Government of Western Australia
North Metropolitan Health Service
Sir Charles Gairdner Osborne Park Health Care Group

SCGOPHCG HREC

Standard Operating Procedures

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Contents

Document history

Editor	Date	Version	Amendments
HREC Office	June 2016	-	SOPs originally drafted by HREC Office
HREC Office	July 2016	1.0	Final draft developed with input from stakeholders
HREC Office	March 2019	1.1	New Sections: • HREC education • secretariat education Updated to reflect: • WA joining NMA • changes to safety reporting • fixed dead links • deployment of RGS • fee changes Formatting changes and fixing broken hyperlinks
HREC Office	August 2019	1.2	Revisions required by NHMRC
HREC Office	January 2021	1.3	Update to reflect NMHS style guide, changes to process, NHMRC requirements

Abbreviations	
CDTC	Clinical Drugs Trial Committee
DOH	Department of Health
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
NS	National Statement
OD	Operational Directive
RGO	Research Governance Office
SCGOPHCG	Sir Charles Gairdner and Osborne Park Health Care Group
SOP	Standard Operating Procedures
SRS	Scientific Review Subcommittee
SSI	Significant Safety Incident
USM	Urgent Safety Measure
WAAHEC	Western Australian Aboriginal Health Ethics Committee

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 Sir Charles Gairdner and Osborne Park Health Care Group (SCGOPHCG). These SOPs outline the responsibilities and functions of the various stakeholders involved in research and have been written in line with the requirements of Section 5.1.37 of the National Statement.

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 and training of researchers and managing institutional risk (*Australian Clinical Trials*; NHMRC).

The *WA Health Research Governance Policy and Procedures 2012* (OD 0411/12) was 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. In line with this policy, SCGOPHCG has a two-tiered system of review which includes:

- scientific and ethical review
- site specific assessment.

Scientific and ethical review

To assess the scientific and ethical integrity of proposed research, and monitor its ongoing conduct, SCGOPHCG has an established Human Research Ethics Committee (HREC) which is certified by the National Health and Medical Research Council (NHMRC). The primary purpose of the HREC is to protect the welfare and rights of participants in research. The operation of the HREC is governed by its *Terms of Reference 2021* and the terms set out by the NHMRC in the *National Statement on Ethical Conduct in Human Research 2007* (*National Statement*).

These SOPs should be read in conjunction with the HREC *Terms of Reference 2021* which provide detail on the operation, responsibilities and functions of the HREC.

SCGOPHCG HREC is an NHMRC HREC certified under the National Certification Scheme. As such, the committee may provide ethical review which may be used to support research nationally.

Site specific assessment

The site-specific assessment at SCGOPHCG is designed to protect the interests of the institution and ensure that it is not exposed to any undue risk. This process is documented in the WA Health Research Governance Policies and Procedures (2012) and runs in parallel to the ethical and scientific review process. The site-specific review assesses aspects of proposed research which may have legal or financial implications for the institution, including resource utilisation, budgets, contracts, insurance policies and indemnities. Once the site-specific assessment has been completed a recommendation is made to the SCGOPHCG Executive Director, or delegate, as to whether the research project should be authorised to commence at

SCGOPHCG. The institution retains the right not to authorise the commencement of a research project, regardless of the outcome of the site specific or HREC review. Applicants have the right to appeal this decision directly with the Executive.

Reducing duplication in ethical review

Over the past decade, there has been an effort to reduce the cross-institutional and jurisdictional duplication of ethical review. As each HREC is required to assess adherence to the requirements of the National Statement, there was limited justification for research to undergo a HREC review at each participating institution. As such, both state-specific and national schemes for single ethical review have been developed and have operated successfully for several years.

WA Health Single Ethical Review

A research project approved by any accredited or certified WA Health HREC will be accepted by another participating WA Health institution.

National Mutual Acceptance

The National Mutual Acceptance (NMA) scheme has been implemented in public health organisations across several Australian states including Western Australia. Multi-centre research projects being conducted at public health organisations within the participating jurisdictions must be ethically and scientifically reviewed only once by a NHMRC Certified Lead HREC. A 'certified' HREC differs from an 'accredited' HREC in that certified HRECs and institutional processes have undergone a higher level of review by the NHMRC to assess their ability to undertake a review that can be accepted nationally.

SCGOPHCG HREC is a NHMRC Certified Lead HREC and as such may provide national ethical approval. Inversely, approval from another certified public HREC will be accepted in place of a review from the SCGOPHCG HREC.

Further information on the National Certification Scheme may be located here.

Other Required Approvals

In some cases, review by additional specialist HRECs may be required. These may include:

WA Aboriginal Health Ethics Committee (WAAHEC)

Research involving Aboriginal and/or Torres Strait Islander peoples or communities specifically requires an additional review by WAAHEC if:

- indigenous status is a key determinant
- data collection is explicitly directed at Indigenous peoples
- indigenous people, as a group, will be examined in the results
- the information has an impact on one or more Indigenous communities
- indigenous health funds are a source of funding.

Further information on WAAHEC application and review can be found here.

WA Health Department of Health (DoH) HREC

Research involving access or linkage between WA Health Data collections requires an additional review by the DoH HREC in collaboration with the Data Linkage Unit. Further

information on the DoH HREC and the Data Linkage Unit can be found here and here, respectively.

Coronial Ethics Committee

All human research projects that require access to coronial samples, data or information must be referred to the Coronial Ethics Committee WA. Further information may be obtained by contacting Coronial Ethics Committee WA; contact information may be found here.

Resources and Reference Documents

In addition to the National Statement on Ethical Conduct in Human Research (2007), there are a range of resources those wishing to conduct research should familiarise themselves with. The documents below are essential for any medical researcher working in Australia, WA and within the WA public health sector. Researchers should be familiar with the following key documents before preparing a submission.

Understanding your broad responsibilities as a researcher in Australia:

- Australian Code for the Responsible Conduct of Research, 2018

Understanding the fundamentals of conducting clinical trials and all human research

- Australian Clinical Trials Handbook

Guidance on NHMRC requirements on safety reporting and monitoring requirements:

- Safety monitoring and reporting in clinical trials involving therapeutic goods, November 2016
- Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods 2018

Application for ethical review

In January 2017, an online research submission platform known as the WA Health Research Governance Service (RGS), , was deployed. All research applications and amendments must be submitted to the SCGOPHCG HREC using RGS. Note: researchers new to the system may wish to consult the various user guides provided by RGS.

Submission to the SCGOPHCG HREC

Investigators are responsible for ensuring that applications are:

- complete and include all required documentation
- submitted prior to the submission deadline; and,
- notifying the HREC in the event the researcher has a potential or perceived conflict of interest.

The following documents are required for all studies and should be provided when submitting a research application for ethical review:

- application form – WA Health Ethics Application Form (WAHEAF) OR the Human Research Ethics Application (HREA) and WA Specific Module (WASM); and,

- protocol/research plan.

In addition to the above, the following documents should be provided as required:

- participant information sheet and consent form/s,
- recruitment documents (letters, posters, advertisements),
- questionnaires, surveys, interview outlines,
- other participant documents (identification card, diaries),
- investigator brochure,
- other relevant HREC approvals,
- radiation safety officer/Radiological Council report.

The HREC Office is responsible for:

- checking applications for completion and quality; and,
- assigning complete applications to the next available scientific and ethics meeting as appropriate.

All required forms necessary for the submission of a research application are available on the WA Health Research Governance website.

Late and/or incomplete applications will not be accepted.

If an investigator has an actual or perceived conflict of interest this must be declared to the HREC at the time of submission.

Investigators' contact details will be added to the Department of Research distribution list.

Investigators are required to register studies with a public trials registry which must be:

- accessible to the public at no charge
- open to all prospective registrants
- managed by a not-for-profit organisation
- electronically searchable

Examples of appropriate trial registries include, but are not limited to:

- Australian and New Zealand Clinical Trials Registry
- Clinicaltrials.gov
- International Standard Randomised Controlled Trial Number [ISRCTN] Register

Resubmission

The HREC and subcommittees reserve the right to request the resubmission of an application if substantial queries are raised during review.

The HREC Office is responsible for:

- notifying the investigator within 7 calendar days of the decision
- offering support and advice to the investigator in regard to extant queries.

Investigators are responsible for:

- responding to all queries within 4 months
- resubmitting all amended documentation.

Once resubmitted the proposal will be reviewed at the next available meeting or, if approved during the initial review, out of session in accordance with the SCGOPHCG HREC Terms of Reference.

Process of Review

The type of review each application undergoes is dependent on the nature of the research.

The review streams include:

- standard ethical review
- Single Ethical Review (WA Health)
- ethical review under National Mutual Acceptance
- low risk review.

A flow chart of the submission and approval process is provided on the SCGOPHCG HREC website.

Standard review

Studies undergoing a standard review will be assessed for their scientific and ethical integrity by the full HREC and any associated subcommittee.

All research involving humans which is deemed to pose more than low risk to participants will be reviewed through the standard review stream.

This includes single-site research as well as research for which the SCGOPHCG HREC will act as the lead HREC.

Single Ethical Review (WA Health)

A Single Ethical Review of multi-centre research allows a study being conducted at multiple sites within WA Health to be reviewed by an HREC only once. This review must be conducted by an approved lead WA Health HREC. Other WA Health sites may then accept the lead HRECs approval.

If ethics approval has been granted by an approved lead HREC, SCGOPHCG will accept this approval. However, the study will still need to undergo site specific assessment.

Ethical Review under National Mutual Acceptance

An interjurisdictional ethical approval requires the HREC to consideration the implications of research within each jurisdiction in which it is to take place. These include consideration of the

legislative environment within each participating jurisdiction and reviewing any relevant state specific modules appended to the HREA.

NMA approvals, even if they meet the criteria of low risk research, cannot be undertaken out of session on behalf of the HREC.

Any addition of sites outside of WA will necessitate a project undergoing a further HREC review and may incur subsequent review fees, if applicable.

Low risk review

A review by the full HREC is the default pathway to which all research projects are assigned. However, in cases where studies may be deemed to meet the criteria to be considered 'low risk', (NS 4.2) the HREC Chair, or their delegate, will determine the appropriateness of a proportionate, expedited review. Accepting a project for low risk review is at the discretion of the HREC Chair, and/or the Delegate of the Chair.

In addition to the points included under Section 4.2 of the National Statement, the following applies to studies deemed to be low risk.

- There are no submission deadlines for low risk research and applications may be submitted at any time.
- Low risk research will be reviewed by a low risk committee which will contain a minimum of three individuals from the HREC, Department of Research and any associated subcommittees.
- Applications with characteristics that require full HREC review as per the National Statement will not be accepted via this expedited pathway. These include but are not limited to:
    - Projects which request consent be waived
    - Projects which involve groups without capacity to consent
    - Projects utilising an opt-out approach.

Committees

HREC

The HREC will be constituted and operate as per the SCGOPHCG HREC *Terms of Reference 2021* and will adhere to the requirements of the National Statement in the conduct of all business.

HREC Education

The HREC Chair, Secretariat and Department of Research will develop and, as often as practicable, provide education to the HREC members (NS 5.1.28 and 5.2.3c)

At minimum, the secretariat will conduct an in-depth induction with all members at the beginning of each term served and produce a quarterly educational newsletter that contains:

- any current department of research news
- discussion of a salient ethical issue, including a summary, references to peer-reviewed research articles and other relevant documentation to educate members

- the summarised outcome of a research project approved by the SCGOPHCG HREC including discussion of successes, challenges and outcomes of the study
- links to recent e-learning modules, webinars and any upcoming local lectures, seminars and workshops that HREC members may find useful.

Where possible the secretariat will seek approval from the Director of Research to fund HREC member's participation in, or attendance at, paid education when the material provided is sufficiently relevant or of high enough quality to justify the expense. The secretariat will also circulate any free seminars or webinars to the HREC members to attend where able.

Secretariat

The Department of Research will provide secretariat support to the HREC as per the SCGOPHCG HREC *Terms of Reference 2021*.

The secretariat is responsible for:

- being the first point of contact for applicants wishing to make application or liaise with the Committee;
- ensuring that proposals are provided to the Committee for consideration and are of sufficient quality for review;
- ensuring that the decisions of the Committee are conveyed to investigators in a timely manner;
- ensuring that Committee records are maintained and are made available for review by the Hospital Executive;
- ensuring that the appropriate applications, renewals and reports required to maintain the conduct of the HRECs business are completed and submitted;
- coordinating committee meetings including scheduling, allocation of members
- recruiting and appointing new committee members
- organising ongoing training for HREC members as available; and,
- maintaining the HREC's records in accordance with state and Commonwealth requirements.

Secretariat Education

Where possible the secretariat will seek approval from the Director of Research to take part in education relevant to the coordination and administration of an ethics committee.

Subcommittees

Subcommittee meetings will be conducted in accordance with their associated terms of reference.

The decisions available to the committee include:

- approval granted. These proposals may proceed to the HREC for review.

- approval granted with queries. These proposals may proceed to the HREC for review, however approval will not be granted until the issues are resolved.
- approval not granted. These applications must be revised and resubmitted to the subcommittee for review.

If the subcommittee has raised any queries regarding the proposal, or if the proposal requires resubmission, the investigator will be notified within 7 calendar days of the meeting.

HREC meetings

HREC meetings will be conducted in accordance with its Terms of Reference 2021.

HREC meetings may take place either in-person or virtually. Following the review of a proposal by a subcommittee, the HREC will consider each project on the agenda at all times taking into consideration the principles and requirements of the National Statement.

Consistent with the National Statement, if at a meeting of the HREC there is less than full attendance of the minimum membership, the Chair should be satisfied that the views of those absent have been considered before a decision is reached (NS5.2.30-5.2.33)

HREC decisions are made by consensus. Where a difference of opinion occurs, the Chair will facilitate discussion with the aims of reconciling this difference. In the event that a difference of opinion cannot be resolved, a decision will be made by a two-thirds majority with any significant dissenting opinion recorded.

Members are required to declare any potential, perceived or actual conflict of interest prior to deliberations beginning. Failure to report a conflict of interest may be grounds for termination of committee membership.

The decisions available to the committee include:

- approval granted.
- approval granted with queries. These queries may be resolved out of session.
- approval not granted. These applications must be revised and resubmitted to the HREC for review.

If the HREC has raised any queries regarding the proposal, or if the proposal requires resubmission, the investigator will be notified within 7 calendar days of the meeting. All formal communication from the HREC will be conducted in letters provided via RGS. However, the secretariat may conduct informal communication on behalf of the HREC to provide advice to researchers in order to facilitate approval. Any relevant outcomes related to these informal correspondences should be tabled at the relevant HREC meeting for information.

At the request of the HREC Chair, researchers may be invited to attend the HREC meeting in order to provide information or context about a research project which may assist the HREC in their review. Attendees are required to depart prior to deliberations taking place.

Similarly, prospective HREC members may be asked to attend a HREC meeting as an observer. Attendance will be recorded in the minutes. Observers are permitted to ask questions after the meeting but should not interrupt the proceedings unless given leave to do so by the Chair.

Minutes

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

Minutes of the meeting will provide a record of:

- the studies considered
- any queries raised
- committee decisions
- attendance of non-HREC members
- any reported conflicts of interest and how these were mitigated
- whether the Delegate of the Chair has been given responsibility to approve proposals out-of-session.

Following ratification by the committee, an abridged version of the minutes will be made available online.

As per the SCGOPHCG HREC *Terms of Reference 2021,* while independent, the HREC is accountable to the Executive Director of SCGOPHCG. All material related to the conduct and review of the HREC is available to the Executive Director and the Director of Research. An annual report will be provided to the Executive of the hospital as described in Section 6 of the *SCGOPCHG HREC Terms of Reference.*

Delegate of the Chair

The Delegate of the Chair will conduct themselves in accordance with the criteria set out in the SCGOPHCG HREC ToR's, including:

- signing correspondence on behalf of the Chair
- assisting in the review of low risk applications
- reviewing responses to HREC queries
- providing timely communication and advice to investigators
- approving studies, with clearance from the HREC
- monitoring approved research through reviewing and acknowledging amendments and reports.

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

Approval

Granting approval

For a project undergoing standard review, the minimum time to approval is one month from the submission deadline. The timeline for approval is dependent on the time taken for investigators to respond to any queries posed by the HREC, or associated subcommittees.

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

- approval date
- a list of approved study documents
- a list of sites for which approval is granted.

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

This letter provides ethical approval only. Site authorisation is required from each site that the study will be conducted prior to the commencement of the study at that site. Site authorisation is provided by the Research Governance Office.

Approval expiry

HREC approval will be provided for an initial period of five years.

An extension of up to three additional years may be granted out-of-session. Any extension is conditional on the performance and monitoring of the project.

Extensions beyond this must be reviewed by the HREC.

Approval withdrawal

All approved research must continue to meet the standards outlined in the National Statement as well as the terms of ethics approval (appendix 2).

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

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.

Monitoring

All research approved by the SCGOPHCG HREC must adhere to the requirements of the National Statement and the Terms of Approval (see appendix 2) throughout the life of the study. The HREC will monitor the ongoing conduct of research through the review of amendments,

annual and final reporting and safety reporting. Finally, research may be referred to a research monitor for interim assessment.

Amendment

All amendments to research projects must be submitted for review and approval to the lead HREC via RGS.

The HREC Office reserves the right to assess whether an amendment needs to be reviewed by the HREC or whether the amendment can be reviewed out-of-session.

Amendments which do not require review by the HREC may be approved by the Delegate of the Chair and can include, but are not limited to:

- typographical and grammatical corrections to project documentation
- minor changes to project documentation which do not impact on the participant experience
- protocol changes which do not have associated changes to the participant information sheet.

Amendments which have an impact on the participant experience or the management of their data must be reviewed by the HREC. This includes:

- significant changes to recruitment strategies
- significant changes to analysis strategies
- project extensions beyond eight years from original approval.

Investigators are responsible for:

- submitting amendments via RGS
- utilising the appropriate forms
- responding to HREC Office queries in a timely manner.

The HREC Office is responsible for:

- processing complete amendments within 10 working days
- issuing approval letters
- recording all amendments in the appropriate database and/or record keeping system.

Safety monitoring and reporting

Reporting to the SCGOPHCG HREC should be conducted in line with *NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)*

The sponsor, coordinating principal investigator or other member of the research team are responsible for:

- providing an annual safety report to the HREC that provides an adjudicated list of all safety events encountered in the study each year.
- provide an assessment as to whether these events necessitate a change to the protocol or additional safety measure be put in place.

The HREC Office is responsible for:

- reviewing the annual safety report and ensuring the risk-benefit ratio that are reported by the sponsor are compatible with continued ethical approval
- satisfying itself that the sponsor's ongoing safety monitoring arrangements are adequate

The HREC Office reserves the right to acknowledge multiple safety reports for the same study in a single letter.

Annual Progress reports

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.

Failing to submit an annual report will lead to the suspension of approval for research. No amendments will be approved if annual reports are overdue.

Investigators are responsible for submitting:

- an annual report to the lead HREC covering all approved WA Health sites (multi-centre trials)
- a site-specific annual report at each site the study is being conducted
- annual reports on, or prior to, the anniversary of study approval.

The HREC Office is responsible for:

- reviewing all annual reports
- providing acknowledgment of annual reports within 10 working days of receipt.

Final Project Reports

Once all participating sites have been closed through submission of a site final report to the relevant Research Governance Office, a Final Project Report should be provided to the HREC. Final 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 progressed as expected
- whether the aims of the research have been met.

Investigators are responsible for:

- submitting a final report and project summary for all approved WA Health sites to the lead HREC
- submitting all reports in a timely manner
- circulating the final report to all sites at which the study was conducted
- providing the reasons for a decision to discontinue or suspend a study prior to expected completion
- provide evidence on how the safety of participants will be managed if a study has been discontinued or suspended
- notifying the HREC if a suspended study is to be recommenced.

The HREC Office is responsible for:

- reviewing all final reports
- providing acknowledgment of final reports within 10 working days of receipt
- archiving all documents pertaining to the study held within the HREC Office.

Once a final project report has been accepted, the project status will be set to “Closed”. RGS will automatically archive any closed project after five years of inactivity.

Assessment by a Research Monitor

The HREC, or their delegate, may refer any research project being conducted using a SCGOPHCG HREC approval to a research monitor employed by the North Metropolitan Health Service. This monitor may undertake a desktop audit, in-person monitoring visit/s or some combination of these processes to ensure approved research continues to operate in accordance with the National Statement, the HREC and institutional Terms of Approval (see appendix 2) and within the scope of the protocol approved by the HREC.

Ongoing HREC approval is conditional upon compliance with reporting obligations and cooperation with monitoring visits.

Fees

Studies which are fully sponsored or funded by commercial entities, such as pharmaceutical sponsors, attract a submission fee. Fees are payable on submission.

Additional fees may be charged for amendments made throughout the life of the study, if they require review by the HREC or associated subcommittee.

A schedule of fees is outlined in Table 1. These fees will be reviewed every 3 years.

Table 1: SCGOPHCG Schedule of Fees

Type of application	Fee
New Submission – Commercially sponsored clinical trial (Single Site)	$3,500 + GST
Substantive amendments to the study e.g. non-administrative change to the protocol	$600 + GST

These fees are inclusive of GST.

Complaints

The SCGOPHCG HREC complaints policy is established in compliance with the WA Health Complaints Management Policy (MP 0130/20)

All complaints regarding the conduct of research be directed to the HREC office. Complaints will be recorded and processed with outcomes communicated to all parties within the timeframes stated in the WA Health Complaints Management Policy

Where possible, informal complaints should be managed between the HREC secretariat and the complainant. If a complaint cannot be resolved and a formal complaint needs to be lodged it will be recorded, assessed and investigated using the Complaints Management Toolkit.

The HREC Office is responsible for:

- recording all complaints.
- informing the HREC Chair of any complaints immediately
- informing any other relevant parties, including the subject of the complaint, within five working days
- informing the complainant of the outcome of the investigation.

If the complainant is not satisfied with the outcome of the Chairperson's investigation, then they can refer the complaint to the Executive Director.

The Executive Director will determine whether there is to be a further investigation of the complaint. Where no further investigation is to occur, the Executive Director will inform the complainant and the Chairperson of this.

Record Keeping

Research records

All records are maintained electronically and disposed of in accordance with Section 5.2.24 of the *National Statement* and the SCGH Records Management Policy.

Investigators are responsible for maintaining comprehensive records of all study material and procedures in line with the *State Records Act 2000* and *WA Department of Health Retention and Disposal Schedule for Administrative and Functional Records 2007*.

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

Confidentiality

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

Only those 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 HREC via an amendment.

Any investigators wishing to give individuals who are not involved in their research access to details of their application are required to confirm these intentions to the HREC.

Appendix 1 – Conditions of Ethics Approval

CONDITIONS OF ETHICS APPROVAL FOR A RESEARCH PROJECT

The following general conditions apply to the research project approved by the Human Research Ethics Committee (HREC) and acceptance of ethical approval will be deemed to be an acceptance of these conditions by all project investigators:

1. The responsibility for the conduct of this project lies with the Coordinating Principal Investigator (CPI).
2. The investigators recognise the reviewing HREC is registered with the National Health and Medical Research Council and that it complies with the current version of the National Statement on Ethical Conduct in Human Research.
3. A list of HREC member attendance at a specific meeting is available on request, but no voting records will be provided.
4. The CPI will immediately report anything that might warrant review of ethical approval of the project.
5. The CPI will notify the HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments to approved documents, or any new documents, for ethics approval. Amendments cannot be implemented at any participating site until ethics approval is given.
6. The CPI will submit any necessary reports related to the safety of research participants in accordance with the WA Health Research Governance Standard Operating Procedures.
7. Where a project requires a Data Safety Monitoring Board (DSMB), the CPI's will ensure this is in place before the commencement of the project and notify the HREC. All relevant reports from the DSMB should be submitted to HREC.
8. For investigator-initiated and collaborative research group projects the CPI may take on the role of the sponsor. In this case, the CPI is responsible for reporting to the Therapeutic Goods Administration (TGA) any unexpected serious drug or device adverse reactions, and significant safety issues in accordance with the TGA guidelines.
9. If the project involves the use of an implantable device, the CPI will ensure a properly monitored and up to date system for tracking participants is maintained for the life of the device.
10. The CPI will submit a progress report to the HREC annually from the ethics approval date and notify the HREC when the project is completed at all sites. The HREC can request additional reporting requirements as a special condition of a research project. Ethics approvals are subject to the receipt of these reports and approval may be suspended if the report is not received.
11. The CPI will notify the HREC of his or her inability to continue as CPI and will provide the name and contact information of their replacement. Failure to notify the HREC can result approval for the project being suspended or withdrawn.
12. The CPI will notify the HREC of any changes in investigators and/or new sites that will utilise the ethics approval.
13. The HREC has the authority to audit the conduct of any project without notice if some irregularity has occurred, a complaint is received from a third party or the HREC decides to undertake an audit for quality improvement purposes.
14. The HREC may conduct random monitoring of any project. The CPI will be notified if their project has been selected. The CPI will be given a copy of the monitor's report along with the HREC and Research Governance (RG) Office at the site/s.
15. Complaints relating to the conduct of a project should be directed to the HREC Chair and will be promptly investigated according to the WA Health's complaints procedures.

16. The CPI should ensure participant information and consent forms are stored within the participant's medical record in accordance with the WA Health's Record Keeping Plan.
17. The CPI will notify the HREC of any plan to extend the duration of the project past the expiry date listed above and will submit any associated required documentation. A request for an extension should be submitted prior to the expiry date. One extension of 5 years may be granted but approval beyond this time period may necessitate further review by the HREC.
18. Once the approval period has expired or the project is closed, the CPI will submit a final report. If the report is not received within 30 days the project will be closed and archived.
19. Projects that do not commence within 12 months of the approval date may have their approval withdrawn and the project closed. The CPI must outline why the project approval should remain.
20. The CPI will notify the HREC if the project is temporarily halted or prematurely terminated at a participating site before the expected completion date, with reasons provided. Such notification should include information as to what procedures are in place to safeguard participants.
21. If a project fails to meet these conditions the HREC will contact the CPI to address the identified issues. If, after being contacted by the HREC, the issues are not addressed, the ethics approval will be withdrawn. The HREC will notify the RG Office at each site within WA Health that the project procedures must discontinue, except for those directly related to participant's safety.

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