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

Western Australian Health Central Human Research Ethics Committee

Terms of reference

29 July 2024

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1 Preamble

The WA Health Central Human Research Ethics Committee (HREC) is registered with the National Health and Medical Research Council's (NHMRC's) Australian Health Ethics Committee (AHEC) to provide ethics review of research involving humans, their biospecimens and/or their information and is bound by state and national policies and legislation.

The operation of the HREC is governed by the terms set out by the NHMRC in the National Statement on Ethical Conduct in Human Research 2023 (*National Statement*; and subsequent updates).

The WA Health Central HREC is charged with providing advice to both the WA Department of Health (the Department) and the wider WA Health System on matters of ethical conduct in human research. The WA Health Central HREC is also responsible for the ethical oversight of human research involving the use and linkage of information held by the Department.

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 function as the Chairperson for meetings of the Central HREC will be referred to collectively as the 'Chair" unless specified otherwise. Where the following Terms of Reference (ToR) describe actions pertaining to a specific project, 'Chair' will refer to the person who oversaw the meeting where the project was first reviewed.

2 Overview

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

The *WA Health Research Governance Policy and Procedures* (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 ethics 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))*.

2.1 Alternative review pathways

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

2.1.2 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 ethics 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 Ethics Review*).

2.2 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 ethics 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 ethics 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 ethics review process is underway.

2.2.1 Ethics 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 Ethics Review - National Mutual Acceptance (NMA)*) and on the *RGS website.*

2.2.2 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 ethics review conducted by the WA Health Central HREC that determines if the project is ethically and scientifically sound.

2.2.3 Other approvals required to conduct research in the WA Health system

2.2.3.1 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*).

2.2.3.2 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 ethicsl 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*).

2.2.3.3 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 ethics 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 19.2 (*Data Governance*).

2.2.3.4 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*).

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

Research funded by any US government agency, for example 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.

2.4 Registration of clinical trials

Both the National Statement (Section 3.1.7) and the International Committee of Medical Journal Editors (ICMJE) member journals require clinical trials to be registered in a public clinical trials registry.

The ICMJE member journals have made registration in a public clinical trials registry a condition of consideration for publication. Neither the National Statement nor the ICMJE advocates one registry, the clinical trial must be added to a registry that meets the following 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].*

3 Objectives

3.1 The objectives of the Central HREC

3.1.1. To protect the welfare, rights, privacy, and dignity of individuals, as well as the confidentiality of their information (including health information).

3.1.2. To assess the conduct of proposed human research against the ethical principles outlined in the *National Statement*.

3.1.3. To facilitate ethically acceptable and scientifically sound research through efficient and effective review processes.

3.1.4. To promote ethical standards of human research.

4 Functions

4.1 The functions of the Central HREC

4.1.1 To review, in accordance with the National Statement, research projects involving humans of any age, their data and biospecimens, including, but not limited to, research involving:

- pharmaceuticals.
- medical devices.
- medical radiation and imaging.
- surgical procedures.
- biological samples.
- heath information.
- epidemiological, social, psychological investigations.
- data collections held or linked by the department.

4.1.2 To provide ethics and scientific review of research projects.

4.1.3 To give independent, competent, and timely advice with respect to the ethical and scientific acceptability of human research projects.

4.1.4 To provide ethical oversight, monitoring and advice for projects approved by the Central HREC.

4.1.5 To monitor and report to the Director General of the WA Department of Health (DG) or their delegate on research projects including those involving data collections held or linked by the department.

4.1.6 To advise the Department of Health on the principles, guidelines and procedures governing the use of its information (including health information).

4.1.7 To assess the involvement of individuals in research without their consent in accordance with the National Statement Section 2.3.10 (a-i) as follows:

- involvement in the research carries no more than low risk to participants.
- the benefits from the research justify any risks of harm associated with not seeking consent.
- it is impracticable to obtain consent (for example, due to the quantity, age, or accessibility of records).
- there is no known or likely reason for thinking that participants would not have consented if they had been asked.
- there is sufficient protection of their privacy.
- there is an adequate plan to protect the confidentiality of data.
- in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them.
- the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled.
- the waiver is not prohibited by State, federal, or international law.

4.1.8 To apply the approved guidelines under Section 95 and/or 95A of the Privacy Act 1998 for research projects involving access to participant records or data from a Commonwealth agency and/or private organisation (e.g., GP or private hospital) without

the consent of the individual. Further, to apply the privacy statutes and accompanying guidelines of other Australian jurisdictions where required.

5 Scope of responsibility

5.1 The responsibilities of the Central HREC

5.1.1 The Central HREC shall consider the ethical implications and scientific rigour of human research projects in the following categories:

- Where the staff, patients, or resources of the WA Health System are involved.
- Multi-centre research proposals submitted by researchers, in line with the National Mutual Acceptance (NMA) program or any other program or agreement entered into by the Department that facilitates single ethics review of multi-centre research approvals. Participation in the NMA program is subject to the certification of the Department by the NHMRC.
- All research projects involving personal and non-personal, record-level information from the data collections held by the department.
- Research projects requesting aggregate level information from the data collections held by the department may also be reviewed by the Central HREC at the discretion of the Data Custodian or Data Steward.
- The establishment of new linkages to the WA Data Linkage System infrastructure

5.1.2 The Central HREC will provide the monitoring of research projects it approves until completion so that the HREC may be satisfied that the project continues to conform with approved ethical standards.

5.1.3 Quality improvement projects utilising HSP resources will not be reviewed by the Committee. Such projects will instead fall within the remit of that HSP's relevant Quality Improvement review pathway.

5.1.4 The Central HREC may advise on the principles, guidelines and procedures governing specific ethical issues of importance as requested by the Department.

5.1.5 The Central HREC will monitor and report to the DG or their delegate on human research conducted in the WA Health system.

5.1.6 The Central HREC may from time to time, bring to the attention of the DG issues of significant concern within the scope of the Central HREC's responsibilities.

6 Status of the WA Health Central Human Research Ethics Committee within the WA health system

6.1 Status

6.1.1 The Central HREC is an advisory committee of the Department functioning under the authority of the DG.

6.1.2 Site authorisation of research that has been approved by the Central HREC to be conducted at WA health sites other than the Department is the responsibility of the Executive of the relevant HSP(s) as described in that HSP's Standard Operating Procedures.

6.1.3 The DG or their delegate is responsible for granting institutional approval for:

- The use of personal or non-personal (record-level) information from data collections held or linked by the Department.
- The establishment of new linkages with data collections held by the Department and other data sources.

6.1.4 The advice of the Central HREC will be given due consideration by the DG or delegate when granting institutional approval.

7 Accountability of the WA Health Central Human Research Ethics Committee

7.1 Accountability

7.1.1 The Central HREC is accountable to the DG in the conduct of its business.

7.1.2 The minutes of each meeting will be made available to the DG.

7.2 Reporting

7.2.1 The Central HREC will provide an annual report for each calendar year to the DG or their delegate, which will include information on:

- membership.
- the number of proposals reviewed.
- status of proposals.
- a description of any complaints received and their outcome.
- and any other issues within the scope of the Central HREC's responsibilities.

The report will be available to the public and will be posted on the Central HREC website.

7.2.2 The Central HREC will also provide reports:

- to AHEC in accordance with the requirements of NHMRC, and
- in accordance with any other statutory reporting requirements in force at the time.

7.2.3 The ToR, Standard Operating Procedures (SOPs) and membership details will be posted on the Central HREC website and available to the public.

8 Membership

8.1 Composition of the WA Health Central HREC

8.1.1 The composition of the Central HREC at each meeting shall comply with the National Statement (5.1.30 - 5.1.32), and shall include at least:

- a Chair with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the Central HREC's capacity to conduct its obligations under the National Statement.
- two people who bring a broader community or consumer perspective and who have no paid affiliation with the department.
- a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor, Aboriginal Health Practitioner, or allied health professional.
- a person who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or another religious leader.
- a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters; and
- two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

8.1.2 Other members, such as those listed below, may be called upon to attend meetings as required by the Central HREC.

- subject matter experts with expertise relevant to the research proposals under review (e.g., rural, and remote health, mental health, biospecimens, pharmacy etc.)
- people with lived experience
- representatives of culturally and linguistically diverse populations
- people of Aboriginal descent
- at least one member with knowledge of and current experience in information security.
- at least one member with knowledge of and current experience in the management and uses of statewide health data collections who is employed by the WA health system.

8.1.3 Members of the Central HREC may be appointed to one or more categories described in Section 8.1.1 but can only represent one of those categories at a specific meeting.

8.1.4 As far as practicable, the membership of the Central HREC should be diverse, and at least one third of the members should be from outside the WA Health system.

8.1.5 To ensure that the membership of the Central HREC is equipped to address all the relevant considerations arising from the projects likely to be submitted, additional members in any category may be appointed and deputy or alternating members may be appointed.

8.1.6 The DG may appoint a Deputy Chair of the Central HREC from among the membership of the Central HREC who may exercise the powers of the Chair of the Central HREC when the Chair of the Central HREC is unavailable.

8.2 Appointment of members

8.2.1 The DG shall appoint the Chair of the Central HREC and the members of the HREC, in consultation with the other senior officials within the Department, as deemed appropriate.

8.2.2 A selection committee, which will include at least one representative of the Central HREC, may be established to interview prospective applicants for membership of the Central HREC and to make recommendations to the DG on appointments.

8.2.3 Prospective members of the Central HREC may be recruited by direct approach, nomination, or by advertisement for Expressions of Interest.

8.2.4 Prospective members must provide a copy of their *Curriculum Vitae* to the Central Office for Research Ethics (CORE). Members will also need to complete Good Clinical Practice (GCP) training and are required to provide valid certificates of completion to the CORE.

8.2.5 Appointments will be staggered to ensure continuity of expertise and knowledge within the Central HREC.

8.2.6 Members will be appointed for their knowledge, qualities, and experience, and not as representatives of any organisation, group, or opinion.

8.3 Terms of appointment

8.3.1 Appointments to the Central HREC are fixed term for a period of three years.

8.3.2 Members are recruited and appointed to these fixed term positions as they become vacant.

8.3.3 Members may serve two terms with the possibility of an extension granted by the DG.

8.3.4 The DG may approve further terms, of varying duration, for members to ensure continuity of expertise and knowledge.

8.3.5 Deputy members are appointed to the Central HREC to provide category representation when the relevant member is unable to attend meeting(s).

8.3.6 Deputy members are appointed to fixed term deputy positions as they become vacant. Deputy members may only serve two consecutive terms unless otherwise approved by the DG.

8.3.7 Membership will lapse if a member fails without reasonable explanation, or without notifying the Chair of the Central HREC, to attend three consecutive meetings that they have been scheduled to attend or if the member fails to attend in full at least five meetings in anyone calendar year, unless there are exceptional circumstances.

8.3.8 The Chair of the Central HREC will notify the member, in writing, of such lapse of membership.

8.3.9 The Chair of the Central HREC will initiate the process to appoint a new member to fill the vacancy of the lapsed member.

8.3.10 A member may resign at any time by giving notice in writing to the Chair of the Central HREC. A period of 4 weeks' notice is required.

8.3.11 The Chair of the Central HREC will initiate the process to appoint a new member to fill the vacancy of the former member.

8.3.12 Where a member resigns, the appointment of the new member will be for fixed term for a period of three years.

8.3.13 Members will be provided with a letter 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 member of the Central HREC
- meeting attendance responsibilities, and
- general responsibilities as a Central HREC member and eligibility for financial remuneration.

8.4 Conditions of appointment

8.4.1 Members will be required to sign a statement undertaking:

- that all matters of which they become aware during their work on the Central HREC will be kept confidential.
- that any interests in a project under review which exists or may arise during their tenure on the Central HREC will be disclosed.
- that they have not been subject to any criminal conviction or disciplinary action in accordance with the Criminal Record Screening Policy and Guidelines
- and there is no other matter which may prejudice their standing as a Central HREC member.

8.4.2 Upon appointment, members will be provided with a list of key documentation (see WA Central HREC SOP 2.2.10.)

8.5 Education and training

8.5.1 Newly appointed members shall be provided with adequate orientation, training, and reference materials.

8.5.2 Throughout their tenure, members shall be given the opportunity to participate in online training and attend workshops relevant to the work and responsibilities of the Committee.

8.6 Remuneration

8.6.1 Members will be remunerated in accordance with the Department's Consumer, Carer, and Community Paid Participation in Engagement Activities Policy.

8.6.2 Members who are already remunerated as part of their service on a WA Government board or committee will not be eligible for remuneration under ToR 6.6.1.

8.6.3 Expenses for training and educational activities will be covered by the Department at the discretion of the DG or delegate.

9 Establishment of HREC review panels and expert reviewers

9.1 Lower risk research

9.1.1 The Central HREC delegates consideration of Lower Risk Research (LRR) activities to a LRR Review Panel. This panel will be drawn from members of the Central HREC, a pool of expert reviewers, and the CORE.

9.1.2 The Committee may appoint such review panels as it sees fit to conduct ethics review of lower risk projects submitted to the Committee.

9.1.3 Members of any appointed panel need not be members of the Central HREC, however at least one Central HREC member will be appointed to each review panel.

9.1.4 The review of lower risk projects will be conducted in accordance with the Central HREC SOP 6.2.

9.2 External review and advice

9.2.1 The Central HREC may seek external review and or advice to assist with consideration of a research project if it decides that additional expertise is required to assess ethical matters related to the research project.

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

9.2.3 Where a research project involves the participation of persons unfamiliar with the English language, the Central HREC may require that any documents for participants are translated into the participant's language and that an interpreter is present during the consenting discussion on the project.

10 Liability coverage

10.1 Investigator led or cooperative research group sponsored projects

10.1.1 The Department provides indemnity for members of the Central HREC for any legal liabilities that arise because of decisions and advice by the member exercising their duties as a member in good faith.

11 Conduct of business

11.1 Procedures

11.1.1 The Central HREC will perform their functions by adopting the requirements laid out in the National Statement and according to the Central HREC's SOPs, these ToR, and relevant Department policies (Research Policy Framework).

11.1.2 These ToR and the SOPs of the Central HREC will be reviewed every three years and amended and updated, as necessary. All Central HREC members will have access to these procedures and the Chair of the Central HREC and their delegates shall be consulted regarding changes.

11.1.3 In conducting its functions the Central HREC shall:

- ensure that communication with researchers will be made in a spirit of courtesy and support, to develop mutual respect and a sense of partnership in the development of sound ethical practice.
- provide the decisions of the Central HREC in writing and within a reasonable timeframe to the persons nominated in the submission.
- determine the method of monitoring appropriate to each project. Projects that have received ethical approval will be monitored and may be audited to ensure that they conform to the protocol approved.

11.1.4 The Central HREC shall request that any amendments to approved protocols be submitted to the Central HREC for review by the appropriate ethics review process.

11.1.5 The Central HREC Chair 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.

11.2 Secretariat

11.2.1 The department will provide secretariat support for the Central HREC in the form of the CORE.

11.2.2 The CORE will employ staff to function as Ethics Officers (EOs) to attend meetings of and provide secretariat support to the Central HREC. EOs will not be members of the Central HREC.

11.3 Submissions, notifications, and approvals

11.3.1 Project submissions notifications and approvals must comply and be managed in accordance with the Central HREC SOPs.

11.4 Exemption or expedited review

11.4.1 The Central HREC may exempt projects from ethics and scientific review in accordance with the National Statement and the Central HREC SOP 6.4.

11.4.2 The Central HREC will provide an expedited review process for projects in accordance with the Central HREC SOPs 6.3.

11.5 Advocates and interpreters

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

11.5.2 Where research involves the participation of persons unfamiliar with the English language, the Central HREC may require that any documents for participants are translated into the participant's language, or where possible, employ an interpreter to ensure appropriate consent.

12 Meetings

12.1 Schedule of meetings

12.1.1 The Central HREC will meet on a regular basis, with meetings spread evenly throughout all months of the year except for January.

12.1.2 Meeting dates will be published on the Central HREC website and in the meeting calendar on the Research Governance Service (RGS).

12.2 Minimum membership

12.2.1 The minimum membership required to be present at a meeting is eight members, including:

- a chair the Deputy Chair or an Acting Delegate of the Chair with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to conduct its obligations under the National Statement.
- 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 including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or another religious leader.
- a qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters.
- two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

12.2.2 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 Section 8.1.1 have received all the papers and have had an opportunity to contribute their views in writing and that those views have been recorded and considered at the meeting.

13 Conflict of interest

13.1 Procedure

13.1.1 Any member who has any interest, financial or otherwise, in a proposal or other related matter to be considered by the Central HREC, should as soon as practicable, disclose such interest.

13.1.2 If the member is present at the meeting where the project or related matter is to be considered, the Chair will determine if the disclosed interest constitutes a conflict of interest. If it is determined that the member does have a conflict of interest, then the member may participate in the discussion but must withdraw from the meeting while the decision is made. If the member represents a minimum membership category as described in the National Statement, another member in that category will be asked to provide comments on the submission before the decision is finalised.

13.1.3 The member will not participate in the discussions and will not be entitled to participate in the decision on the matter. All disclosures of interest and absence of the member concerned will be minuted.

14 Decision making

14.1 Consultation

14.1.1 The Central HREC may consult with any person(s) considered by the Central HREC to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s):

- having no conflict of interest, and
- providing an undertaking of confidentiality.

Such person(s) shall not be entitled to participate in the decision on the matter.

14.2 Consensus

14.2.1 The Central HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by consensus.

14.2.2 Where consensus is not reached, the decision will be carried by a majority of two-thirds of members present at the meeting, provided that the majority includes at least one layperson.

14.2.3 Any significant minority view (i.e., two or more members) shall be noted in the minutes.

14.2.4 While voting is neither required nor prohibited by Section 5.2.8 of the National Statement; when the Committee is acting in its role as an Institutional Review Board (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.

15 Fees

15.1 Charges

15.1.1 A fee will not be charged for non-commercial applications submitted for assessment by the Central HREC.

15.1.2 Fees will be charged for review of commercially sponsored projects and the schedule of fees published on the Central HREC website and outlined in Section 9 of the Research Governance Procedures.

16 Record keeping

16.1 Responsibility

16.1.1 The CORE EOs will prepare, manage, and retain records of the Central HREC in accordance with the Central HREC SOPs.

17 Monitoring of approved projects

17.1 Role of the Central HREC

17.1.1 The Central HREC will monitor the conduct of approved projects in accordance with the Central HREC SOPs.

18 Complaints and review

18.1 Breaches or complaints concerning the conduct of a project

18.1.1 Any reports of breaches or concerns and complaints about the conduct of a project must be recorded and managed in accordance with the complaints management process detailed in the Central HREC SOPs.

18.2 Complaints concerning review processes or the rejection of an application

18.2.1 Any concern or complaint concerning the Committee review process, or the rejection of an application must be recorded and managed in accordance with the complaint management process detailed in the Central HREC SOPs.

19 Amendments to the terms of reference

19.1 Minor amendments

19.1.1 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 ToR.

19.1.1 Minor amendments to the ToR can be actioned by the CORE.

19.2 Major amendments

19.2.1 For major amendments, including changes in meaning, purpose, or intent, which 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 and any members should be discussed at the next scheduled meeting of the Chair 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 agree to the amendment.
- the CORE shall send the amendment to the DG on behalf of the Chair for consideration and approval where appropriate.

19.2.2 For major amendments including changes in meaning, purpose, or intent, which are proposed by the DG or delegate:

- The DG or delegate will send the proposal to the Central HREC and seek the views of the Chair before making any amendment.
- The Chair may also seek the views of Central HREC members to help inform their advice.

20 Glossary

Term	Definition
Australian Health Ethics Committee (AHEC)	The committee that advises the National Health and Medical Research Council on ethical issues related to health.
Confidentiality	The obligation of people not to use or disclose information for any purpose other than which it was given to them, without consent.
Consent	Consent means voluntary agreement to some act, practice, or purpose.
Data Collection	A systematic gathering or organised collection of information, in any format, for a particular purpose, including manual entry into an application system, questionnaires, interviews, observation, existing records and electronic devices. This includes, but is not limited to, statewide and statutory data collections managed by the Department of Health (e.g., Emergency Department Data Collection, Hospital Morbidity Data Collection, Midwives Notification System, Western Australian Cancer Registry).
Data Custodian	The person(s) responsible for the day-to-day management of a data collection, as nominated by the Data Steward. Data Custodians assist the Data Steward to protect the privacy, security, and confidentiality of information within data collections. Data Custodians also aim to improve the accuracy, usability, and accessibility of data within the data collection.
Data Linkage	A complex technique connecting data records within and between datasets thought to relate to the same person, place, family, or event. Data linkage typically uses demographic data (for example: name, date of birth, address, sex, medical record number) and facilitates analysis of linked information in a way that protects individual privacy.
Data Steward	A position with delegated responsibility from the Director General of Health to manage a data collection. The Data Steward's primary responsibility is to protect the privacy, security, and confidentiality of information within data collections. Data Stewards also approve the conditions for appropriate use and disclosure of information for clearly defined purposes that comply with Department of Health's statutory obligations and Information Management Policy Framework.

Term	Definition
De-identified Information	Has the meaning given in the *Privacy Act 1988 section 6*, being: Personal information is de-identified if the information is no longer about an identifiable individual or an individual who is reasonably identifiable.
Duty of Confidentiality	The legal duty of confidentiality obliges health care practitioners to protect their patients against inappropriate use or disclosure of personal health information.
Ethics	Ethics in human research refers to the set of principles that guide research design and practices to ensure that the dignity, rights, and welfare of research participants are protected. Research ethics govern the standards of conduct for scientific researchers.
Ethics Review	All research involving human beings should be reviewed by an ethics committee to ensure that the appropriate ethical standards are being upheld.
Evaluation	The systematic collection and analysis of information to make judgements, usually about the effectiveness, efficiency and or appropriateness of an activity.
Health Information	Information, or an opinion, which is also personal information, about: ▪ the health (at any time) of an individual; or ▪ a disability (at any time) of an individual; or ▪ an individual's expressed wishes about the future provision of health services to the individual; or ▪ a health service provided, or to be provided, to an individual. or other personal information collected to provide, or in providing, a health service. (*Section 213 of the Health Services Act 2016*).
Health Service Provider	An entity that delivers medical care or treatment as established under *Section 32 of the Health Services Act 2016* and may include: ▪ Child and Adolescent Health Service (CAHS), ▪ East Metropolitan Health Service (EMHS), ▪ Health Support Services (HSS). ▪ North Metropolitan Health Service (NMHS), ▪ PathWest ▪ Quadriplegic Centre ▪ South Metropolitan Health Service (SMHS), ▪ WA Country Health Service (WACHS),
Human Research Ethics Committee (HREC)	A committee constituted in accordance with, and acting in compliance with, the *National Statement* to review and, where

Term	Definition
	appropriate, approve and monitor the ethical and scientific aspects of human research.
Information	Data that has been processed in such a way as to be meaningful to the person who receives it. Information can be personal or non-personal in nature. The terms 'data' and 'information' are often used interchangeably and should be taken to mean both data and information in this document.
National Health and Medical Research Council (NHMRC)	Australia's primary health and medical research funding agency. It plays a crucial role in supporting research, providing health advice, and promoting ethical behaviour in health care and medical research.
Multi-centre Research	Multicentre research refers to clinical trials or research studies conducted at multiple facilities or sites. In such trials, participants are enrolled and followed across more than one independent medical institution.
National Statement	Also known as the *National Statement on Ethical Conduct in Human Research* provides essential guidelines for researchers, Human Research Ethics Committees (HRECs), and others involved in the ethics review of research involving humans.
Non-personal Information	Refers to information or opinion about a person whose identity is not apparent and cannot be reasonably ascertained from the information or opinion.
Personal Information*	Information or an opinion, whether true or not, and whether recorded in a material form or not, about an individual, whether living or dead: ▪ whose identity is apparent or can reasonably be ascertained from the information or opinion; or ▪ who can be identified by reference to an identification number or other identifying particular such as a fingerprint, retina print or body sample. **Refer Freedom of Information Act 1992*
Principal Investigator (PI)	The individual responsible for the overall conduct, management, monitoring and reporting of a particular research project conducted at a site.
Privacy	The individual's right or expectation to be able to control who can see or use information about them.
Quality Assurance	An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation with the aim of improving that service.

Term	Definition
	Terms such as 'peer review,' 'quality assurance,' 'quality improvement,' 'quality activities,' 'quality studies and 'audit' are often used interchangeably. In this document the term quality assurance is used to include all these terms.
Research	The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way to generate new concepts, methodologies, inventions, and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.
Research Governance	Research governance ensures that the principles, requirements, and standards of research are upheld. It addresses the protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management, and monitoring arrangements. Effective research governance promotes a positive research culture and sustainable practices that facilitate the conduct of high-quality clinical research.
Standard Operating Procedures (SOPs)	The documented procedures and processes supporting the WA Health Central Human Research Ethics Committee.
Statutory Data Collections	Refers to the information about a medical event, condition and disease that must be collected by law and reported to the WA Department of Health.
Use	Refers to the communication or handling of personal and non-personal information by individual(s) internal or external to the WA Health system.
WA Health system	Pursuant to section 19(1) of the *Health Services Act 2016*, the WA health system means: ▪ Department of Health. ▪ Health Service Providers; and ▪ To the extent contracted health entities provide health services to the State, the contracted health entities.
Western Australian Data Linkage System (WADLS)	The system used to connect available health and other related information for the population of Western Australia. This incorporates database tables holding demographic data and linkage keys, and the bespoke tools used by linkage staff to process, create, store, and retrieve them.

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