Government of **Western Australia**
Department of **Health**

WA Health Central Human Research Ethics Committee

Standard operating procedures

28 May 2024

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Purpose

The purpose of these Standard Operating Procedures (SOPs) is to guide the process of ethical review for research involving human participants, their data and/or biospecimens within the Western Australian (WA) Health System. These SOPs specifically relate to the operation of the WA Health Central Human Research Ethics Committee (HREC).

These SOPs outline the responsibilities and functions of 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 are available from the relevant institution's website.

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* (MP 0156/21) were implemented to ensure that all human research conducted within WA Health meet the highest ethical, scientific, regulatory, and professional governance standards. These policies and procedures also aim 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.

The WA Health Central HREC assesses submissions against the guidelines developed by the National Health and Medical Research Council (NHMRC) known as The *National Statement on Ethical Conduct in Human Research* (*National Statement*).

All research projects that are conducted at a WA Health site, or use WA Health data, biospecimens or resources, require ethical and scientific review.

All research project submissions are to be made *via* the Research Governance Service (RGS) regardless of the risk level posed by the proposed research (SOP 15 (*Application Requirements)*).

Alternative review pathways

Lower risk research

The *National Statement* defines lower risk research as "*research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden."* Furthermore, the *National Statement* defines minimal risk research as "research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience."

The Lower Risk Review (LRR) Panel and the Central Office for Research Ethics (CORE) will have the responsibility of determining if a project is eligible for LRR.

The ethical review process for lower risk research being conducted across the WA Health System is provided in SOP 6.2 (*Lower Risk Review Pathway*).

Non-research activity

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

Projects that are a non-research activity are exempt from the full ethical and scientific review process outlined in this document. These projects should be submitted for review via the review processes in place at the institution where the project will be conducted (SOP 6 *Proportional Ethical Review*).

Approval to conduct human research projects at WA Health sites

The WA Health System has a two-tiered system for approval to conduct human research projects. It comprises:

- An ethical review by an appropriate Human Research Ethics Committee (HREC).
- A research governance review, also known as a site-specific assessment.

Approval by both a HREC (ethics approval) and the delegated authority of the institution(s) where the project will be conducted (site authorisation) is necessary before research can commence.

A letter of ethical approval from an appropriate HREC must be provided before the governance review can be completed and site authorisation granted. To avoid delays in review processes, governance review submission forms may be drafted while the ethical review process is underway.

Ethical review

The primary role of the WA Health Central HREC is to protect the welfare and rights of participants in human research projects conducted within the WA Health System and does so in accordance with the *National Statement*.

In July 2012 (updated 2021), the WA Department of Health (the Department) implemented a standardised set of procedures and policies and template forms to cover the review and approval of research within WA Health. Further information is available here: *Research Policy Framework*.

The WA Health Central HREC may, as necessary, co-opt or access experts to assist in the review of research. This may involve attendance at meetings.

The members of the WA Health Central HREC shall be appointed (or re-appointed) by the Director General, WA Department of Health (DG) for a term of up to three years. The term of appointment of each Committee member shall commence from the date of the member's appointment. Members of the Committee may be reappointed for one or more terms.

All members of the Committees will be fully aware of (but not limited to) the following:

- *National Statement*.
- Terms of Reference for the WA Health Central HREC
- *Australian Code for Responsible Conduct in Research* (The Code).
- New Member Information.
- Membership list.
- Meeting dates.
- *Good Clinical Practice (GCP) for Clinical Trials in Australia.*

New HREC members shall familiarise themselves with the *National Statement* and other local policies and procedures. All members shall be provided with opportunity to attend on-going training.

The National Mutual Acceptance (NMA) scheme has been implemented in public health organisations within the Australian Capital Territory, New South Wales, Queensland, South Australia, Western Australia, Tasmania, Victoria, and the Northern Territory. Under the NMA, all multi-centre research projects being conducted at public health organisations within the participating jurisdictions must be ethically and scientifically reviewed only once by a Lead HREC from a NHMRC certified institution participating in the NMA. More information on submitting an application through the NMA scheme can be found in SOP 14.2 (*Inter-Jurisdictional Ethical Review - National Mutual Acceptance (NMA)*) and on the *RGS website.*

Research governance review

Research governance is a framework through which each institution is accountable for the scientific quality, ethical acceptability, and safety of the research they sponsor or permit to occur under their auspices. It is a risk management activity that facilitates standards of research practice and allows for a more detailed and institutionally relevant review of research applications.

The Research Governance Officer (RGO) provides an independent systematic evaluation of research applications, which ensures the safety, and minimises the risk, for the participant, the researcher, and the institution. The RGO then provides a recommendation to the health service executive regarding whether the project should be given authorisation to be conducted at that site.

Research governance review is a site-specific activity conducted by RGOs employed by the Health Service Provider (HSP) which has responsibility for the site(s) where the project will be conducted. A research governance review determines if a project can be conducted at the site(s) specified. It is not to be confused with the ethical review conducted by the WA Health Central HREC that determines if the project is ethically and scientifically sound.

Other approvals required to conduct research in the WA health system

Aboriginal or Torres Strait Islander Peoples

Research involving Aboriginal or Torres Strait Islander Peoples may require additional specialist approval from the *WA Aboriginal Health and Ethics Committee* (WAAHEC). For more information, refer to SOP 5.3 (*WA Aboriginal Health Ethics Committee*).

Access to coronial data or information

All human research projects that require access to coronial data or information must obtain endorsement from the National Coronial Information System and ethical approval from the *Justice Human Research Ethics Committee* in addition to the approval of the WA Health Central HREC. For more information, refer to SOP 5.4 (*Access to Coronial Data or Information*).

WA Health data collections

Research that requires access to WA Health data collections and/or involves data linkage should be submitted to the WA Health Central HREC for review. However, given the specific requirements around data custodian approvals that must be in place prior to ethical review it is advisable that researchers explore *Resources - Data Linkage Services WA* for further information on accessing WA Data sets.

Research involving access to linked health data from PeopleWA must first undergo their review process before a submission can be made to the WA Health Central HREC. For more information, please contact PeopleWA at *PeopleWA@dpc.wa.gov.au* or refer to their *website*.

Where data linkage *via* the Population Health Research Network (PHRN) is being sought, researchers should contact the PHRN team at the University of Western Australia to discuss data application requirements and whether the request is viable. More detail on the process for applying for the use of data linked by the PHRN can be found on the *PHRN* website.

For more information on application requirements for projects involving access to WA Health data sets and/or data linkage, refer to SOP 18.2 (*Data Governance*).

Access to WA Department of Justice data, facilities, staff, and/or clients

All human research projects that require access to WA Department of Justice data, facilities, staff, and/or clients must obtain endorsement from the Department of Justice's Research Application and Advisory Committee (RAAC) in addition to the approval of the WA Health Central HREC. For more information, refer to SOP 5.5 (*Access to WA Department of Justice data, facilities, staff, and/or clients*).

The WA Health Central HREC as an institutional review board and federal wide assurance

Research funded by the National Institutes of Health (NIH) must be approved by an Institutional Review Board (IRB) that is registered with the Office of Human Research Protections (OHRP) in the United States of America (USA). The WA Health Central HREC is registered as an IRB with the OHRP.

The organisation conducting the research must also have a Federal Wide Assurance (FWA) that is also issued by the OHRP.

Both the IRB registration and FWA are renewed on a regular basis as required by the USA authorities.

Details of the IRB registration number is available from the CORE on request. Please contact the relevant site RGO to ascertain the FWA registration number.

Registration of clinical trials

The International Committee of Medical Journal Editors (ICMJE) member journals require registration in a public trials' registry as a condition of consideration for publication. The ICMJE does not advocate one registry, but its member journals will require authors to register their trial in a registry that meets several criteria:

- must be accessible to the public at no charge.
- must be open to all prospective registrants.
- must be managed by a not-for-profit organisation.
- must be a mechanism to ensure the validity of the registration data.
- should be electronically searchable.

An acceptable registry must include the following information as a minimum:

- a unique identifying number.

- a statement of the intervention and comparison studied.
- a statement of the study hypothesis.
- definitions of the primary and secondary outcome measures.
- eligibility criteria.
- key trial dates (registration date, anticipated or actual start date, anticipated or actual date of last follow-up, planned or actual date of closure to data entry, and date trial data considered complete).
- target number of subjects.
- funding source.
- contact information for the principal investigator.

To be eligible for publication, trials must register at or before the onset of patient enrolment. Registries recognised by ICMJE include:

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

Abbreviations

Acronym	Term
CALD	Culturally and linguistically diverse
CORE	Central office for research ethics
CPI	Coordinating principal investigator
Department	Wa department of health
DG	Director general, wa department of health
DSMB	Data safety monitoring board
EEO	Ethics executive officer
GCP	Good clinical practice
GEKO	Governance evidence knowledge and outcomes
GP	General practitioner
HREA	Human research ethics application
HREC	Human research ethics committee
HSP	Health service provider
ICH	The international council for harmonisation
IRC	Incident review committee
IT	Information technology
LRR	Lower risk review
National Statement	National statement on ethical conduct in human research
NHMRC	National health and medical research council
NIH	National institutes of health
NMA	National mutual acceptance
OMRI	Office of medical research and innovation
RGO	Research governance officer
RGS	Research governance service
SOP	Standard operating procedures
SSI	Significant safety issue
SUSAR	Sudden unexpected serious adverse reaction
TGA	Therapeutic Goods Administration

Acronym	Term
The Code	The australian code for responsible conduct in research
TOR	Terms of reference
USA	United states of america
USADE	Unexpected serious adverse device effect
USM	Urgent safety measure
WA	Western australia
WAHEAF	Wa health ethics application form
WASM	Western australian specific module

Note:

The WA Health Central HREC (hereafter referred to as the Central HREC) is a single committee which holds up to six meetings every four weeks.

The Chair of the Central HREC and those Central HREC members who are delegated by the Chair to act as the Chairperson for meetings of the Central HREC will be referred to collectively as the 'Chair" unless specified otherwise. Where the following Standard Operating Procedures (SOPs) describe actions pertaining to a specific project, 'Chair' will refer to the person who oversaw the meeting where the project was first reviewed.

1 Purpose and structure of the WA Health Central HREC

1.1 Purpose

Human research is broadly defined by the *National Statement* as research "with or about people, or their data or tissue."

1.1.1. The primary function of the Central HREC is to protect the welfare and rights of participants in all human research activities that occur under the purview of any WA Health Service Provider (HSP) and/or seek access to record level information from an information system held or linked by the WA Department of Health (the Department).

1.1.2. To approve a research project, the Central HREC must be satisfied that the proposed project is:

- ethically sound according to the principles of merit, integrity, justice, beneficence, and respect as specified in the *National Statement*.
- scientifically sound, designed using methods appropriate for achieving the aims of the research proposal and based on a thorough study of current and historical literature.

1.2 Structure

The Central HREC is appointed by and reports to the DG. Further information regarding the accountability of the Central HREC can be found in the terms of reference, available on the WA Health Central HREC website.

1.2.1 The Central HREC will hold up to six meetings every four weeks; each one overseen by the Chair of the Central HREC or their delegate and established in accordance with the requirements laid out in the *National Statement*.

1.2.2 One of the six scheduled meetings will focus on the review of research involving Mothers and the foetus, Infants, Children, and Adolescents (MICA).

1.2.3 Another one of the six scheduled meetings will focus on the review of research projects seeking access to WA Health Data Sets and Data Linkage.

1.2.4 The four remaining meetings will assess all types of projects and will meet on rotation (one meeting per week for the duration of each four-week meeting cycle).

1.2.5 All members and subject matter experts of the Central HREC will work closely together, receive training centrally and be available to attend any meeting of the Central HREC to promote consistency of review.

1.2.6 The Chair of the Central HREC and their delegates will meet regularly to discuss the functioning of the Central HREC and any changes that may be required to practice or process.

Figure 1. Structure of the WA Health Central HREC.

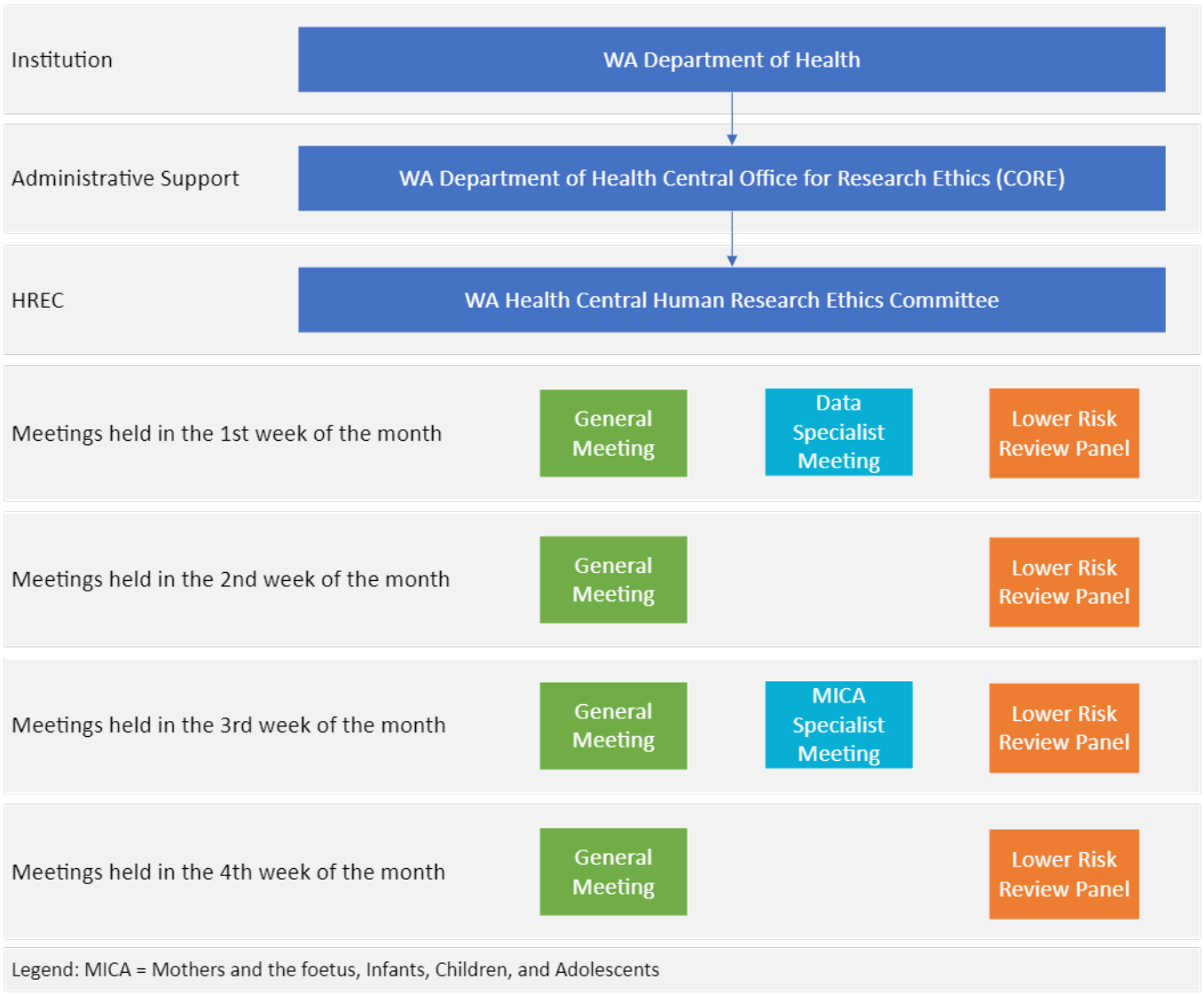
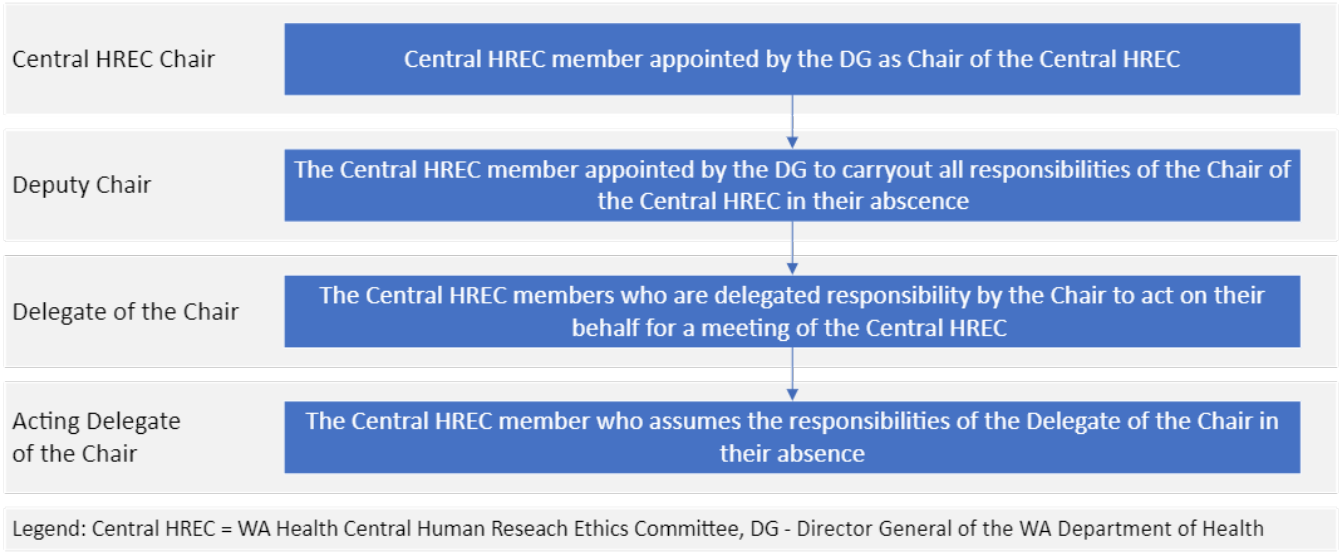


Figure 2. Delegation of responsibility



2 WA Health Central HREC membership

2.1 Membership

2.1.1 The Central HREC will be populated, in accordance with the *National Statement*, from a pool of members sufficiently large enough to responsibly fulfill the meeting schedule laid out in SOP 3 (*Conduct of Meetings*).

2.1.2 Each meeting of the Central HREC will comprise of the minimum membership that constitutes an HREC (as defined by Section 5.1.30 of the *National Statement*) and will occur once in each four week meeting cycle.

2.1.3 To supplement the minimum membership, subject matter experts will be appointed as members and will attend specific meetings as and when their expertise is required. The subject matter experts will be called upon approximately once a month to avoid unduly burdening individual members (Section 5.1.26 (i), *National Statement*).

2.1.4 Members will be expected to participate in relevant specialised working groups as required.

2.1.5 In the case that the Central HREC requires expert knowledge from outside the membership pool, relevant external experts will be consulted on an *ad hoc* basis (SOP 3.8 (*Expert Reviewers*)).

2.1.6 The Chair will be expected to be available between meetings to participate in *ad hoc* reviews where required.

2.1.7 In the absence of the Chair of the Central HREC, their delegate, or the Deputy Chair of the Central HREC, an Acting Delegate of the Chair will perform the role and duties of the Chair at a specific meeting.

2.1.8 The Chair of the Central HREC, their delegates, the Deputy Chair and any Acting Delegate of the Chair will conduct themselves in accordance with the criteria set out in the *National Statement* and Central HREC Terms of Reference, including:

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

2.2 Appointment

2.2.1 Members are appointed as individuals for their knowledge, qualities, and experience and not as representatives of any organisation, group, or opinion.

2.2.2 Prospective members of the Central HREC may be recruited by direct approach, nomination, or by advertisement for Expressions of Interest. Prospective members will be asked to provide a copy of their Curriculum Vitae and a valid Good Clinical Practice certificate.

2.2.3 Prospective members may be invited to attend a committee meeting as an observer and will be subject to a duty of confidentiality in relation to the proceedings of that meeting.

2.2.4 Members must have basic computer skills as well as access to the internet, a private email address and printing resources for the purpose of reviewing applications, project amendments and responding to out of session queries.

2.2.5 The positions within the Central HREC are fixed term, three-year appointments. Recruitment is staggered to ensure continuity of expertise and knowledge.

2.2.6 Members are recruited and appointed to these fixed term positions as they become vacant. Members may be re-appointed for additional terms if they desire and with approval from the DG.

2.2.7 Deputy members are appointed to each Committee to provide category representation in accordance with the *National Statement* when the relevant member is unable to attend meeting(s). Deputy members are appointed to fixed term sitting deputy positions as they become vacant. Deputy members may only serve two consecutive terms unless otherwise approved by the DG.

2.2.8 The Chair and Deputy Chair of the Central HREC, members, and deputy members are appointed by the DG on the recommendation of the CORE and in consultation with other senior officials within the Department, as deemed appropriate.

2.2.9 New members will receive a formal notice of appointment which will include:

- the date of appointment.
- length of tenure.
- assurance that indemnity will be provided in respect of liabilities that may arise during *bona fide* conduct of their duties as a committee member.
- the circumstances whereby membership may be terminated, and
- the conditions of their appointment.

2.2.10 Upon appointment, members will be provided with the following documentation:

- Terms of Reference (TOR).
- Standard Operating Procedures (SOPs).
- An up-to-date list of members' names and contact information including that of the Central Office of Research Ethics (CORE) Ethics Officers (EOs).
- *National Statement.*
- *Australian Code for the Responsible Conduct of Research.*
- *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for researchers and stakeholders (2018).*
- *Keeping Research on Track (2018).*
- *Guidelines approved under s95 and s95A of the Privacy Act 1988 (2014).*
- International Council for Harmonisation's Guidelines for Good Clinical Practice (ICH GCP)
- The WA Department of Health *Information Access, Use and Disclosure Policy.*
- The latest reports on the Committee's activities.
- RGS Training Manual.
- Any other relevant information about the Committee's processes, procedures, and protocols.

2.2.11 Members will be required to sign a confidentiality form upon appointment, stating that all matters of which they become aware during their work on the Central HREC will be kept confidential.

2.2.12 Members will be required to declare any conflicts of interest which exist, are perceived, or may arise during their tenure on the Central HREC.

2.2.13 Members will be required to confirm that they have not been subject to any criminal conviction or disciplinary action which may prejudice their standing as a member.

2.3 Orientation and training

2.3.1 New members must be provided with adequate orientation and are expected to attend training sessions as soon as practicable after their appointment.

2.3.2 Reasonable costs associated with attendance at training and education sessions will be met in accordance with the *Department's Consumer, Carer, and Community Paid Participation in Engagement Activities Policy*.

2.3.3 Orientation of new members may involve:

- introduction to other members at the next available and appropriate Central HREC meeting.
- informal meeting with the Chair, their delegate, or the Deputy Chair and a member of the CORE to explain the responsibilities as a committee member, including processes and procedure.
- the opportunity to sit in on meetings before their appointment takes effect.
- 'partnering' with another member in the same category.
- priority access to training sessions.

2.4 Remuneration and leave of absence

2.4.1 Members will be remunerated at the rate described in the Department's *Consumer, Carer, and Community Paid Participation in Engagement Activities Policy*.

2.4.2 Members may seek a leave of absence from the Central HREC for extended periods. Steps will be taken to fill the vacancy as required.

2.5 Resignation of membership

2.5.1 A member may resign at any time upon giving notice in writing to the Chair of the Central HREC or their delegate. A period of 4 weeks' notice is required. Steps will be taken to fill the vacancy of the former member as soon as possible. Where a member resigns, the appointment of the new member will be for the remaining term of the fixed term position.

2.6 Termination of membership

2.6.1 Membership will lapse if a member fails without reasonable explanation, or without notifying the Chair of the Central HREC, to attend three consecutive meetings where their attendance is expected, or if the member fails to attend in full at least 7 meetings in each year, where their attendance is expected, unless there are exceptional circumstances. The Chair of the Central HREC will notify the member, in writing, of such lapse of membership. The Chair of the Central HREC will initiate the process to appoint a new member to fill the vacancy of the lapsed member.

2.6.2 The DG or their delegate may terminate the appointment of any member at the recommendation of the Chair of the Central HREC if:

- it is necessary for the proper and effective functioning of the Central HREC.
- the person is not a fit and proper person to serve on the Central HREC.
- the person has failed to carry out their duties as a member of the Central HREC.

3 Conduct of meetings

3.1 Attendance

3.1.1 The Central HREC will meet on a regular basis, with weekly meetings occurring February to mid-December each year. Meeting dates will be publicly available on the WA Health Central HREC website and on the RGS website.

3.1.2 Members may attend meetings in person, *via* teleconference, or video link.

3.1.3 Members who are unable to attend must submit their written comments in lieu of attendance. Those written comments will be provided to the other members prior to or at the meeting. These comments should be received by the CORE at least three working days prior to the meeting so that copies may be made available to members in advance of the meeting. The minutes should record the submission of written comments.

3.1.4 Members unable to attend a meeting are to notify the CORE as soon as possible to ensure their apologies can be tendered at the meeting.

3.1.5 Central HREC meetings will be conducted in private, to ensure confidentiality and open discussion. Members will be advised of the meeting room and video conference details in the meeting agenda.

3.2 Quorum

3.2.1 Where there is less than full attendance at a meeting, the Chair must be satisfied, before a decision is reached, that the minimum membership listed in the *National Statement* have received all the papers and have had an opportunity to contribute their views in writing and that those views have been recorded.

3.2.2 A quorum will exist when all 8 members are present (either in person, teleconference/videoconference, or by providing comments in advance of the meeting), including one of each of the following categories:

- Chair/Acting Delegate of the Chair,
- two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution,
- a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor, or allied health professional,
- a person who performs a pastoral care role in a community,
- a qualified lawyer who may or may not be currently practicing,
- two people with current research experience that is relevant to research proposals.

At least one third of those present must be from outside the WA Health system.

3.2.3 A quorum must be present for the Central HREC to reach a final decision on any agenda item.

3.2.4 The Chair may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the Central HREC will reconvene the meeting within five working days of the cancelled meeting to ensure all agenda items are considered.

3.2.5 If the meeting does not achieve quorum, the Chair may decide it can proceed but only in exceptional circumstances. In such circumstances, decisions made at the meeting must be ratified by at least one representative from those membership categories not present, within five working days.

3.2.6 Where the CORE is concerned that a forthcoming meeting will not be attended by a quorum of members, the CORE will notify the Chair and the following options will be considered:

- postponing and re-arranging the meeting,
- cancelling the meeting.

3.3 Meeting schedule

3.3.1 Meetings will be scheduled for an allocated time.

3.3.2 If the business of a Central HREC meeting has not been completed within the allocated time, then the meeting may either continue until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called for, then the meeting should be held within five working days.

3.4 Meeting agenda

3.4.1 The meeting agenda and associated documents will be prepared by the CORE and made available *via* the RGS to all members at least 7 calendar days prior to the meeting.

3.4.2 All complete and valid applications and relevant documents received through the RGS will be included on the agenda for consideration at the next relevant meeting.

3.4.3 Documentation received after the agenda has been disseminated will be tabled at the next appropriate meeting at the discretion of the Chair and/or EO.

3.4.4 Agenda items will include the following items at a minimum:

- apologies.
- confirmation of quorum.
- conflicts of interest.
- minutes of the previous meeting.
- business arising from the previous minutes.
- new applications.
- amendments to approved projects.
- monitoring reports.
- other business.
- close and next meeting.

3.5 Meeting minutes

3.5.1 The CORE will prepare and maintain minutes of all Central HREC meetings within RGS in accordance with Section 5.1.37 of the *National Statement.*

3.5.2 The minutes will include at least the following at a minimum:

- attendance.
- apologies.
- confirmation of quorum.
- conflicts of interest.
- minutes of the previous meeting.
- business arising from the previous minutes.
- new applications.
- amendments to approved projects.
- monitoring reports.
- other business.
- close and next meeting.

3.5.3 The minutes will record the decisions taken by the Central HREC as well as a summary of relevant discussion, including reference to any views expressed by absent members.

3.5.4 To encourage free and open discussion and to emphasise the collegiate character of the Central HREC, particular views should not be attributed to individuals in the minutes, except in circumstances where a member and/or expert reviewer requests their opinions or objections are recorded.

3.5.5 In recording a decision made by the Central HREC, the occurrence of a dissent should be minuted and, with the agreement of the dissenting member(s), the reason(s) for dissent should also be minuted.

3.5.6 In relation to the review of new applications and amendments, the minutes will record a summary of the main ethical issues considered, including any requests for additional information, clarification, or modification of the project. Where possible, reference to the *National Statement* should be made.

3.5.7 Declarations of a conflict of interest by any member of the Central HREC and the absence of the member concerned during the deliberation of the relevant matter will be minuted.

3.5.8 The minutes will be produced as soon as practicable following the relevant meeting and should be reviewed by the Chair for accuracy.

3.5.9 The minutes will be circulated to all members of the meeting as an agenda item for the next appropriate meeting.

3.5.10 All members will be given the opportunity to seek corrections to the minutes prior to their ratification.

3.5.11 The minutes will be ratified at the next appropriate meeting.

3.6 Notification of decisions

3.6.1 The Central HREC and CORE EOs will endeavour to complete the ethical review within a 60-calendar day timeframe, which allows for a ‘stop clock’ capability when additional input is required from a sponsor or researcher before consideration can continue.

3.6.2 The Central HREC will advise the Coordinating Principal Investigator (CPI) or their delegate in writing whether the application has been granted ethical approval (including any conditions of approval) within five working days of the meeting, unless otherwise notified.

3.6.3 The Central HREC reserves the right to request the resubmission of a project if there are substantial issues identified in the review.

3.6.4 If the Central HREC determines that further information, clarification, or modification is required for the consideration of a project, the correspondence to the CPI should articulate the reasons for this determination, and clearly set out the information that is required.

3.6.5 Where possible, requests for additional information/clarification/modification should refer to the *National Statement* or relevant legislation.

3.6.6 The Central HREC will communicate openly with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues.

3.6.7 The Central HREC will only notify the applicant of ethical approval of a project once all outstanding requests for additional information or modification have been resolved.

3.6.8 If the requested information is not received from the applicant within three months, the application may be dismissed, and the applicant will be required to resubmit the project application in full.

3.6.9 Notification of ethical approval will be in writing *via* the RGS, and will contain the following information:

- title of project.
- name of the CPI.
- unique RGS project identification number.
- date of Committee meeting at which the project was considered.
- date and duration of Committee approval.
- a list of approved project documents.
- explicit approval of waiver of consent if any.
- explicit approval to include incapacitated adults as participants in the research under the provisions of the Guardianship and Administration Act 1990, Part 9E (GAA)
- a list of approved, but not authorised sites.
- a list of special conditions, if any, and
- conditions of Committee approval, if any.

3.6.10 The Central HREC's approval is granted for three years with option for five years if justified, except where action is taken to suspend or terminate the decision. The Committee has the authority to set a shorter approval period dependent upon the risk and complexity of the project.

3.6.11 If the Central HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the *National Statement* or other relevant pieces of legislation, where applicable.

3.6.12 A lay summary of the approved project will be made publicly available on the WA Health Central HREC website, with the consent of the CPI.

3.7 Guests and observers

3.7.1 Researchers are encouraged to attend the relevant meeting to discuss any issues relating to their project to minimise the need for correspondence after the meeting. Once the

Central HREC's questions/concerns have been addressed, the researcher will be required to leave the room prior to any decisions being made. The researcher's presence should be noted in the minutes against the item(s) they discussed.

3.7.2 The Central HREC may agree to the presence of visitors or observers, other than researchers wishing to discuss their projects, to a meeting. The presence of observers or visitors and the agenda items they observed will be minuted.

3.7.3 Any invited observers are bound by the same confidentiality requirements as full Central HREC members and will be requested to complete a Confidentiality Agreement prior to their attendance at the meeting.

3.8 Expert reviewers

3.8.1 Section 5.1.38 of the *National Statement* allows a HREC to seek external expertise to facilitate the ethical and scientific review of research projects.

3.8.2 A pool of expert reviewers with the requisite skills required to review a wide range of human research projects will be available to the Central HREC. The pool will be maintained by the CORE.

3.8.3 As per SOP 2.1.5, if the expertise sought is not available among the members of the pool the CORE will seek the opinion of an external expert in consultation with the Chair.

3.8.4 Appropriate expert reviewers will be contacted by the CORE and asked to provide written comments and/or attend the relevant meeting, at least 7 calendar days prior to the meeting.

3.8.5 Written comments should be received at least three working days prior to the meeting so that copies may be made available in advance to members.

3.8.6 Expert reviewers who are invited to attend a meeting should only be present for the discussion of the projects they have been asked to review and must withdraw from the meeting before a decision is made. Attendance at the meeting and the content of the advice given to the Central HREC should be minuted.

3.8.7 Expert reviewers are bound by the same confidentiality and conflict of interest requirements that apply to members.

4 Conflict of interest

4.1 HREC members

4.1.1 Any member of the Central HREC who has any actual or perceived conflict of interest, financial or otherwise, in a project or any other related matter(s) that is to be considered by the Central HREC must declare such an interest as soon as practicable.

4.1.2 If the member is present at the meeting which will consider the project, or any other matter, which is the subject of their conflict of interest (financial or otherwise) the member must inform the Chair as soon as practicable.

4.1.3 If a member has an actual or perceived conflict of interest related to a matter before the Central HREC, the member will withdraw from the meeting until the meeting completes its consideration of the relevant matter. The member will not participate in the discussions and will not be entitled to participate in the decision on the matter.

4.1.4 If the Chair has a conflict of interest, an Acting Delegate of the Chair is to assume the role as Chair during this time.

4.1.5 Both the declaration of a conflict of interest and the absence of the member concerned will be minuted.

4.1.6 If a Central HREC member has an actual or perceived conflict of interest in a project they have been asked to review they must, as soon as practicable, recuse themselves from the review of that application. The CORE will then appoint another suitable committee member to review the project. The CORE will document the conflict of interest and that the member recused themselves from the review in the meeting minutes.

4.1.6 Any breach of the above process will be managed as per the *WA Health Managing Conflicts of Interest Policy (MP0138/20)* and in accordance with the *WA Health Discipline Policy (MP 0127/20)* whereby a member may have their appointment to the Committee terminated.

4.1.7 More detailed information around managing conflicts of interest in research occurring in the WA Health System should refer to the:

- *National Statement.*
- *Australian Code for Responsible Conduct of Research (2018).*
- *WA Health Managing Conflicts of Interest Policy (MP 0138/20).*
- *WA Health Managing Conflicts of Interest Information.*
- *WA Health Research Governance Policy and Procedures (MP 0162/21).*

4.2 Researchers

4.2.1 Any project team member who has a personal or professional interest that may constitute an actual or perceived conflict of interest must complete a Conflict of Interest Form in the Declarations Tab of the project's RGS workspace as soon as they become aware of the conflict. The following must be described:

- The nature of the conflict of interest.
- Proposed actions to resolve or manage the conflict.

4.2.2 It is the responsibility of the researcher to include declarations of a conflict of interest as part of the submission for ethical approval of the project concerned.

4.2.3 If the Conflict of Interest arises during the conduct of the project the researcher must advise the Central HREC as soon as is practicable *via* an amendment in the RGS. The amendment will be tabled at the next appropriate Central HREC meeting.

4.2.4 Ethical approval may, in some circumstances, be suspended until the conflict of interest is mitigated in a way that satisfies the Central HREC.

5 Considerations in ethical review

5.1 Assessment of applications

5.1.1 The Central HREC will consider a new application at the next available and appropriate meeting provided that the application is complete as determined by the CORE during the validation process.

5.1.2 The application will be reviewed by all members present at the meeting or by providing written comments in lieu of attendance.

5.1.3 The Central HREC will assess each application in accordance with the:

- *National Statement.*
- *Australian Code for the Responsible Conduct of Research (2018).*
- *NHMRC Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2018).*
- *Keeping Research on Track (2018).*
- *Information Access Use and Disclosure Policy.*
- *Guidelines approved under s95 of the Privacy Act 1988 (2014).*
- *Guidelines approved under s95A of the Privacy Act 1988 (2014).*
- *Guidance document: Involving Incapacitated Adults in Health and Medical Research* (Application of the Guardianship and Administration Act 1990 in WA).
- any other applicable principles or guidelines required by the NHMRC, legislation or industry standard.

5.1.4 The Central HREC must ensure that it is sufficiently informed on all aspects of a project protocol, including its scientific validity, to make an ethical assessment.

5.1.5 Where the project involves an application for record level information from an information system held or linked by the Department, the Central HREC will consider the information governance reports provided by Information and System Performance Directorate (ISPD) Client Services.

5.1.6 The Central HREC will consider whether an advocate for any participant or group of participants should be invited to the relevant meeting to ensure informed decision making.

5.1.7 The Central HREC will consider whether the project adequately takes account of consumer and community perspectives, where relevant, with reference to NHMRC's Statement on Consumer and Community Involvement in Health and Medical Research.

5.1.8 Where the project involves the targeted recruitment of persons who require assistance with the English language (e.g., culturally, and linguistically diverse and visual or hearing-impaired patients), the Central HREC will ensure that the participant information is made available in an accessible format.

5.1.9 The Central HREC, after consideration of an application, will make one of the following decisions:

- it will approve the project as being ethically acceptable, with or without conditions.
- it will defer deciding on the project until the clarification of information or the provision of further information to the Committee.
- it will request modification of the project.
- it will reject the application for ethical review.

5.1.10 The Central HREC will endeavour to reach a decision concerning the ethical acceptability of a project by general agreement or consensus.

5.1.11 While voting is neither required nor prohibited by Section 5.2.8 of the *National Statement*; when the Central HREC is acting in its role as an IRB, *US Federal regulation 45 CFR Part 46 Subpart A* requires that IRB members vote on applications. The votes for and against an application must be recorded in the meeting minutes.

5.1.12 Where a general agreement or consensus cannot be reached, the decision will be carried by a majority of two-thirds of members who examined the project provided that the majority includes at least one layperson.

5.1.13 The occurrence of a dissent should be minuted and, at the request of the dissenting member(s), the reasons for dissent should also be minuted.

5.1.14 For projects where the Central HREC has requested clarification, the provision of further information, or modification of the project, the Central HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:

- the Chair alone, or
- the Chair, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application.

In such circumstances, the Central HREC will be informed at the next appropriate meeting, of the final decision taken on its behalf, including the applicant's response and the reason for the decision taken.

5.1.15 The Central HREC may decide that the information should be considered at a further meeting.

5.1.16 The Central HREC may consult with any person(s) they consider to be qualified to provide advice and assistance in the review of any project proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) may not be entitled to vote on any matter.

5.1.17 The Central HREC may consider the views or opinion of another HREC in relation to a project.

5.2 Participant groups requiring additional consideration

5.2.1 As per *National Statement* Chapter 4, there are specific groups of participants that require special consideration if they are to be included in the proposed research.

5.2.2 The composition of the Central HREC meeting that is reviewing a project involving participants belonging to the groups identified in *National Statement* Chapter 4 should ensure they have the requisite expertise either present in the membership or as an external expert reviewer.

5.2.3 The Central HREC must be satisfied that all relevant sections of *National Statement* Chapter 4 have been fulfilled in the study documentation and that the appropriate risk mitigation strategies and special considerations are in place.

5.3 WA Aboriginal Health Ethics Committee

5.3.1 Ethical approval from the *WA Aboriginal Health Ethics Committee* (WAAHEC) is required in addition to the approval of the Central HREC when:

- the research is related to health and wellbeing; and
- the experience of Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research; or
- data collection is explicitly directed at Aboriginal people; or
- research outcomes explicitly related to Aboriginal people; or
- it is proposed to conduct sub-group analysis or separately analyse Aboriginal people in the results; or
- the information, potential over-representation in the dataset, or geographic location has an impact on one or more Aboriginal communities; or
- Government Aboriginal health funds are a source of funding.

5.4 Access to coronial data or information

5.4.1 All human research projects that require access to coronial data or information must obtain endorsement from the *National Coronial Information System (NCIS) Research Committee* and ethical approval from the *Justice Human Research Ethics Committee* in addition to the approval of the Central HREC.

5.5 Access to WA Department of Justice data, facilities, staff, and/or clients

5.5.1 All human research projects that require access to WA Department of Justice data, facilities, staff, and/or clients must obtain endorsement from the Department of Justice's Research Application and Advisory Committee (RAAC) in addition to the approval of the WA Health Central HREC. Researchers should contact the RAAC team to discuss application requirements and whether the request is viable prior to making a submission.

6 Proportional ethical review

6.1 Determination of appropriate review pathway

All research project submissions are to be made through the RGS, regardless of the risk level posed by the proposed research.

6.1.1 The National Statement supports the idea that the risk level of the proposed research should guide the institution in determining the level of ethical review that is appropriate.

6.1.2 As part of the application the researcher is asked to designate the level of risk (in accordance with the guidance provided in Chapter 2.1 of the National Statement) of the research proposal. However, the final determination of the risk level of a project will be made by experienced CORE staff with input from committee members as required.

6.1.3 Applications for ethical review by the Central HREC will be assessed to determine the appropriate pathway for review by experienced CORE staff trained and experienced in ethical and scientific review and the application of relevant guidelines and legislation.

6.1.4 CORE staff will draw on the expertise of the membership pool of the Central HREC to make the determination as required.

6.1.5 Where the CORE considers that a project may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered at a full meeting and cannot be dealt with by the review pathways outlined in SOP 6.2.

6.1.6 Applications will be assessed to determine if they are eligible for:

- review by the lower risk review pathway.
- expedited ethical review.
- exemption from ethical review.

6.1.7 A report of the projects assessed by the review pathways described in SOP 6.

6.2 Lower risk review pathway

The National Statement defines lower risk research as “research in which there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden.” Further, the National Statement defines minimal risk research as “research in which there is no risk of harm or discomfort, but which includes a potential for minor burden or inconvenience.”

6.2.1 A Lower Risk Review (LRR) Panel will be established to assess each application that is eligible for review via the Lower Risk Review Pathway. The LRR Panel will comprise:

- a CORE staff member who is trained and experienced in ethical and scientific review and the application of relevant guidelines and legislation, and
- two members of the Central HREC membership pool with appropriate expertise related to the proposal under review.

6.2.2 While the CPI can initially identify the proposed research as lower risk guided by the LRR toolkit, the CORE and, if required, the LRR Panel will make the final determination. Additional information will be requested from the CPI if required.

6.2.3 If the research involves access to participant records or data from a Commonwealth agency or private organisation (e.g., GP or private hospital) without the consent of the participant, Section 95, or Section 95A of the Privacy Act 1988 is applicable and therefore the project requires full ethical review.

6.2.4 External funding bodies may require full ethical review regardless of the project's risk rating.

6.2.5 Multi-jurisdictional projects that may be eligible for review by the LRR Pathway should be discussed on a case-by-case basis with the CORE as there are variations in lower risk review processes across the country.

6.2.6 To facilitate their review, the LRR Panel members will require the following documents:

- All project documents requiring ethical review, (e.g., project protocol, information and consent forms, survey texts, advertising, and recruitment materials).
- Lower Risk Review checklist, and
- a summary of the review undertaken by the CORE.

6.2.7 LRR Panel members will review the submission and come to a decision within 7-10 calendar days of receipt of the application.

6.2.8 The LRR Panel will reach one of the following decisions by majority:

- Proposal is approved.
- Further information is required.
- Proposal is not suitable for review via the Lower Risk Review Pathway. It requires full ethical review and is to be tabled at the next available and appropriate Central HREC meeting.
- Research is not approved.

6.2.9 The LRR Panel's decision and any requests for additional information will be collected by the CORE and communicated to the CPI via the RGS. Where relevant the appropriate section of the National Statement will be referenced in the communication.

6.2.10 Proposals approved by the LRR Panel must follow the same monitoring requirements as proposals that have been approved by a full committee review (SOP 7 Monitoring of Approved Projects).

6.2.11 In accordance with Section 2.3.9 of the National Statement "only an HREC may grant waiver of consent for research using personal information in medical research, or personal health information". Consequently, any lower risk research proposal that includes a request for a waiver of consent must be considered at a full Central HREC meeting.

6.3 Expedited review

6.3.1 Expedited review of research proposals that have not been reviewed by the Central HREC previously, may be undertaken between scheduled meetings at the discretion of the Chair of the Central HREC.

6.3.2 A quorum must participate in the expedited review of the project but need not be physically present. The expedited review will be conducted in accordance with SOP 5 (Considerations in Ethical Review)

6.3.3 Research proposals with the potential for physical and/or psychological harm will not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and projects exploring sensitive personal, social, or cultural issues.

6.3.4 The Chair may undertake expedited review of:

- Amendments requesting:
  - a change of membership of the research staff, including changes to the CPI and/or PI role.
  - extensions of ethical approval
- progress reports.
- urgent amendments to previously approved protocols for safety reasons.
- other items of business such as adverse events.
- projects undertaken within the WA Health system to prevent or lessen a serious and imminent threat to the life, health, or safety of an individual or the public that requires the use or linkage of personal information from information systems held by the Department.

6.4 Exemption from ethical review

In accordance with the National Statement Section 5.1.15, some research may be eligible for exemption from ethics review. Where appropriate, exemption is granted, or not, by the institution responsible for the research.

6.4.1 Projects may be exempt from ethical review where they:

- involve only lower risk to participants and/or the community, and
- satisfies at least one of the conditions listed in National Statement Section 5.1.17 (a–d)

6.4.2 The process for seeking exemption from ethical review does not occur through RGS.

6.4.3 If a CPI believes their research proposal should be exempt from ethical review, they must approach the institution responsible for the research for a determination. The Central HREC or its delegate will provide advice to the institution if requested.

6.5 Non-research activities

6.5.1 Non-research activities should not be submitted via the RGS.

6.5.2 Projects that are a non-research activity are exempt from ethical review. A tool to help identify projects as research or not is available on the WA Health Central HREC website.

6.5.1.1 Quality assurance/ quality improvement activities

6.5.1.1 (i) Quality assurance/quality improvement activities should not be submitted for review via the RGS.

6.5.1.2 (ii) Quality assurance/quality improvement activities should be assessed through the relevant HSP's Governance Evidence Knowledge and Outcomes (GEKO) pathway, or equivalent, provided the relevant criteria are met.

6.5.1.2 Authorised prescriber

6.5.1.2(i) Applications from medical practitioners seeking to become an Authorised Prescriber of an 'unapproved' therapeutic good should not be submitted via the RGS.

6.5.1.2(ii) The Committee accepts applications from medical practitioners seeking to become Authorised Prescribers of an 'unapproved' therapeutic good with the Therapeutic Goods Administration (TGA).

6.5.1.2(iii) The medical practitioner's application for HREC approval to apply for Authorised Prescriber status with the TGA must be made in writing and provide sufficient evidence to justify the use of the 'unapproved' therapeutic good. More information on applying to be an Authorised Prescriber can be found on the TGA website or from the CORE or your relevant HSP research office.

6.5.1.3 Case reports and case series

6.5.1.3(i) Case reports and case series should not be submitted via the RGS.

6.5.1.3(ii) Case reports, a report of a single individual with a unique disease or condition, or case series, a retrospective, noncomparative investigation that evaluates a group of patients with a known medical condition, disease, exposure, or who have undergone a similar procedure, are considered anecdotal and can proceed without ethical review.

6.5.1.3(iii) Case reports and case series must always withhold the identity of the participant(s).

6.5.1.3(iv) If publication is a possibility, researchers must discuss the publication with the participant (or their parent(s)/guardian if under the age of 18 years) and obtain their signed consent to publish.

6.5.1.3(v) Where consent cannot be obtained, guidance must be sought from the relevant HSP on a case-by-case basis. The matter may be referred to the Committee if deemed necessary.

7 Monitoring of approved projects

7.1 Monitoring

7.1.1 The Central HREC will monitor each approved project throughout its lifetime to ensure that it is conducted ethically, and in compliance with the approved protocol. In doing so the Central HREC and/or its representative may request from and discuss with the CPI any relevant aspects of the project.

7.1.2 The Central HREC may adopt any additional appropriate mechanism(s) for monitoring, as deemed necessary, including:

- random inspections of project sites, data, and signed consent forms.
- interview, with their prior consent, of project participants.

7.1.3 On-site monitoring or audits by sponsors, HSPs and the Central HREC may also be used to monitor specific projects and to randomly review the conduct of research in the WA Health system to inform planning, educational initiatives, and priorities and to ensure a high standard of research conduct is being maintained.

7.1.4 The Central HREC requires, as a condition of approval of each project, that the CPI immediately report anything that might warrant review of ethical approval of the protocol, including:

- proposed changes in the protocol.
- any unforeseen events that might affect continued ethical acceptability of the project.
- new information from other published or unpublished studies which may have an impact upon the continued ethical acceptability of the project, or which may indicate the need for amendments to the project protocol.

7.1.5 In determining the frequency and type of monitoring required for approved projects, the Central HREC will consider the degree of risk to participants in the project.

7.2 Annual progress reports

7.2.1 The Central HREC require an annual progress report for each approved proposal to be submitted *via* the RGS. The annual progress report is due, each year, on the anniversary of ethical approval of the proposal.

7.2.2 Continuing approval of the project will be subject to the submission of an annual progress report within three months of the due date. The review of any new amendments will be paused until a progress report is submitted.

7.2.3 Repeated failure to submit annual progress reports will result in the project being tabled at the next available and appropriate Central HREC meeting where suspension and/or withdrawal of ethical approval for the project will be considered.

7.2.4 The following information must be provided in the annual progress report:

- progress to date, including details of publications, and difficulties encountered.
- site specific participant recruitment.
- maintenance and security of records and information.
- compliance with the approved protocol.

- compliance with any conditions of approval.
- changes to the protocol or conduct of the project.
- changes to the personnel or contact details of the CPI.
- adverse events and any changes to the research arising from these events.
- complaints relating to the project.

7.2.5 Annual progress reports shall be, in the first instance, reviewed by the CORE and may be referred to the Chair or next relevant Central HREC meeting.

7.3 Site and project final reports

7.3.1 Site final and project final reports should only be submitted once all research activity has been finalised at the relevant site that is participating in the research.

7.3.2 If applicable, the plan for the ongoing care of participants should be reported.

7.3.3 Project final reports will be reviewed by a full Central HREC meeting.

7.3.4 Once the researcher receives the project final report approval letter, no further research activity can occur.

7.3.5 Research findings generated from the research should be disseminated to participants as per Section 3 Element 6 of the *National Statement*.

8 Suspension and/or withdrawal of ethical approval

8.1 Suspension and/or withdrawal of ethical approval

8.1.1 The Central HREC has the right to suspend and/or withdraw ethical approval.

8.1.2 The Central HREC will consider suspending or withdrawing ethical approval if:

- the continuation of the research represents an unacceptable risk or disadvantage to participants.
- there has been significant deviation from the protocol.
- satisfactory annual progress reports have not been received by the Central HREC by the due date.
- the annual progress report is overdue and a request for an extension to the due date has not been received within three months of the original due date of the annual progress report.

8.1.3 If the ethical approval for a project is suspended, the CPI will be notified that no further activity can be conducted until the matter is resolved.

8.1.4 Ethical approval will remain suspended until researchers have addressed the Central HREC's concerns to their satisfaction.

8.1.5 If the project's approval is suspended or withdrawn, project activity must cease immediately and cannot be recommenced without the written approval of the Central HREC.

8.1.6 When the ethics approval for a research project is withdrawn the researcher must:

- halt the research immediately.
- inform the participants of the withdrawal where possible.
- inform the institution/s where the project is being conducted of the withdrawal.
- plan to meet the needs of participants.
- notify the Central HREC and any institutions where the research was being conducted that these steps have been taken.

8.1.7 Where a project also holds ethical approval from another institution or review body, the CPI must notify the institution(s) or review bodies that they have had their ethical approval suspended/terminated.

8.2 Notification of suspension and/or withdrawal of ethical approval

8.2.1 If the ethical approval for a project is suspended or withdrawn a letter to that effect will be sent to:

- the CPI and the PI(s).
- the contact person nominated for the project (typically the CPI delegate or PI delegate).
- and the Executive of the HSP(s) Head of Department / School / Research Organisation overseeing the project.

8.2.2 The letter of notification will include:

- the name of the project and its project reference number (PRN).

- the date of ethical approval and the date the approval was suspended or withdrawn.
- a description of the concern/s of the Central HREC.
- notice that the concerns raised by the Central HREC must be addressed within 28 days of receipt of the letter.
- the response should include a description of the implications for participants and how risks will be mitigated to prevent adverse outcomes.
- a statement that, in line with the requirements of Section 5.4.17 of the *National Statement*, that suspend ethical approval will be either withdrawn or suspended until the matter is resolved to the satisfaction of the Central HREC.

8.2.3 If the matter remains unresolved 28 calendar days from date of the notification of suspension of ethical approval, a second letter will be sent from the Chair. This letter will advise that the project's ethical approval has been withdrawn.

8.3 Urgent suspension of ethical approval

8.3.1 If the Central HREC or the Chair, acting on behalf of the Central HREC, considers the urgent suspension of a research project is necessary, this notification will come from the CORE in the form of a telephone call or email.

8.3.2 The suspension of ethical approval will be confirmed in writing within 24 hours *via* RGS.

8.4 Reinstatement of ethical approval

8.4.1 While the project is suspended, the Central HREC and relevant HSP(s) will take reasonable steps to determine whether the project should continue.

8.4.2 The process of determining whether the project should continue will be conducted fairly and with respect to the investigators, the participants and others involved in the project.

8.4.3 Two designated members of the Central HREC, a member of the CORE trained and experienced in ethical and scientific review and the application of relevant guidelines and legislation will in association with RGOs from relevant HSP(s) undertake this assessment.

8.4.4 A recommendation of whether the project can continue or not will be made to the Executive of the relevant HSP(s).

8.4.5 If the case for recommencement of the research is not accepted by the relevant HSP(s) Executive, the site authorisation for the project at that site will be withdrawn.

8.5 Reinstatement of ethical approval (WA Department of Health only)

8.5.1 Where a project that is being conducted at the Department, or using departmental resources, is not being or cannot be conducted in accordance with the approved study protocol, or where remedial measures are insufficient to address the concerns raised by the Central HREC this must be reported to the Chair and Director, OMRI.

8.5.2 The Chair and Director, OMRI may then determine whether the project's ethical and governance approvals will be terminated.

8.5.3 The CPI, PI, the contact person nominated for the project (typically the CPI delegate or PI delegate), and the Head of Department/School/Research Organisation overseeing the project will be informed of the decision in writing by the Chair *via* the Director, OMRI.

8.5.4 This letter will advise whether the project's ethical and governance approval has been terminated or if the suspension of approval has been removed.

9 Adverse event and safety reporting

9.1 Adverse events

9.1.1 An adverse event is defined in the International Council for Harmonisation's Guidelines for Good Clinical Practice (ICH GCP) and refers to: "*Any untoward medical occurrence in a patient or clinical investigation subject administered an investigational product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product, whether related to the investigational product.*"

9.1.2 Interventional studies must have a Data Safety Monitoring Board (DSMB) or equivalent in place to monitor the safety of the participants as per Section 5.4.5 of the NHMRC's *National Statement*.

9.1.3 Data Safety and Management Boards should be set up in accordance with the NHMRC's guidance document *Data Safety Monitoring Board (DSMB) 2018*.

9.2 Adverse event reporting

9.2.1 The Central HREC has adopted the adverse event reporting requirements detailed in *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016)* published by the NHMRC.

9.2.2 Investigators must also comply with all mandatory reporting obligations required at the site(s) where the project is being conducted at (refer to the *WA Health Research Governance Framework*).

9.2.3 All safety reports must be submitted *via* the RGS.

9.3 Safety reports

9.3.1 Events requiring the submission of a safety report to the Central HREC, (as described in the NHMRC's Safety monitoring, and reporting in clinical trials involving therapeutic goods, 2016) include:

- Serious breaches of protocol.
- Significant Safety Issues (SSI).as required
- Sudden Unexpected Serious Adverse Reactions (SUSAR).
- Unexpected Serious Adverse Device Effect (USADE).

9.3.2 These types of events are defined in the NHMRC's *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016),* and the reporting requirements are described therein.

9.3.3 It is essential that all clinical trial investigators and their delegates understand the safety reporting requirements expected of them.

9.3.4 Any urgent reports as described in the NHMRC's *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016)* will be forwarded to the Chair for out of session review.

9.3.5 The Chair may request input from one or more Central HREC members with expertise relevant to the reports content.

9.3.6 Safety reports reviewed out of session will be tabled at the next available and appropriate Central HREC meeting for review or noting.

9.3.7 Review of safety reports will result in one or more of the following actions:

- acknowledgement of receipt of the report.
- the event will be noted.
- additional information will be requested.
- ethical approval will be suspended with immediate effect.
- ethical approval will be withdrawn with immediate effect.
- other actions as recommended by the Committee.

9.3.8 Where immediate action is required, the CORE will contact the CPI/PI and their delegates in the form of a telephone call or email as soon as possible to inform them of the required actions.

9.3.9 The CPI will be notified by letter *via* the RGS of the outcome of review.

9.3.10 Notification and outcomes of the Central HREC's decisions and/or requests will be recorded in RGS.

9.4 Urgent safety measures

9.4.1 Responding to an adverse event may require an Urgent Safety Measure (USM) to eliminate an immediate hazard to participant welfare.

9.4.2 While a USM may be implemented prior to Central HREC review of the safety report, they should be notified in writing that the measure has been taken as soon as practicable.

9.5 Annual safety reports

9.5.1 Interventional research projects are required to submit annual safety reports to the Central HREC , regardless of whether any qualifying safety events have occurred.

9.5.2 Annual safety reports must include the following information:

- details of any planned actions resulting from safety reports.
- current approved product information (e.g., Investigator's brochure), if appropriate.
- executive summary from the DSMB or equivalent, if appropriate.
- any other reports consistent with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH-GCP).

9.5.3 Investigator's brochure updates, aggregate safety reports and DSMB meeting minutes provided to sites during an annual reporting period which state that the risk/benefit analysis for the investigational product is unchanged **and** that no amendments to the trial

protocol are required should be summarised in the annual safety report instead of being reported *ad hoc*.

9.5.4 Annual safety reports will be reviewed under the same process described above for safety reports.

10 Amendments

10.1 Amendments to project documentation

10.1.1 Proposed changes to approved research projects (including requests for extensions to the duration of ethical approval) must be submitted as an amendment *via* the RGS.

10.1.2 The amendment request must describe the nature of the proposed change(s) to the project and the reasons for making the change(s).

10.1.3 An assessment of any ethical implications arising from the change(s) to the conduct of the project should also be provided.

10.1.4 All documents that are being updated must be provided in both tracked changes (with changes in red line) and clean copies with updated version control.

10.1.5 Documents that have not been reviewed by the Central HREC previously should be submitted in clean copy only.

10.1.6 If there are substantial changes required to project documentation, a summary of changes may be requested by the CORE.

10.2 Urgent amendments in response to safety issues

10.2.1 Urgent protocol amendments required to address safety reasons can be implemented immediately, prior to ethical approval, provided an imminent risk to participant safety is demonstrated.

10.3 Extensions of ethical approval

10.3.1 Extension of ethical approval is limited to a maximum period of three years.

10.3.2 Any further extension beyond 3 years will be granted at the discretion of the Chair who may request that the research proposal is resubmitted as a new application.

10.3.3 Projects that have completed all study activities, bar data analysis for the purpose of writing a publication and ceased all contact with participants do not require an extension of ethical approval if only de-identified data is being used for analysis, and there are no arising ethical issues.

This provision does not apply to research projects accessing data sets held by the Department, such projects require ongoing ethical approval until all publications have been completed.

10.4 Delegated review of amendments

10.4.1 Ethical review of amendments may be undertaken by the Chair or delegated to members of the Central HREC or to the CORE at the discretion of the Chair of the Central HREC.

10.4.2 The following changes to an approved project can be delegated to one or more members of the Central HREC's membership pool or to the CORE and are eligible for review outside the Central HREC's meeting schedule:

- minor amendments (including changes to the investigators conducting the project).
- requests for extension of ethical approval.
- urgent amendments to approved protocols for safety reasons.

10.4.3 The delegated reviewers can, at their discretion, request an amendment be reviewed by the Central HREC at the next available and appropriate meeting, provided the request and necessary documentation has been received by the CORE.

10.4.4 Data Custodians will review amendment requests where applicable.

10.5 Notification of the outcome of the review of amendments

10.5.1 The CPI will be advised of the outcome of the review within five working days of the completion of the review. A letter will be issued *via* the RGS.

10.5.2 If further information, clarification, or modification is required, a letter that explains why clarification or modification is required will be issued *via* the RGS. The letter will also set out the information that needs to be provided. Where possible, requests for additional information, clarification or modification should refer to the *National Statement* or relevant legislation.

11 Discontinuation of a research project

11.1 Discontinuation of a research project

11.1.1 If an approved project has not been started or has been terminated earlier than anticipated the Committee requires that:

- The PI(s) inform the Central HREC and the relevant RGO *via* a Site Final Report in the RGS.
- The CPI informs the Central HREC *via* a Project Final Report submitted in the RGS.

11.1.2 If an approved project is suspended, then the CPI must submit an Amendment *via* the RGS explaining:

- why the project has been suspended.
- the measures taken to inform consented participants as soon as possible.
- the measures being taken to ensure the participants safety and ongoing care.

11.1.3 Prior to research activities resuming, the CPI must demonstrate that the issues that led to the project's suspension have been adequately addressed, and that the Sponsor has granted permission to recommence.

11.1.4 The project may recommence only after receipt of a written notification from the Central HREC and RGO to that effect.

11.1.5 If the research project is not resumed, the CORE will request a site final report and information (if not previously provided) about the actions being taken to ensure the safety and ongoing care of participants.

11.1.6 The submission of the site final report can only occur after the plan for the ongoing management of participants is approved by the Central HREC and relevant institutions.

11.1.7 After approval of the site final report, the investigators must enact and comply with the approved Retention and Disposal Plan.

12 Complaints regarding the review of an application

12.1 Complaints about the ethical review of an application

12.1.1 All complaints must be submitted in writing by the CPI and be addressed for the attention of the Chair of the Central HREC. Also, the CPI is required to lodge a complaint form in RGS.

12.1.2 Any complaints or concerns about the Central HREC's review processes should be sent by email to *HREC@health.wa.gov.au.*

12.1.3 The CORE will send an acknowledgment to the CPI within seven calendar days of receipt of the complaint. The CORE will notify the Chair and the Director, OMRI.

12.1.4 The Chair of the Central HREC or their delegate, provided that they did not attend the Central HREC meeting which is the subject of the complaint, will investigate the complaint and its validity, ascertaining whether the Central HREC acted in accordance with its ToR, SOPs, the *National Statement* and otherwise acted in a fair and unbiased manner at the relevant meeting. Following this assessment, the investigator who examined the complaint will make a recommendation to the Chair of the meeting that first reviewed the project on the appropriate course of action.

12.1.5 The investigation will be conducted within 30 calendar days from the date the complaint was lodged, exceptional circumstances not-withstanding.

12.1.6 The complainant will be informed of the outcome of the investigation within 7 calendar days of the investigation being completed.

12.1.7 If the complainant is not satisfied with the outcome of the investigation, they can request that the Chair of the Central HREC refer the complaint to the DG, or their delegate.

12.1.8 The Chair of the Central HREC will provide the DG or delegate with all relevant information about the complaint, including:

- details of the complaint.
- material reviewed in the investigation.
- the outcome of the investigation.
- the recommended course of action.
- any other relevant documentation.

12.1.9 The DG or delegate will determine whether further investigation is warranted. Where no further investigation is required, the DG or delegate will inform the complainant and the Chair of Central HREC.

12.1.10 If there is to be further investigation, then the DG or delegate will establish a panel to consider the complaint. The Panel will include, at least, the following members:

- the DG or the DG's nominee as the convenor of the Panel.
- a person from the Central HREC membership pool who was not involved in the meeting that was subject of the complaint.
- a person experienced in the ethical review of projects (who is not a member of the meeting that was the subject of the complaint).
- an expert in the discipline of the project under consideration, and
- additional members, as required by the DG.

12.1.11 The Panel may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.

12.1.12 The panel will assess the complaint and its validity, ascertaining whether the Central HREC acted in accordance with its ToR, SOPs, the *National Statement* and otherwise acted in a fair and unbiased manner.

12.1.13 The DG or delegate will notify the complainant and the Central HREC of the outcome of the investigation in writing.

12.1.14 The outcomes may include:

- dismissing the complaint, or
- referring the complaint back to the Central HREC for reconsideration in the light of findings of the panel.

12.1.15 The panel may also make recommendations about the operation of the Central HREC including:

- review of the ToR.
- review of SOPs.
- review of the Central HREC membership.

12.1.16 The panel or the DG or delegate cannot provide ethical approval.

12.1.17 If the Central HREC is requested to review its decision, then the outcome of this review by the Central HREC will be final.

12.1.18 If the complainant is not satisfied with the decision of the DG, then depending on the nature of the complaint the matter may be referred for external review to the Ombudsman of Western Australia, the Health, and Disability Services Complaints Office or the State or Federal Information Commissioner.

12.1.19 The details of the review must be recorded in the RGS, including the date of review, who conducted the review, the outcome of the review and any additional information that is required.

13 Complaints and breaches – research integrity

13.1 Complaints and breaches

The Australian Code for the Responsible Conduct of Research, 2018, (The Code) states: "*Institutions have an obligation to encourage and support responsible research conduct. They are accountable to funding organisations and the Australian community for how research is conducted*."

13.1.1 A breach is defined as a failure to meet the principles and responsibilities of The Code and may refer to a single breach or multiple breaches. Investigating research integrity issues is the responsibility of the Institution. Examples of breaches of The Code include, but are not limited to, the following:

- Not meeting required research standards (e.g., conducting research without approval, misuse of research funds).
- Fabrication, falsification, misrepresentation (e.g., fabrication or falsification of research data or source material).
- Plagiarism (e.g., plagiarising someone else's work).
- Research data management (e.g., failure to appropriately maintain research records).

13.1.2 A potential breach of the Code occurs when a concern is raised or identified that one or more researchers have conducted research that is not in accordance with the principles and responsibilities of The Code.

13.1.3 Complaints regarding the conduct of Committee approved projects can be made by participants, researchers, staff of institutions, or any other interested parties.

13.1.4 Where it is possible a complaint has breached the standards governing the conduct of research, it will be handled in accordance with The Code and the relevant research integrity policy of the Institution where the research is being conducted.

13.2 Reporting a complaint or breach

13.2.1 Researchers are required, as a condition of approval, to report any complaints received or potential breaches identified to the CORE immediately via HREC@health.wa.gov.au

13.2.2 Reports of complaints or potential breaches received by the CORE will be referred, as a matter of urgency, to the HSP(s) where the project is being conducted for investigation in accordance with that HSP's research integrity policy. If the project concerned involves accessing WA Health datasets or Data Linkage the matter will be managed in accordance with the Department's Research Integrity Policy

13.2.3 Complaints and notifications of potential breaches can be made in a variety of ways, *via* phone contact, written correspondence, or in person. Depending on the method of contact, consent to share details to allow the complaint to be dealt with may be required.

13.2.3 A report of a potential breach in the conduct of a Central HREC approved project should include the following information:

- the nature of the breach.

- the steps taken to prevent any further injury, damage, or disclosure of confidential information.
- whether any breach was inadvertent, negligent, or intentional,
- proposed changes to the protocol because of the breach, and
- the sensitivity of any information concerned, including the amount and type of information and the level of identifiability.

13.2.4 Complainants have the right for their complaint to be:

- received and treated in confidence.
- treated with respect and dignity.
- addressed in a spirit of helpful co-operation.
- dealt with in a manner that includes appropriate communication and progress updates.
- treated as genuine and thoroughly investigated.

13.2.5 The CORE will notify the relevant personnel at the site of the complaint as soon as possible after notification of the complaint.

13.2.6 The CORE will send an acknowledgment to the complainant and notify the CPI and relevant PI(s), of the complaint, advising that the complaint will be investigated by the institution where the research is being conducted in accordance with its research integrity policy.

13.3 Investigating a complaint or breach

13.3.1 Where it is possible a complaint has breached the standards governing the conduct of research, it will be handled in accordance with the Code.

13.3.2 The relevant personnel at the HSP where the project is being conducted will investigate the complaint and its validity and provide a report and recommendation to the Central HREC within 30 days of receipt of the complaint.

13.4.3 The outcome of the institutional review must be notified to the CORE, recorded in the RGS and within the project's file. The entry in the RGS must include the date of review and by whom it was conducted and any additional relevant information.

13.3.4 The CPI and relevant PI(s) will be notified of any changes to the ethical approval for the project concerned by the Chair within 5 days of receipt of the review report and recommendations.

14 Multicentre research – ethical review pathways

14.1 Ethical review in WA

14.1.1 All WA Health sites accept the ethical and scientific review undertaken by the Central HREC.

14.1.2 The requirements for additional ethical approval from the *WA Aboriginal Health Ethics Committee* (WAAHEC) and *National Coronial Information System (NCIS) Research Committee* are outlined in SOP 5.3 (*WA Aboriginal Health Ethics Committee*) and 5.4 (*Access to Coronial Data or Information) respectively*.

14.1.4 Research being conducted at non-WA Health sites may require separate ethical review at that institution, unless the institution has a pre-existing agreement with WA Health.

14.2 Inter-jurisdictional ethical review – national mutual acceptance (NMA)

14.2.1 The National Mutual Acceptance (NMA) scheme has been implemented in public health organisations across all Australian states and territories.

14.2.2 Multi-centre research projects being conducted at public health organisations in Australia must be ethically and scientifically reviewed only once by an NHMRC Certified Lead HREC participating in the NMA scheme.

14.2.3 All WA Health sites accept the ethical and scientific review undertaken by an NHMRC Certified Lead HREC participating in the NMA scheme. Conditional to this acceptance is the submission of original copies of all documents to each relevant RGO *via* RGS

14.2.4 Some projects may require additional specialist review.

14.2.5 In WA, projects that meet the criteria set out in Section 5.3 (*WA Aboriginal Health Ethics Committee*) require the specialist review of the WAAHEC.

14.2.6 Projects that meet the criteria set out in Section 5.4 (*Access to Coronial Data or Information*) require the specialist review of the NCIS Research Committee and Justice Human Research Ethics Committee.

14.2.7 For research involving sites across multiple Australian jurisdictions and including at least one WA health system site, NMA must be used to ensure efficient review.

15 Application requirements

15.1 Application requirements

15.1.1 All applications for ethical review, be it for single site or multi-centre research, must be submitted *via* the RGS.

15.1.2 Applications can be submitted at any time and will be assigned for review at the next appropriate meeting.

15.1.3 Applications must be submitted in the appropriate format, be complete, and include all documentation as determined by the Central HREC.

15.1.4 Projects applying for a waiver of consent should ensure they address all the criteria set out in Section 2.3.10(a)-(i) of the *National Statement* in their RGS application.

15.1.5 Projects applying for a waiver of consent for access to participant records or data from a Commonwealth agency or private organisation (e.g., GP or private hospital) should also ensure that they address the criteria set out in the approved guidelines under Section 95 or 95A of the Privacy Act 1998 (where applicable).

15.1.6 Projects that involve the recruitment of incapacitated adults under the provisions of the GAA should ensure that all necessary information on how the GAA will be implemented is included in their submission.

15.1.7 The CPI or delegate is responsible for submitting the ethics application.

15.1.8 The CPI or delegate is also responsible for inviting project team members to the project on RGS.

15.1.9 Non-WA Health employees seeking access to the RGS are required to provide a referee who is employed by WA Health.

15.2 Fees for review of applications

15.2.1 A fee will not be charged for non-commercial applications submitted for assessment by the Committee.

15.2.2 Fees must be charged in full for all commercially sponsored research projects, except for teletrials where the Department may choose to cover all or part of the costs in-kind to encourage participation during the set -up of a teletrial.

15.2.3 Where commercial sponsor charges apply, the payment must be invoiced directly to the sponsor to cover the review costs incurred by the site, irrespective of whether the research project commences.

15.2.4 Protocol amendments that introduce significant changes or which introduce major new safety considerations, and which require full Central HREC review may attract a higher fee for those commercially sponsored projects. This includes the addition of new sub-studies.

15.2.5 Fees for reviewing commercial applications will apply and are outlined on the WA Health Central HREC website and in Section 9 of the *Research Governance Procedures.*

15.3 Application forms required for an intra-jurisdictional (within WA) application

15.3.1 For single-centre or multi-centre research that will involve one or more WA Health sites and will only be conducted within WA, the WA Health Ethics Application Form (WAHEAF) should be submitted to the Central HREC for review *via* RGS.

15.4 Application forms required for an NMA application

15.4.1 For multicentre projects conducted at WA Health sites, submission of the Human Research Ethics Application (HREA) form and the Western Australian Specific Module (WASM) is required irrespective of whether the Lead HREC is within or outside of WA.

15.4.2 The WASM is a WA-specific addendum to the HREA that enables the reviewing committee to understand and apply the WA legislative requirements that affect research conducted in WA. Guidance on additional forms that should be submitted to meet other jurisdictional requirements is available from the *NMA Standard Principles for Operation.*

15.5 Validation of applications for review

15.5.1 Applications will be checked for completeness and validity by the CORE prior to their acceptance for review by the Central HREC.

15.5.2 Researchers will be advised if their application is incomplete and/or incorrect during the RGS validation process. Additional information will be requested if it is required.

15.5.3 The CORE will acknowledge acceptance of the application for ethical review by marking each relevant document as valid in RGS.

15.5.4 When the application is complete it will be added to the agenda for the next appropriate meeting.

15.5.5 Central HREC members will be advised that the application and associated documents are available for review in the RGS at least seven calendar days prior to the meeting at which the submission will be discussed.

16 Record keeping

16.1 Record keeping

16.1.1 The RGS is a web-based Information Technology (IT) platform, that facilitates the preparation, submission, review, approval, and monitoring of human research projects conducted at WA Health Sites.

16.1.2 The Central HREC's activities, including agendas and minutes for all meetings, are maintained in an electronic format within the RGS.

16.1.3 All project records received and reviewed will be maintained electronically in the RGS in accordance with Section 5.2.15-20 of the *National Statement*.

16.1.4 Within the RGS, each project record will be kept confidential and in accordance with the *State Records Act 2000* and any other applicable legislation.

16.1.5 The RGS project record will include:

- a unique project identification number.
- the title of the project.
- the names of the Coordinating Principal Investigator (CPI), the Principal Investigator(s) (PI(s)) and other project team members.
- the name of the institution or organisation responsible for the project; the Sponsor.
- the decisions of the HREC and the dates those decision were made.
- the terms and conditions, if any, of approval of the project.
- whether approval was by expedited review.
- action taken to monitor the conduct of the project.
- a copy of the application, including signatures, all approved documents, material used to inform potential participants and any relevant correspondence (including that between the applicant and the CORE).
- the relevant records of the Committee, including minutes and related correspondence.

16.1.6 To ensure confidentiality, all paper documents provided to or produced by members, which are no longer required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal should leave their documents with the CORE for disposal.

16.1.7 Records pertaining to projects will be held for sufficient time to allow for future reference. Retention periods will comply with the *General Retention and Disposal Authority for State Government Information* issued by the State Records Office and the Department's *Information Retention and Disposal Policy.*

17 Reporting requirements

17.1 Meeting minutes

17.1.1 The minutes of each meeting will be available to the DG following ratification by the Central HREC.

17.2 Annual progress report

17.2.1 The Central HREC will provide the DG with a progress report each calendar year.

17.2.2 The report will contain updates on:

- membership and changes to membership.
- number of meetings held.
- number of applications reviewed, approved, and rejected.
- any issues encountered by the Central HREC while monitoring research activity.
- a description of any complaints received and the outcome.
- a description of any projects where ethical approval has been suspended or withdrawn and the reason(s) for suspension or withdrawal of approval.
- general issues of note.

17.3 Australian Health Ethics Committee (AHEC)

17.3.1 The Central HREC will provide reports to the *Australian Health Ethics Committee* in accordance with the requirements of the NHMRC and will comply with all statutory reporting requirements.

17.4 Quarterly reports

17.4.1 The Central HREC will provide a report on the projects it has approved for each quarter of the year. These reports will include the project summary provided by researchers in their application form. Researchers will be asked to provide their consent before the project summary can be included in the quarterly report.

17.5 Public facing reports

17.5.1 The Central HREC's ToR, SOPs Annual Reports, Quarterly Reports, and compliance with *National Statement* membership requirements will be posted on the WA Health Central HREC website and will be made available upon request.

18 Communication

18.1 Communication between the Central HREC and researchers

18.1.1 The Central HREC will have a public facing webpage which will include contact information, these SOPs, the Central HREC's ToR, guidance documents and reference materials on research application processes and research conduct (including but not limited to, the National Statement and The Code). Furthermore, the home page of the RGS will provide researchers with access to the same information.

18.1.2 The Central HREC and CORE will engage in open communication with researchers via telephone, emails, and face to face meetings as appropriate.

18.1.3 The CORE, on behalf of the Central HREC, will provide researchers with education and guidance on ethics review and the preparation of ethics submissions. Further, where possible, the CORE will provide researchers with relevant documentation and training opportunities to address specific issues relating to the ethical review of their project.

18.1.4 The CORE, on behalf of the Central HREC will notify researchers of the HREC's decision via the RGS within 3 working days of the decision being finalised.

18.1.5 Where modifications to the application are requested, communication will be managed within the RGS. In some instances, the request may be provided in an email or communicated informally over the telephone. Such telephone conversations will be followed by an email detailing the conversation and instructing the researcher on how to respond to the request.

18.1.6 Communication between the CORE and a research sponsor should be limited and regulated to avoid undue influence on the review process.

19 Research governance and data governance

19.1 Research governance

19.1.1 The Committee will be responsible for ethical review and oversight only. Matters of research governance are the responsibility of the relevant institution(s). The contact details of the WA Health RGOs can be found on the *RGS*.

19.2 Data governance

19.2.1 Where the applicant is requesting data held or linked by the Department, the DG or their delegate is responsible for granting approval for the use or disclosure of the data in accordance with relevant departmental policies.

19.2.2 Researchers are required to contact ISPD Client Services when requesting access to data held or linked by the Department to discuss data application requirements and whether the request is viable. More detail on the process for applying for the use of data held or linked by the Department can be found on the *WA Data Linkage Services* website.

19.2.3 Where access to data held by PeopleWA is being sought, researchers are required to contact the PeopleWA team in the Office of Digital Government, Department of Premier and Cabinet to discuss data application requirements and whether the request is viable. More detail on the process for applying for the use of data held or linked by PeopleWA can be found on the *PeopleWA* website.

19.2.4 Where data linkage *via* the Population Health Research Network (PHRN) is being sought, researchers should contact the PHRN team at the University of Western Australia to discuss data application requirements and whether the request is viable. More detail on the process for applying for the use of data linked by the PHRN can be found on the *PHRN* website.

19.2.5 Where the applicant is requesting access to data collected at WA Health sites under the *Health Services Act 2016*, a Data Request Form should be completed for review and approval by the relevant data custodian/s as part of the Site Authorisation process.

19.2.6 All researchers conducting research within WA Health must comply with the Department's Information Security Policy (MP 0067/17) and Cloud Policy (MP 0140/20). This includes ensuring that electronic devices are assessed as appropriate for use by the institution of the site/s involved. Breaches to data security should be reported to the Committee and the relevant RGO of the site/s where the project is conducted as soon as practicable.

19.2.7 Researchers will be requested to provide a data management plan for projects involving access to health data as part of their application to the Central HREC.

20 Review of standard operating procedures and terms of reference

20.1 Review of standard operating procedures and terms of reference

20.1.1 The SOPs and ToR will be reviewed at least every three years and amended, as necessary.

20.1.2 Minor amendments to the SOP and ToR can be actioned by the CORE.

20.1.3 A minor amendment means a correction or change which is administrative in nature and does not significantly change the specific meaning, purpose, or intent of the document.

20.1.4 For major amendments, including changes in meaning, purpose, or intent, that are proposed by a Central HREC member:

- The proposal must be in writing and circulated to the members of the Central HREC for consideration.
- The Chair of the Central HREC may also seek the views of Central HREC members to help inform their decision.
- The views of the Chair of the Central HREC and any members should be discussed at the next scheduled meeting of the Chair of the Central HREC and their delegates, and a vote taken at that meeting.
- Any delegate unable to attend the meeting may provide their views in writing.
- The proposal shall be ratified if two thirds of the delegates of the Chair of the Central HREC agree to the amendment.
- The CORE shall send the amendment to the DG on behalf of the Chair of the HREC for consideration and approval where appropriate.

20.1.5 For amendments proposed by the DG or their delegate:

- the DG or their delegate will send the proposal to the Central HREC and seek the views of any relevant person.
- The DG or their delegate will consider the views of the members of the Central HREC and other relevant persons and will determine whether the amendment should be made.

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