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

Western Australian Health Central Human Research Ethics Committee

Terms of reference

28 May 2024

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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 ethical 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 act 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.

1 Objectives

1.1 The objectives of the Central HREC

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

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

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

1.1.4. To promote ethical standards of human research.

2 Functions

2.1 The functions of the Central HREC

2.1.1 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.

2.1.2 To provide ethical and scientific review of research projects.

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

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

2.1.5 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.

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

2.1.7 To assess the use of information in research without the consent of the individual 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.

2.1.8 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.

3 Scope of responsibility

3.1 The responsibilities of the Central HREC

3.1.1 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. This responsibility 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

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

3.1.3 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.

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

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

3.1.6 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.

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

4.1 Status

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

4.1.2 Institutional approval of research 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.

4.1.3 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.

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

5 Accountability of the WA Health Central Human Research Ethics Committee

5.1 Accountability

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

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

5.2 Reporting

5.2.1 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.

5.2.2 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.

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

6 Membership

6.1 Composition of the WA Health Central HREC

6.1.1 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 carry out 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.

6.1.2 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 backgrounds
- 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.

6.1.3 Members of the Central HREC may be appointed to one or more categories described in Section 7.1.1 but can only represent one of those categories at a specific meeting.

6.1.4 As far as practicable, the membership of the Central HREC should be diverse, including equal numbers of men and women and at least one third of the members should be from outside the WA Health system.

6.1.5 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.

6.1.6 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.

6.2 Appointment of members

6.2.1 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.

6.2.2 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.

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

6.2.4 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.

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

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

6.3 Terms of appointment

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

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

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

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

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

6.3.6 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.

6.3.7 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 5 meetings in anyone calendar year, unless there are exceptional circumstances.

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

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

6.3.10 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.

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

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

6.3.13 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.

6.4 Conditions of appointment

6.4.1 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 conflicts of interest which exist or may arise during their tenure on the Central HREC will be declared.
- 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.

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

6.5 Education and training

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

6.5.2 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.

6.6 Remuneration

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

6.6.2 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.

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

7 Establishment of HREC review panels and expert reviewers

7.1 Lower risk research

7.1.1 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.

7.1.2 The Committee may appoint such review panels as it sees fit to carry out ethical review of lower risk projects submitted to the Committee.

7.1.3 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.

7.1.4 The review of lower risk projects will be conducted in accordance with the Central HREC SOP 6.6.

7.2 External review and advice

7.2.1 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.

7.2.2 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.

7.2.3 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.

8 Liability coverage

8.1 Investigator led or cooperative research group sponsored projects

8.1.1 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.

8.2 Commercially sponsored projects

8.2.1 Where the project under consideration is being sponsored by a commercial entity that entity may provide indemnity in line with the Medicines Australia Indemnity and Compensation Guidelines (Form of Indemnity HREC only).

9 Conduct of business

9.1 Procedures

9.1.1 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).

9.1.2 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 and will have access to these procedures and the Chair of the Central HREC and their delegates shall be consulted regarding changes.

9.1.3 In carrying out its functions the Central HREC shall:

- ensure their enquiries of the researcher 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.

9.1.4 The Central HREC shall request that any amendments to approved protocols be presented to it for approval.

9.1.5 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.

9.2 Secretariat

9.2.1 The department will provide secretariat support for the Central HREC by the provision of the CORE.

9.2.2 The CORE will employ staff to act 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 with voting rights.

9.3 Submissions, notifications, and approvals

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

9.4 Exemption or expedited review

9.4.1 The Central HREC may exempt projects from ethical and scientific review in accordance with the National Statement and the Central HREC SOP 6.2.

9.4.2 The Central HREC will provide an expedited review process for projects in accordance with the Central HREC SOP 6.5.

9.5 Advocates and interpreters

9.5.1 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.

9.5.2 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.

10 Meetings

10.1 Schedule of meetings

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

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

10.2 Quorum

10.2.1 A quorum for meetings shall exist when at least 8 members are present at a meeting including one of each of the following categories:

- 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 carry out 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 other 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.

10.2.2 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 6.1.1 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.

11 Conflict of interest

11.1 Procedure

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

11.1.2 If the member is present at the meeting where the project is the subject of consideration, the member will withdraw from the meeting until the Central HREC ’s consideration of the relevant matter has been completed. If this member holds a key role in the HREC, another member in that category will be asked to comment.

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

12 Decision making

12.1 Consultation

12.1.1 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.

12.2 Consensus

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

12.2.2 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.

12.2.3 Any significant minority view (i.e. 2 or more members) shall be noted in the minutes.

12.2.4 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.

13 Fees

13.1 Charges

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

13.1.2 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.

14 Record keeping

14.1 Responsibility

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

15 Monitoring of approved projects

15.1 Role of the Central HREC

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

16 Complaints and review

16.1 Breaches or complaints concerning the conduct of a project

16.1.1 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.

16.2 Complaints concerning review processes or the rejection of an application

16.2.1 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.

17 Amendments to the terms of reference

17.1 Minor amendments

17.1.1 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.

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

17.2 Major amendments

17.2.1 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 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.

17.2.2 For major amendments including changes in meaning, purpose, or intent, that 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.

18 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.
Ethical 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, that 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. (S*ection 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 ethical 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.

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