will act as Delegate of the HREC Chair. There may be more than one individual delegated in this role. The Delegate of the Chair may, in the absence of the HREC Chair:

- Ratify the minutes of the HREC meeting.
- Sign correspondence relating to projects submitted for review by the HREC (e.g., ethics approval letters and project closure letters).

7. Approval

7.1 Granting approval

7.1.1 For a project undergoing ethical review the minimum approval time is six weeks from the submission deadline. The timeline for approval is dependent on the committee meeting agenda and time taken for investigators to respond to any queries posed by the HREC or SASC.

7.1.2 When a study is approved an approval letter will be issued which contains the following information:

- Study title and number
- Approval date
- Approval expiry date
- A list of approved study documents
- Explicit approval of waiver of consent, where appropriate
- A list of sites for which approval is granted
- A list of special conditions, where appropriate
- Conditions of Approval

7.1.3 The approval letter may be signed by the HREC Chair or an approved delegate.

7.1.4 The letter provides ethical approval only. Site authorisation is required for each pertinent site prior to the commencement of the study at that site. Research may commence at KEMH only following receipt of a site authorisation letter signed by the WNHS Director of Clinical Services.

7.2 Approval expiry

7.2.1 HREC approval is usually valid for up to three years, but can be approved for up to five years where deemed appropriate by the committee.

7.2.2 An extension of up to three additional years may be granted by the HREC committee, renewable indefinitely depending on circumstances.

7.2.3 Any extension is conditional on compliance with reporting requirements (e.g. annual progress reports, safety reports) and HREC approval of submitted reports until the amended expiry date and/or submission of a project final report.

7.2.3 Ethical approval is closed once all core aspects of the project (recruitment, data collection and analysis, and achievement of pre-stated primary and secondary outcomes) have been completed. Publication of findings can occur after closure of the project.

7.2.3 A Site Final Report is to be submitted in RGS to KEMH Governance to close the site and a Project Final Report submitted in RGS to the HREC for final project closure (see 10.3.2).

7.2.4 Once the project is closed in RGS, it is not possible to re-open the project at a later stage. If any future activity on the project occurs after closure (e.g., further external analysis), an application to carry out the proposed work requires an application to the HREC for review and approval.

7.3 Approval withdrawal

7.3.1 All approved research must continue to meet the standards outlined in the National Statement as well as the conditions of approval stipulated by the HREC. This includes all reporting requirements.

7.3.2 The HREC retains the power to withdraw or suspend approval for the study in accordance with Section 5.5.7 of the National Statement.

7.3.3 If approval is withdrawn the investigator is responsible for:

- Immediately suspending research.
- Informing participants of any impact this will have on their care.
- Modifying research to ensure sufficient protection of participants.
- Resuming research only after ethical approval of any modifications.
- Providing any annual or final reports as appropriate.

8. Monitoring

8.1 Amendments

8.1.1 All amendments to research projects must be submitted for review and approval by the Lead HREC overseeing the site.

8.1.2 Investigators are responsible for:

- Adding, completing, and submitting amendments via the 'Monitoring' tab on RGS.
- Attaching a 'tracked' and 'final' copy of amended documentation to the amendment form on RGS. All changes to documentation MUST be evident in the "tracked changes" copy.
- Providing a Summary of Changes if the amendments are extensive.
- Updating the version number and date on amended documentation.
- Responding to the HREC in a timely manner.
- Monitoring project expiry date and submitting an amendment for extension of the project prior to expiry - often submitted at the same time as an Annual Progress Report.

8.1.3 The Research Ethics and Governance Office is responsible for:

- Recording all amendments in the appropriate database and/or record keeping system.
- Validating all amendments in RGS and requesting further information if required.

- Storing electronic copies of all amendments in the appropriate record keeping system.
- Tabling the amendment at the next available SASC and HREC meetings.
- Communicating SASC or HREC concerns to the investigators in a timely manner.
- Signing and issuing approval letters where appropriate.

8.2 Safety monitoring and reporting

8.2.1 The CPI is responsible for submitting safety reports via the RGS to the HREC and the relevant RGO(s), as per the National Statement. Safety reports that must be submitted include:

- Safety report in the case of Adverse Events (AE) such as serious breaches of protocol, Significant Safety Issues (SSI), Sudden Unexpected Serious Adverse Reactions (SUSAR) and Unanticipated Serious Adverse Device Effect (USADE), within the appropriate timeframe
- Annual safety report, if the project involves an intervention; this report must be submitted independent of whether an AE has occurred.

For more information, definitions of the types of AEs, submission timeframes and the requirements for annual reports, please see the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods.

8.2.2 Responding to an AE may require an Urgent Safety Measure (USM); that is, a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety. A USM may be implemented prior to HREC review of the safety report; however, the HREC should be notified of the USM in writing without undue delay and no later than 72 hours of the measure being taken (NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods).

8.2.3 The CPI may delegate at his/her discretion certain trial duties to individuals where appropriately qualified by education, training and experience. The delegation of trial activities must be clearly recorded in a Delegation of Responsibilities Logbook, and the CPI retains overall responsibility for any delegated activity.

8.2.4 The following procedures should be clearly outlined in the protocol prior to commencement of a clinical trial as appropriate:

- Medical history assessment prior to the commencement of a trial by a medical practitioner or registered nurse delegated to this task to identify any pre-existing medical conditions, and to ensure these are not reported as new AEs once the participant begins active involvement in the trial. Note: If a pre-existing medical condition worsens after the participant has signed informed consent this is usually recorded as a

new AE. It could be documented as "worsening of…" or "exacerbation of…" the event described in the medical history.

- Initial identification and reporting of potential AEs to the Sponsor/CPI (e.g. self-reported by a participant, reported by clinical trial or non-clinical trial staff etc.).
- Assessment and evaluation of potential AEs, including an assessment by a medical practitioner.
- Recording/logging of all AEs, including how and where the date, type, nature, severity etc. of the AE will be recorded.

8.2.5 The HREC is responsible for reviewing all safety reports. The HREC Office is responsible for:

- Acknowledging receipt of any adverse event, SSI or serious breach notifications provided by investigators.
- Notifying the HREC and SASC Chairs of any adverse events, SSIs or serious breaches within 24 hours of receiving the notification.
- Tabling all safety reports at the next SASC and HREC meetings.
- Providing confirmation of HREC review of the safety report within five working days of the HREC meeting.

8.3 Annual progress reports

8.3.1 Annual progress reports should include information pertaining to:

- Adverse events and any changes arising from these events.
- Publications.
- Staffing changes.
- Current findings.
- Issues with recruitment or results.
- Whether the project is progressing as expected.

8.3.2 Investigators are responsible for submitting:

- Annual progress reports to the lead HREC covering all approved HREC sites on, or prior to, the anniversary of the ethics approval date. When appropriate (close to project expiry date) an amendment application for extension of approval is also submitted with the Annual Report.
- Annual progress reports at each site the study is being conducted on, or prior to, the anniversary of the ethics approval date.

8.3.3 Investigators will receive automated email reminders from RGS one month and one week before their annual report is due.

8.3.4 If the annual report is not submitted before the due date, investigators will receive an automated email from RGS one week after the due date. Investigators will be sent a second reminder of their overdue report by the Ethics Administrator if the annual report has not been submitted by the 14th of the following month (at least two weeks after the due date). Third and fourth

reminders will be sent by the Ethics Administrator on, or soon after, the 21st and 28th of the same month as needed.

8.3.5 Failure to submit an overdue annual report prior to the deadline stated in the fourth reminder (approximately two months from the original due date) will lead to the project being tabled at the next HREC meeting and the project may be suspended. Approval for a suspended project will need to be restored by the HREC upon review of a late annual report before the research activity can recommence.

8.3.6 The HREC is responsible for reviewing all annual reports. The review of the annual reports is taken into consideration when the HREC reviews and approves a submitted amendment application for extension of the project (see 9.1.2).

8.3.7 The HREC office is responsible for tabling the annual report at the next SASC and HREC meetings.

8.4 Final reports

8.4.1 Final reports should include information pertaining to:

- Adverse events and any changes arising from these events.
- Publications arising from the study.
- Summary of findings.
- Issues with recruitment or meeting objectives.
- Whether the project progressed as expected.
- Whether the aims of the research have been met.

8.4.2 Investigators are responsible for:

- Submitting a site final report to the respective RGO of each authorised WA Health site involved in the project, followed by a project final report to the Ethics Committee (once all WA Health sites have been closed).
    - *Note:* For projects conducted at KEMH only, the Ethics Committee will accept the submission of a site final report in lieu of a project final report. The site final report must be submitted to both the WNHS RGO and WNHS Ethics Committee simultaneously.
- Submitting all reports prior to the ethics approval expiration date.
- Immediately notifying the HREC and the RGO at each site if a project is suspended or terminated by the CPI or a project sponsor. Such notification should include (1) the circumstances necessitating the suspension or termination of the project, and (2) what procedures are in place to safeguard participants and/or how any materials collected will be disposed of safely.
- Notifying the HREC if a suspended study is to be recommenced.

8.4.3 The HREC office is responsible for:

- Tabling all final reports at the following SASC and HREC meetings.
- Providing acknowledgment of final reports within five days of the HREC meeting.
- Maintaining electronic records of all documents pertaining to the study.

8.4.4 If the investigators fail to submit an Annual Report and Amendment form for extension, or a Project Final Report, prior to the Ethics approval expiry date, the HREC Office will:

- Upon receipt of the RGS email reminder that the project has expired, email a first reminder to the investigators one week after project expiry.
- Email a second reminder to the investigators one month after project expiry notifying the investigators that if a final report (or request for extension and annual report) is not received by a nominated date, the project will be tabled at the next HREC meeting with the recommendation of closure.
- Email a third reminder to the investigators two months after project expiry. The third reminder will include a formal letter advising of the final opportunity to submit a final report (or request for extension and annual report).
- If no final report (or request for extension and annual report) is received within three months of project expiry, the project will be tabled at the next HREC meeting with the recommendation of closure.
- Pending HREC decision, Ethics approval may be withdrawn and the project closed. Investigators will be notified of the HREC decision and that no further work can be conducted via a formal letter signed by the Director of Clinical Services. The HREC Office will liaise with the Research Governance Office to permanently close the project on RGS.
- If the HREC has concerns that the project is ongoing, the HREC may recommend continued attempts to contact investigators and/or notifying the Director of Clinical Services.

9. Fees

Applications by individual researchers for non-sponsored projects or for competitive grant applications will **not** attract a fee.

Application for projects which are sponsored by commercial agencies (e.g. Pharmaceutical companies or other industry bodies) will attract a submission fee. Fees are payable on initial submission; further fees may be charged for amendments:

Commercial sponsorship may be financial or in-kind (e.g. provision of drugs or devices). Fees for in-kind support by commercial agencies may be waived for investigator-initiated studies if the following conditions are included in a WA Health approved clinical trial agreement:

- The IP arising from the study is not restricted by the commercial agency

- The data arising from the study is not provided to the commercial agency for marketing or publicity purposes
- The investigator retains full publication rights. There should not be a right-of-review restriction by the commercial agency.

The fee* structure for commercially sponsored trials is as follows:

Table 1. HREC fee structure

Service	Fee (inc. GST)
New applications that require HREC review	$3,850
Review of an Amendment (including those requesting an extension of approval)**	$660
Further review of an amendment/requirement for resubmission of amendment (each occasion)	$320
Applications that require an excessive level of administrative support	$50 per query to a maximum of $500

Table 2. Site authorisation fee structure

Service	Fee (inc. GST)
Review and Authorisation of new project	$3,850
Review of substantial amendments to approved projects	$660

*fee structure currently under review
**this fee may be waived at the discretion of the HREC

Protocol amendments that introduce major new aims (i.e. a new primary or secondary objective) or which introduce major new safety considerations and which require extensive scientific and/or ethical review may attract a higher fee. This includes the addition of new sub-studies.

Submission of incomplete applications requiring significant administrative support on behalf of the HREC may be subject to additional fees. This charge will apply to both commercially sponsored and non-sponsored studies.

10. Complaints

10.1 Complaints regarding the conduct of research

All complaints regarding the conduct of a researcher or research project will be received, via the Director of Clinical Services, by the Ethics Administrator within the REGO.

10.1.1 The REGO is responsible for:

- Recording all complaints in writing.
- Informing the HREC and SASC Chairs and the Director of Research Ethics and Governance of any complaints immediately.

- Sending a letter of acknowledgment to the complainant within five working days of the complaint being received.
- Notifying the investigator within five working days of the complaint.
- Informing the complainant of the outcome of the investigation.

10.1.2 The Director of Research Ethics and Governance will:

- Contact the researcher or PI of the project to notify them of the complaint, discuss the complaint and request further details (where necessary).
- Investigate the circumstances and confirm details surrounding the complaint.
- Convene an out of session meeting of the SASC and/or HREC if deemed necessary.
- Prepare a report for the HREC and the Director of Clinical Services of WNHS.

10.1.3 If the complainant is not satisfied with the outcome of the Research Ethics and Governance Director's investigation, they can refer the complaint to the WNHS Director of Clinical Services.

10.1.4 The Director of Clinical Services will determine whether there is to be a further investigation of the complaint. Where no further investigation is to occur, the Director of Clinical Services will inform the complainant and the Chair of the HREC.

10.2 Complaints regarding the conduct of the SASC or HREC

All complaints regarding the conduct of the SASC or HREC will be received by the Executive Director, North Metropolitan Health Service.

The Executive Director of North Metropolitan Health Service will:

- Contact the Ethics Administrator to notify them of the complaint regarding the SASC or HREC, discuss the complaint and request further details (where necessary). The Ethics Administrator will notify the SASC or HREC of the complaint at the next meeting and relay any relevant information to the Executive Director.
- Oversee investigation of the circumstances and confirm details surrounding the complaint.
- Inform the complainant of the outcome of the investigation.

11. Case Reports

11.1 A case report is usually a report of a person with a unique disease or condition, associated treatment or outcome. Case reports must not disclose the identity of the patient.

11.2 The review of patients to report as a case study is considered anecdotal. These reviews may proceed without HREC review or approval; however, one of HREC's important roles is to safeguard patients, investigators, institutions, and the public, clarifying and reviewing a researcher's duty of confidentiality to their patient-subjects.

11.3 If publishing a case report is identified as a possibility, investigators must discuss the publication with the participant (or their parent(s) if under the age of 18 years) and obtain their signed consent to publish.

11.4 The signed consent form must be filed with the participant's medical record and a copy retained within the WNHS Research Ethics and Governance Office.

11.5 Where consent cannot be obtained, for example the patient no longer attends the hospital and contact details are out of date, guidance must be sought from the Director of WNHS Research Governance on a case-by-case basis. The matter may be referred to the HREC if deemed necessary.

12. Application for a Waiver of Consent

12.1 Researchers wishing to apply for a waiver of consent must first ensure that their research meets all of the specific criteria set out in Section 2.3.10 of the National Statement. The investigator must address all points (a-i) under this Section within their submission when applying for a waiver of consent. Note that projects for which involvement in the research carries more than low risk are not eligible for waiver of consent.

12.2 Under section 2.3.10.c of the National Statement, the HREC may grant a waiver of consent only if it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records). Researchers should note that the threshold for "impracticable" is relatively high and is not synonymous with "difficult" or "undesirable". For example, if the contact details of the potential research participants are known, then the cost and difficulty of obtaining consent may not satisfy the "impracticable" threshold, depending on the size of the study and the specifics of the participants concerned.

12.3 Researchers should be aware the National Statement recommends under Section 4.4.14 that, where applicable, participants should be informed of the research as soon as reasonably practicable and given the option to withdraw from it without any reduction in quality of care.

12.4 The HREC reviewing the submission will decide whether to grant a waiver of consent at its meeting.

12.5 Researchers who have been granted a waiver of consent by the HREC will receive notification with their approval documents.

12.6 Researchers who are not successful in applying for a waiver of consent will be notified in writing of the Committee's decision and be provided with reasons.

The researcher can amend their submission or request to attend the next HREC meeting to discuss the matter.

13. Record keeping

13.1 Research records

13.1.1 The REGO is responsible for ensuring all study documentation (e.g., ethics applications, approval letters, protocols) pertaining to active or closed research projects are maintained electronically and disposed of in accordance with Sections 5.2.26-27 of the *National Statement* and the *WA Department of Health Patient Information Retention and Disposal Schedule 2014.*

13.1.2 Investigators are responsible for maintaining comprehensive records of all study material and procedures in line with *sections 3.1.44 – 3.1.50 of the National Statement*. Reasonable steps must be taken, and detailed in the data management plan within your protocol, to ensure information is:

- Protected against theft, loss and unauthorised access, use and disclosure
- Protected against unauthorised copying and modification
- Retained, transferred and disposed of in a secure manner as per:
  - *DA 2019-008 Patient Information Retention and Disposal Schedule for the WA health system (PIRDS)*
  - MP0145/20 *Information Storage Policy*
  - MP0144/20 *Information Retention and Disposal Policy*
- Managed in line with MP0067/17 *Information Security Policy*.

13.1.3 All Freedom of Information requests should be lodged with the Freedom of Information Office.

13.2 Confidentiality

13.2.1 All data provided to the WNHS HREC and its subcommittee, including details of research and contact information is kept private and confidential.

13.2.2 Only staff members involved in the study may access the HREC records. Investigators adding additional staff members to the research team are required to submit notification of this to the lead HREC using an amendment form.

13.2.3 Any investigators wishing to give individuals who are not involved in their research access to details of their application are required to confirm these intensions in a letter to the HREC or submit an Amendment Form to the HREC adding the individual as additional project member.

13.3 Signatures

13.3.1 All project forms (e.g., WA Health Ethics application form, amendment form, progress report forms etc.) are to be signed and authorised electronically on

RGS.

13.3.2 Ethics approval letters are signed by either the HREC Chair or their delegate. Site authorisation letters are signed by the Director of Clinical Services. Signed ethics approval and site authorisation letters are distributed to the CPI and PI, respectively, via the RGS.

13.3.2 Correspondence originating from the HREC office will be provided electronically and will make use of electronic signatures.

14. National Mutual Acceptance (NMA)

The State/Territory governments of Australia have signed a Memorandum of Understanding to implement a version of the National Approach which is restricted to public health organisations and the single ethical review of clinical trials, known as the National Mutual Acceptance. Under this process, all multi-centre clinical trials being conducted at sites (participating in the NMA) within Australia must be ethically and scientifically reviewed only once by a NHMRC Certified Lead HREC (participating in the NMA - criteria for Certified Lead HRECs see NHMRC website). The exception is those clinical trials that require additional specialist review. The specialist HRECs within WA Health include:

- The Western Australian Aboriginal Health Ethics Committee (WAAHEC) for health and medical research projects where Aboriginality is a key determinant or are explicitly directed atAboriginal 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 Department of Health data collections or data linkage.

If the CPI is from outside WA Health, then the Certified Lead HREC must be selected in accordance with the applicable jurisdictional requirements.

Applications for research Governance review of a project which has been ethically reviewed and approved by an interstate HREC, under the NMA scheme, must be submitted via the RGS. The WA Specific Module (WASM) must be completed and all related documents uploaded under the 'Ethics Approval' section of the applications tab. The related documents should include:

- A copy of the approved Human Research Ethics Application (HREA) form
- A copy of the HREC approval letter, including approval of KEMH being added as a site and HREC approval or acknowledgment of the WASM
- All HREC approved documentation such as protocols, participant information and consent forms, questionnaires and so forth as appropriate.

The WASM and related documents must be submitted to the Research Governance Office by selecting the button "Submit Ethics to RG Office".

15. Review of GEKO applications

15.1. GEKO applications that are flagged by the GEKO Committee as possibly constituting negligible risk research (rather than quality improvement), indicating intent to publish, or having other outstanding circumstances, must be reviewed by the WNHS Ethics Committee (in addition to the appropriate Directorate/Department Committee) to determine the appropriate application review and approval pathway – GEKO or Ethics application, prior to commencement of the project.

15.2 For the GEKO application to be considered by the Ethics Committee, it must include a completed project outline (including the QI checklist) and blank audit tool.

15.3 The decisions available to the committee include:

- Recommended for the GEKO pathway.
- Not recommended for the GEKO pathway. Reasons for this decision will be provided by the committee and returned to the investigators by the Performance Review and Audit Coordinator. These applications must submit an Ethics application via RGS.