



WA Health

**Research Governance
Policy and Procedures**

Research Development Unit, Office of the Chief Medical Officer
November 2012



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TITLE: RESEARCH GOVERNANCE POLICY

1. BACKGROUND

The Western Australian public health system (**WA Health**) recognises that high quality human research and evidence based practice strengthens the delivery of innovative and quality health care.

The Research Governance Policy has been implemented to ensure that all human research conducted within WA Health meets the highest ethical, scientific, regulatory and professional governance standards; and complies with relevant national and State legislation, guidelines and codes of conduct. The policy establishes the research governance framework through which research is reviewed, approved, conducted and monitored in an effective and efficient manner.

2. SCOPE

This policy applies to human research:

- conducted within WA Health by WA Health employees (including visiting medical officers, visiting health professionals, contractors, consultants, agents and volunteers) and non-WA Health employees (including clinical and non-clinical university academics) who propose to undertake, manage, review and govern human research; and/or
- involving participants, their tissue or data accessed through WA Health.

Activities other than human research are outside the scope of this policy. This may include the management of animal research, quality improvement activities (including clinical audits) and disclosure of information for evaluation of services provided by WA Health¹.

Investigators should ensure they are aware of the differences between research and quality improvement (refer to [Procedures section 3.1](#)).

3. POLICY STATEMENT

WA Health effectively manages the scientific, ethical and governance review, approval, conduct and monitoring of human research, through the implementation of a sound research governance framework and other relevant processes. This is to ensure human research:

- is ethically and scientifically sound;
- is conducted by authorised personnel with appropriate professional qualifications, credentials and institutional approvals;
- is conducted in a safe and responsible manner according to regulatory and professional standards and complies with relevant national and State legislation, guidelines and codes of conduct;
- ethical and governance review and monitoring is transparent, accountable, minimises duplication, risk and is conducted in an efficient and timely manner; and
- is authorised by the Chief Executive or delegate before commencement.

¹ The Department of Health WA HREC approval is required for the disclosure of personal health information from the Department of Health data collections for projects involving the funding, management, planning, monitoring, improvement or evaluation of health services, except disclosure to meet mandatory reporting obligations required by legislation or funding agreements.



All human research and experimentation conducted within WA Health will be reviewed, approved, conducted and monitored, under the guidance of its established bodies and in accordance with the principles that have their origin in the:

- World Medical Association “[Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects](#)” 2008;
- National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors’ Committee “[National Statement on Ethical Conduct in Human Research](#)” 2007 – Updated 2009 (**National Statement**);
- National Health and Medical Research Council, Australian Research Council and Universities Australia “[Australian Code for the Responsible Conduct of Research](#)” 2007 (**The Code**);
- National Health and Medical Research Council “[Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research](#)” 2003;
- Therapeutics Goods Administration “[The Australian Clinical Trials Handbook](#)” 2006, and “[Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)](#)” 2000; and
- Relevant Commonwealth or State legislation and guidelines including the Department of Health “[Occupational Safety and Health Policy](#)” 2005.

All human research that takes place in WA Health must undergo research governance which consists of ethical, scientific and governance review. The research must be reviewed, authorised, conducted and monitored in accordance with the WA Health Research Governance Framework (as outlined in the WA Health Research Governance Policy and Procedures). The Department of Health and Health Services must establish adequate resources, structures and practices (including Research Policies and Standard Operating Procedures) consistent with the implementation of this framework.

Research approval is conditional upon ethical and scientific review by a Human Research Ethics Committee and a WA Health governance review prior to authorisation. The governance review at Health Services involves a Site Specific Assessment by a Research Governance Officer. The governance review for the Department of Health data collections, involves review of the data application by the Data Custodian and approval for the release of personal health information from the Data Steward.

The applicant must receive written notification of authorisation by the Chief Executive or delegate from the Health Service or the Data Steward from the Department of Health before commencement. Once the research has commenced the Department of Health and Health Services are responsible for the appropriate governance of research activity carried out within their services to ensure it is conducted in a safe and responsible manner.



4. REFERENCE DOCUMENTS

4.1 Supporting Documentation

WA Health Research Governance Procedures as attached.
WA Health Single Ethical Review Standard Operating Procedures.²
National Ethics Application Form.
Western Australian-Specific Module.
WA Health Ethics Application Form (for research conducted within WA Health).
WA Health Site Specific Assessment Form.
WA Health Site Specific Assessment Form for Low and Negligible Risk Research.
WA Health Access Request Form.

4.2 Relevant Legislation

Adoption Act 1994 (WA)
Age of Majority Act 1972 (WA)
Australian Research Council Act 2001 (Cwth)
Copyright Act 1968 (Cwth)
Coroners Act 1996 (WA)
Corruption and Crime Commission Act 2003 (WA)
Criminal Code Act Compilation Act 1913 (WA)
Electronic Transactions Act 2011 (WA)
Financial Management Act 2006 (WA)
Freedom of Information Act 1992 (WA)
Gene Technology Act 2000 (Cwth)
Gene Technology Act 2006 (WA)
Gene Technology Regulations 2001 (Cwth)
Guardianship and Administration Act 1990 (WA)
Health Act 1911 (WA)
Health Legislation Administration Act 1994 (WA)
Human Reproductive Technology Act 1991(WA)
Human Tissue and Transplant Act 1982 (WA)
Hospitals and Health Services Act 1927 (WA)
Industry Research and Development Act 1986 (Cwth)
Mental Health Act 1996 (WA)
National Health and Medical Research Council Act 1992 (Cwth)
Occupational Safety and Health Act 1984 (WA)
Occupiers' Liability Act 1985 (WA)
Poisons Act 1964 (WA)
Privacy Act 1988 (Cwth)
Public Interest Disclosure Act 2003 (WA)
Public Sector Management Act 1994 (WA)
Radiation Safety Act 1975 (WA)
Research Involving Human Embryos Act 2002 (Cwth)
State Records Act 2000 (WA)
State Supply Commission Act 1991 (WA)
Therapeutic Goods Act 1989 (Cwth)
Therapeutic Goods Regulations 1990 (Cwth)
Working with Children (Criminal Record Checking) Act 2004 (WA)

² This document will be available in 2013.



4.3 Related Policies, Documents and Websites³

▪ International

[Australian New Zealand Clinical Trials Registry.](#)

[ClinicalTrials.gov.](#)

[International Committee of Medical Journal Editors “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” 2010.](#)

[International Standard Randomised Controlled Trial Number \(ISRCTN\) Register.](#)

[US Department of Health and Services Office for Human Research Protections.](#)

[World Medical Association “Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects” 2008.](#)

▪ Commonwealth

[Australian Department of Health & Ageing “Australian Hospital Patient Costing Standards” 2011.](#)

[Australian Department of Health & Ageing Gene Technology Regulator.](#)

[Australian Electoral Commission “Supply of Elector Information for Use in Medical Research” 2011.](#)

[Australian Government Directory.](#)

[Australian Prudential Regulation Authority.](#)

[Australian Radiation Protection and Nuclear Safety Agency.](#)

[Australian Research Council “National Principles of Intellectual Property Management for Publicly Funded Research” 2001.](#)

[Australasian Evaluation Society “Guidelines for the Ethical Conduct of Evaluations” 2010.](#)
[Medical Technology Association of Australia Clinical Investigation Research Agreement and Indemnity and Compensation Guidelines.](#)

[Medicines Australia Clinical Trial Research Agreements and Indemnity and Compensation Guidelines.](#)

[National Health and Medical Research Council \(NHMRC\), Australian Research Council and Australian Vice-Chancellors Committee “National Statement on Ethical Conduct in Human Research” 2007 – Updated 2009.](#)

[NHMRC, Australian Research Council and Universities Australia “Australian Code for the Responsible Conduct of Research” 2007.](#)

[NHMRC “Biobanks Information Paper” 2010.](#)

[NHMRC “Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research” 2007.](#)

[NHMRC “Flowchart of Single Ethical Review Process for Multi-centre Research” 2011.](#)

[NHMRC “Framework for Monitoring: Guidance for the National Approach to Single Ethical Review” 2012.](#)

[NHMRC “Guidelines for Genetic Registers and Associated Genetic Material” 1999.](#)

[NHMRC “Guidelines Under section 95 of the *Privacy Act 1988*” 2000.](#)

[NHMRC “Guidelines approved under Section 95A of the *Privacy Act 1988*” 2001.](#)

[NHMRC Harmonisation of Multi-centre Ethical Review.](#)

³ All references to policies, documents, websites and legislation within the policy and procedures document are bookmarked back to Sections 4.2 & 4.3. Links in Section 4.2 & 4.3 checked on 20.11.12.



NHMRC [Human Genetics Advisory Committee \(HGAC\)](#).
NHMRC [Human Research Ethics Portal](#).
NHMRC [“Medical Genetic Testing: Information for Health Professionals”](#) 2010.
NHMRC [“Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products”](#) 2009.
NHMRC [National Ethics Application Form](#).
NHMRC [“National, State & Territory Legislative Framework for ethical review of multi-centre research”](#) 2012.
NHMRC [“Statement on Human Experimental and Supplementary Notes”](#) 1972.
NHMRC [“Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research”](#) 2003.
NHMRC [“Research Governance Handbook: Guidance for the national approach to single ethical review”](#) 2011.
[Therapeutic Goods Administration \(TGA\)](#).
TGA [“Access to Unapproved Therapeutic Goods – Clinical Trials in Australia”](#) 2004.
TGA [“Human Research Ethics Committees and the Therapeutic Goods Legislation”](#) 2001.
TGA [“Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting \(CPMP/ICH/377/95\)”](#) 2000.
TGA [“Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)”](#) 2000.
TGA [“The Australian Clinical Trial Handbook”](#) 2006.

▪ **State**

[Aboriginal Health Council of WA](#).
[Data Linkage WA](#).
Department of Health [“Code of Conduct”](#) 2008.
Department of Health [“Consent to Treatment Policy for the Western Australian Health System”](#) 2011.
Department of Health [“Data Stewardship and Custodianship Policy”](#) 2011.
Department of Health [“Data Linkage Branch Access Policy”](#) 2010.
Department of Health [“Guidelines for Human Biobanks, Genetic Research Databases and Associated Data”](#) 2010.
Department of Health [“Health Accounting Manual”](#).
Department of Health [Information About Health Data](#).
Department of Health [“Information about your Health Data”](#) Booklet 2009.
Department of Health [“Information Access and Disclosure Policy”](#) 2012.
Department of Health [“Information Classification Policy”](#) 2010.
Department of Health [“Information Lifecycle Management Policy”](#) 2012.
Department of Health [Intellectual Property Management](#).
Department of Health [“Intellectual Property Management in WA Health”](#) 2006.
Department of Health [“Long Term Management of Electronic Records Policy”](#) 2004.
Department of Health [“Managing Conflict of Interest Policy and Guidelines”](#) 2010.
Department of Health [“Misconduct and Discipline Policy and Guidelines”](#) 2011.
Department of Health [“Non-Coronial Post-Mortem Examinations Code of Practice”](#) 2007.
Department of Health [“Occupational Safety and Health Policy”](#) 2005.



Department of Health [“Patient Confidentiality and Divulging Patient Information to Third Parties” 2006.](#)

Department of Health [“Patient Information Retention and Disposal Schedule” Version 3, 2008.](#)

Department of Health [“Policy on Use of Official Information and Public Comment” 2011.](#)

Department of Health [“Practice Code for the Use of Personal Health Information” 2009.](#)

Department of Health [“Recordkeeping Plan” 2010.](#)

Department of Health [Reproductive Technology Council.](#)

Department of Health [Research Development.](#)

Department of Health [“Retention and Disposal Schedule for Administrative and Functional Records” 2007.](#)

Department of Health [“Style Guide for Corporate Visual Identity” 2011.](#)

Department of Health [“WA Health Complaint Management Policy” 2009.](#)

Department of Health [“WA Health Consumer Carer and Community Engagement Framework” 2007.](#)

Department of Health [“WA Health Risk Management Policy and Framework” 2005.](#)

Department of Health Human Research Ethics Committee [“Application Process for Health Information”.](#)

Kimberley Aboriginal Medical Services Council.
[“Western Australian Aboriginal Health Ethics Committee \(WAAHEC\) Values and Ethics Statement”.](#)

WA Government [Coroner’s Court of WA.](#)

WA [“Government Intellectual Property Policy and Best Practice Guidelines” 2003.](#)

WA Government [“Encouraging Innovation by Government Employees” 2003.](#)

WA Government [“Treasurer’s Instructions”.](#)

WA Government [“Working with Children Check”.](#)

WA Public Sector Commission [“Code of Ethics” 2012.](#)



5. DEFINITIONS/ACRONYMS USED WITHIN THIS POLICY AND SUPPORTING PROCEDURES

Aboriginal	The use of the term “Aboriginal” within this document refers to both Aboriginal and Torres Strait Islander people.
Access Request Review	A mechanism used by WA Health to ensure that the proposed research project complies with governance requirements, and gives consideration whether to support the provision of access to participants, their tissue or data through the Health Service.
Business Manager	The individual who is responsible to the Health Service’s Department, Division, Site or Region for financial information, advice on financial management information systems, financial advice on implications and risks of current and projected services and future financial management strategy within their area of responsibility.
Clinical Trial	A form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.
Clinical Trial Exemption (CTX) Form	<p>A form used to make an application to the TGA under the Clinical Trial Exemption scheme, which is required for clinical investigational use of:</p> <ul style="list-style-type: none"> • any medicine, biological or device not entered in the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or • a marketed medicine, biological or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new patient group and the extension of doses or duration of treatments outside the approved range. <p>Under the CTX scheme the TGA conducts an evaluation of the clinical trial and provides written advice to the reviewing Human Research Ethics Committee.</p>
Clinical Trial Notification (CTN) Form	<p>A form used to notify the TGA of the intent to conduct a clinical trial under the Clinical Trial Notification scheme, which is required for clinical investigational use of:</p> <ul style="list-style-type: none"> • any medicine, biological or device not entered in the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or • a marketed medicine, biological or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new patient group and the extension of doses or duration of treatments outside the approved range. <p>Under the CTN scheme the Human Research Ethics Committee reviews all material relating to the proposed trial.</p>



Clinical Investigation Research Agreement (CIRA)	A written agreement between two or more parties, which sets out the responsibilities of each party. WA Health uses a standard CIRA. Based on the Medical Technology Association of Australia version, the CIRA contain common, standard provisions and should, in most cases, reduce the need for institutions to obtain extensive legal advice in negotiating a CIRA.
Clinical Trial Research Agreement (CTRA)	A written agreement between two or more parties, which sets out the responsibilities of each party. WA Health uses a set of standard CTRAs. Based on the Medicines Australia versions, the CTRAs contain common, standard provisions and should, in most cases, reduce the need for institutions to obtain extensive legal advice in negotiating a CTRA.
Confidentiality Agreement (CA)	A written agreement between two or more parties, which sets out the responsibilities pertaining to the privacy of each party. Parties involved are usually pharmaceutical/device companies who wish to control confidential information relating to clinical trials and investigators/institutions who undertake to keep the provided information confidential. WA Health uses a standard CA to be used by institutions.
Contract Research Organisation (CRO)	A person or organisation (commercial, academic or other) contracted by a sponsor to perform one or more of a sponsor's trial-related duties or functions.
Coordinating Principal Investigator (CPI)	The individual who takes overall responsibility for the research project and submits the project for ethical and scientific review for multi-centre projects. They are responsible for ongoing communication with the Human Research Ethics Committee and passing on any outcomes from this to the Principal Investigators. For single-centre research, the CPI and Principal Investigator's roles are synonymous.
Cost Centre	A financial reporting code specific to a Health Entity.
Data Custodian	The person responsible for the ongoing development, data collection, maintenance and review of the collection. They are responsible for the quality of the data, its security, timeliness and adherence to standards.
Data Safety Monitoring Board (DSMB)	An independent data monitoring committee that may be established by the sponsor/investigator to assess at intervals the progress of a clinical trial, the safety data, and the critical efficiency endpoints, and to recommend to the sponsor whether to continue, modify or stop the trial.
Data Steward	The person responsible for setting the strategic direction of the specific data collection to ensure it's developed, maintained and utilised in accordance with WA Health strategic goals. They authorise the access, use and disclosure of data from the data collection for purposes that comply with WA Health's statutory obligations.
Donor	An individual or organisation donating to the Health Entity. The donation may include money, goods and/or services.
Ethics	As defined in the National Statement (Section 1) .
Grants	Arrangements of financial assistance. Funds provided for a single discrete specified purpose and period and not constituting the entire financial base of an organisation.



Health Entity	A discrete budget holder within an agency or an agency in its own right as a budget holder.
Health Service	A health service within WA's public health system, governed by a council made up of community members and clinicians selected by the Minister for Health. There are five Health Services responsible for the management and delivery of services within WA Health, these include: <ul style="list-style-type: none"> • South Metropolitan Health Service; • North Metropolitan Health Service; • Southern Country Health Service; • Northern and Remote Country Health Service; and • Child and Adolescent Health Service.
Human Research Ethics Committee (HREC)	A committee constituted under the guidance of the National Statement to conduct the ethical and scientific review of a human research project.
Institution	Any public or private entity or medical facility where human research is conducted.
Intellectual Property (IP)	The tangible representation of intellect and creativity that has value and is protectable by law.
Lead HREC	A HREC certified by the NHMRC (from WA or other jurisdictions) to conduct the single ethical and scientific review of multi-centre human research on behalf of WA Health, utilising the National Approach process.
Lead WA Health HREC	A WA Health HREC that is able to conduct the single ethical and scientific review of multi-centre human research on behalf of WA Health, when it is not applicable to use the National Approach. The Lead WA HREC is registered with the NHMRC's Australian Health Ethics Committee (AHEC) and identified in the WA Health Single Ethical Review Standard Operating Procedures.
Legal & Legislative Services (LLS)	Legal & Legislative Services is a Directorate within the Department of Health, responsible for providing legal services to WA Health.
Medicines Australia (MA)	The national association that represents companies in the pharmaceutical industry.
Medical Technology Association of Australia (MTAA)	The national association representing companies in the medical technology industry.
Multi-Centre Research	Research that is conducted at more than one site within the authority of more than one HREC.
National Approach to Single Ethical Review of Multi-Centre Research (National Approach)	The National Approach to Single Ethical Review of Multi-centre Research is a process to enable the single ethical review of multi-centre research, within or across Australian jurisdictions, utilising the NHMRC's certified ethical review processes. This process was formerly known as the Harmonisation of Multi-centre Ethical Review (HoMER) initiative.



Non-HREC level alternative	A person or body (e.g. subcommittee or delegate) that conducts an ethical review of a research project which is an alternative to that of a full HREC.
NHMRC Certified HREC	A HREC associated with an institution that has been certified under the NHMRC National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-Centre Research.
National Ethics Application Form (NEAF)	The NEAF is a national, web-based application form for investigators of all disciplines to complete research ethics proposals for submission to HRECs.
Principal Investigator (PI)	The individual responsible for the overall conduct, management, monitoring and reporting of research conducted at a site and who submits the research project for site authorisation. For single-centre research, CPI and PI roles are synonymous.
Quality Improvement (QI) Audit	A project designed to define optimum therapeutic methods, benchmarks and goals and is the means of ensuring via retrospective or prospective audit, that this aim is being achieved.
Research	Original investigation undertaken to gain knowledge, understanding and insight as described in the NHMRC “Australian Code for the Responsible Conduct for Research” 2007 .
Research Governance	The framework through which WA Health implements the principles, requirements and standards of research. It addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements and promotes good research culture and practice. The governance of research will ensure that its delivery meets its objectives and conforms to relevant institutional, jurisdictional and national ethical, scientific, regulatory and professional standards and applicable laws.
Research Governance Officer (RGO)	The individual appointed within the Health Service who is responsible for the management of research governance site specific applications involving site authorisation and oversight of authorised research projects.
RiskCover	A division of the Insurance Commission of Western Australia, a statutory body created to manage and administer the self-insurance Fund of the Western Australian Government Public Authorities and to promote risk management throughout State Government agencies.
Single-Centre Research	Research that is conducted at only a single site within WA Health or at two or more sites under the authority of a single WA Health HREC.
Site	A facility, location or service (e.g. hospital, institution) where the research is being conducted within a Health Service.
Site Authorisation	The authorisation granted by the Chief Executive or delegate of the Health Service for the commencement of a research project at the site.
Site-Specific Assessment (SSA)	A mechanism used by WA Health to ensure that the proposed research project complies with governance requirements, and to consider whether the research should be conducted and supported at the proposed site.



Special Purpose Account (SPA)	Monies which the Health Service is obliged to spend in accordance with the conditions or restrictions specified by the donor or contributor. They are defined as “restricted assets”, reserved for particular uses and are not available in relation to the general activities of the Health Service.
Standard Operating Procedures (SOPs)	The documented procedures and processes supporting the WA Health Research Governance Policy and Procedures as published by the Department of Health or a Health Service.
State Solicitor's Office (SSO)	The office that is responsible for the provision of legal services to the Government of Western Australia and to State Government client departments and agencies.
Supporting Departments	Health Service departments that are not specifically conducting the research project within their department but will be providing services to support the research project (e.g. pharmacy, pathology and imaging).
Western Australian Department of Health (Department of Health)	The Western Australian public health system including all health systems and hospitals. It includes the five Health Services (South Metropolitan Health Service, North Metropolitan Health Service, Southern Country Health Service, Northern and Remote Country Health Service and Child and Adolescent Health Service) and the Department of Health.
WA Country Health Service (WACHS)	The use of the term WA Country Health Service within this document includes both the Southern Country Health Service and the Northern and Remote Country Health Service.
WA Health	A phrase used to represent the Western Australian public health system including all health systems and hospitals. It includes the five Health Services (South Metropolitan Health Service, North Metropolitan Health Service, Southern Country Health Service, Northern and Remote Country Health Service and Child and Adolescent Health Service) and the Department of Health.
WA Health Single Ethical Review	An initiative intended to expedite the approval of multi-centre research projects by ensuring that the research project conducted under the authority of more than one WA Health HREC must undergo single ethical review by a Lead WA Health HREC.
WA Health Research Governance Portal (RGP)	A secure web-based portal that is part of the WA Health Research Governance Service information technology system that enables investigators to electronically complete their applications for ethical, scientific and governance review, required for research authorisation and ongoing monitoring requirements. <i>Estimated availability 2013.</i>
WA Health Research Governance Service (RGS) Information Technology (IT) System	A research governance IT system that supports the workflow and reporting required for research governance processes. It allows investigators to complete and submit their applications for the authorisation and monitoring of research through the online RGP. All details on the ethics and governance submission can be electronically downloaded into the RGS IT system for processing and review by the Ethics Executive Officer, HREC, RGO and the site. <i>Estimated availability 2013.</i>



6. REVIEW

This policy and procedures will be reviewed every five years unless there are changes to WA Health corporate or research governance directives.

Endorsed by: Kim Snowball, Director General, Department of Health WA

Review Date: 20 November 2017.

This policy remains effective until a subsequent version is endorsed by the Director General.

Accessing Policies via the Whole of Health Holii Policies link at:

http://intranet.health.wa.gov.au/policies/doh_policy.cfm

or externally at <http://www.health.wa.gov.au/circularsnew/>

Primary Contact: Research Development Unit.



TITLE: RESEARCH GOVERNANCE PROCEDURES

IMPLEMENTATION FRAMEWORK

Compliance with these procedures is required to meet research governance standards outlined in the Research Governance Policy.

1. RESEARCH DEVELOPMENT

WA Health's objective is to ensure that:

- structures and support are provided for the implementation of the WA Health Research Governance Policy and Procedures;
- the research organisational structure within WA Health is documented and delegation for research authorisation is documented;
- a working environment is created that encourages and fosters research. Senior clinical positions, where appropriate, have research experience and personnel involved with the conduct of research have adequate training;
- all new investigators receive appropriate training in the disciplines involved with research ethics, research governance and good clinical practice as outlined in the [National Statement, The Code](#) and the TGA "[Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)](#)" 2000;
- sufficient resources are provided for the effective and efficient processing of applications for ethical and scientific review by the HREC and for the effective and efficient processing of applications for site authorisation by the Research Governance Offices;
- all HREC members, Ethics Executive Officers and RGOs receive appropriate education and training in research governance processes;
- all research is monitored for compliance with policy and procedures and systems are in place for the management of complaints about research, including research misconduct and fraud;
- consumer groups are consulted with, in the areas of health policy, planning, research and service delivery as outlined in the Department of Health "[WA Health Consumer Carer and Community Engagement Framework](#)" 2007; and
- an annual report generated by the WA Health Research Governance Service IT system, is produced by the Department of Health and Health Services to identify research activity, revenue, ethics and governance activities by documenting the:
 - (1) categories of research (including phase and number of clinical trials);
 - (2) categories of institutions providing the research including the related personnel involvement at the institution;
 - (3) timeliness of ethics and governance reviews;
 - (4) number of multi-centre project reviews conducted, including those that are using the National Approach, and are inter-jurisdictional (inter-state) or within WA;
 - (5) funding related to research;
 - (6) number of research projects conducted (in progress or completed);
 - (7) research complaints, including research misconduct and fraud; and
 - (8) training attended by HREC members, research governance personnel and investigators.



2. RESEARCH GOVERNANCE REVIEW

Research governance ensures the principles, requirements and standards of research are implemented. It addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management, monitoring arrangements, and promotes good research culture and practice.

Research Governance enables WA Health to:

- ensure that all proposed research projects comply with appropriate ethical, scientific, regulatory and professional standards;
- ensure risk management practices are in place;
- consider whether a project should be supported or conducted at the site;
- monitor research conduct and compliance; and
- have knowledge of all research conducted within its jurisdiction.

Research governance measures should be established for the conduct and monitoring of research in accordance with [The Code](#) and NHMRC “[Research Governance Handbook: Guidance for the national approach to single ethical review](#)” 2011 and in line with the Department of Health “[WA Health Risk Management Policy and Framework](#)” 2005 which provides a whole of health approach to the management of risk.

2.1 Delegation of Authority

The WA Minister for Health (in his capacity as the deemed Board of the Metropolitan Public Hospitals) has appointed the Director General of the Department of Health as the accountable authority for the Health Services. The responsibility for research governance and the authority for signing contracts on behalf of the State are delegated from the Director General to the Health Service’s Chief Executive. Under delegated authority from the Health Service Chief Executive, the Executive Director of a WA Health site must decide whether or not to sign contractual agreements and authorise the commencement of research projects.

Chief Executives of Health Services must determine the appropriate delegation for authorisation and ensure it is documented. Responsibility for authorisation cannot be delegated to a HREC.

The Director General is the delegated owner of all data and information collected, stored, used and disclosed within WA Health. The Director General delegates a number of these responsibilities to senior officers. Data Stewards have delegated responsibility for setting the overall strategic direction of the data collection. They are also responsible for authorising the access, use and disclosure of data from the data collection. Data Custodians have delegated responsibility for the ongoing development, data collection, maintenance and review of the collection for the quality of the data, its security, timeliness and adherence to standards.

2.2 Non WA Health Investigator Agreement

Research personnel who are not WA Health employees but wish to conduct research at a WA Health site must be working under an agreement between their employing organisation (e.g. university) and WA Health, stipulating the responsibilities and liabilities of each organisation. In addition, a Declaration of Confidentiality should be completed by all non-WA Health research personnel, who will be conducting research within WA Health or accessing WA Health participants, their tissue or data. The Declaration of Confidentiality is not project specific and can be completed once to cover all research within a jurisdiction of a RGO.



2.3 Authorisation of Research

All human research conducted in WA Health must undergo scientific and ethical review by a Human Research Ethics Committee (refer to section [3 Ethical and Scientific Review](#)) and governance review before authorisation can be granted by the Chief Executive or delegate for Health Services; or by the Data Steward for the Department of Health data collections. The governance review at Health Services involves a Site Specific Assessment by a Research Governance Officer. The governance review for the Department of Health data collections, involves review of the data application by the Data Custodian and approval for the release of personal health information from the Data Steward.

The Health Service retains the right not to authorise commencement of a research project, even if a HREC has recommended ethics approval. It is the responsibility of the PI to notify those involved in the research project (e.g. Support Departments) when the research has been authorised for commencement.

Both ethical and governance review processes can occur concurrently. A summary of routes to obtain authorisation within WA Health and how they relate to ethical, scientific and governance approval is outlined in [Annexure 1](#).

2.4 Site Specific Assessment

The WA Health research governance review for the authorisation of research at Health Services involves either a SSA for research conducted at the site or an Access Request Review for research that is not conducted at the site but requires access to participants, tissue or data for the research project (refer to section [2.5](#)).⁴

The SSA encompasses assessing the suitability of the site and investigator(s) to conduct research at the site. It entails risk management and the identification of 'actual' or 'in kind' resources that will be required for the conduct and completion of the project and whether they can be met by either the sponsor or the Health Service. The SSA is the mechanism for professional, legal and financial accountability and transparency, and is consistent with [The Code](#) and the [Financial Management Act 2006 \(WA\)](#). It enables Health Services to reduce risk and quantify the contribution of resources and assist with future operational planning and budgets.

A SSA is required when the research conducted at the Site involves:

- enrolling participants into research;
- carrying out protocol specific research procedures with or on participants; and
- managing and analysing data, tissue and responses from surveys and questionnaires collected for or from research.

The SSA is carried out using one of the *WA Health Site Specific Assessment Forms* for each site involved in the research. This must occur irrespective of whether the project has undergone full HREC approval (including those involved in the National Approach or WA

⁴ A research project involving the Department of Health data collections requires the ethical review by the Department of Health WA HREC and governance review by the Data Custodian and approval from the Data Steward. If an application to the Department of Health WA HREC for ethical review involves a WA Health site then a SSA and the access request must be submitted to the Health Service site involved in conducting/requiring access for the research, to enable the governance review and authorisation of the research project at the site. If an application to the Department of Health WA HREC for ethical review involves a site from outside WA Health, the responsibility for governance review remains with the external site conducting the research.



Health Single Ethical Review processes), or low or negligible risk HREC approval (i.e. low or negligible risk research projects).

The following SSA forms are available from the RGO and through the Research Governance Portal (when available); guidance is available on how to complete the forms and supporting documents required for making an application:

1. WA Health Site Specific Assessment Form

This form must be used for single-centre and multi-centre human research projects, conducted within WA Health, that require a full Human Research Ethics Committee (HREC) review.

2. WA Health Site Specific Assessment Form for Low and Negligible Risk Research

This form must be used for single-centre and multi-centre human research projects, conducted within WA Health, that require an ethics review for low or negligible risk research.

The CPI or the local site PI (in multi-centre research) where the research is being conducted, or their delegate, must complete a SSA form for site authorisation. In the case of student projects the SSA form should be completed by the student under supervision of the on-site WA Health Research Supervisor.

In research that requires a full HREC review (i.e. research that is more than low risk) a WA Health SSA form is required for each site (i.e. institution) involved in the research within the Health Service to ensure all resourcing and authorisation is documented for each individual site, except for:

- WA Country Health Service where one SSA form may incorporate several sites within a WACHS Region, but it must include details of the sites and a declaration of support from the relevant site Directors and Regional Director; and
- North Metropolitan Health Service Mental Health (NMHS MH) where one SSA form may incorporate several sites within NMHS MH, but must include details of the sites and a declaration of support from the relevant site Directors.

In the case of a low or negligible risk project, involving multiple sites within the authority of a Health Service RGO, only one WA Health SSA Form for Low and Negligible Risk Research is required for that project. It must include a declaration of support on the SSA form from all the Site Directors (plus Regional Directors for WACHS) that are involved in that Health Service.

The SSA is a separate governance process to ethical and scientific review of a research project and can be conducted in parallel to the HREC process (i.e. it is not necessary to await the HREC outcome before preparing and submitting a SSA application). The HREC will not review the SSA form and its approval/decision is independent from the governance review.

Research projects will be managed and tracked by Ethics and Research Governance Offices utilising the WA Health Research Governance Service IT system, which is linked with the Research Governance Portal (when available). This provides a single platform, with automatic data import capabilities, for investigators to complete HREC and Research Governance applications online and upload documents, as well as monitor the progress of their application.



The completed SSA form and supporting documents e.g. agreements, insurance, budgets must be submitted to the RGO at each site involved with the project. Some RGOs may be responsible for several sites within a Health Service. WA Health Research Governance contact details are available at the Department of Health [Research Development](#) website.

The RGO must assess the SSA application to ensure:

- investigators have the necessary skills, training experience and authorisation to undertake their role;
- potential conflict of interests have been identified;
- the site has suitable and adequate facilities, infrastructure and resources (personnel and support of on-going training) which are available for the duration of the project;
- funding sources have been identified and the actual monetary or 'in kind' cost of the project is detailed, including whether these costs can be met by the sponsor or the Health Service. Approval of this budget is documented (as evidenced by the Business Manager's declaration in the SSA form);
- the Head of Department and Divisional Director (where the research will be conducted) has given a declaration of support in the SSA form, that the research is appropriate to be conducted within that department and at the site. This includes:
 - (1) confirmation of the feasibility and alignment of the project design to institutional and/or departmental strategic plans for research;
 - (2) ensuring the project details are acceptable i.e. peer review of scientific, ethical and practical aspects of the proposed project;
 - (3) ensuring there is sufficient resourcing (including participants) for the research project to be carried out at the site;
- the Heads of Supporting Departments have given declarations of support to provide support or services in the SSA form;
- any legislative requirements, including notification, registration and licence applications have been addressed. Refer to section **3.8. Project Specific Requirements**.
- risk management strategies are implemented i.e. adequate indemnity and insurance arrangements are in place;
- legal agreements are in place with external commercial and non-commercial research and clinical trial sponsors, clarifying obligations, responsibilities and the rights of parties involved;
- research documents comply with the specific requirements of the WA Health sites; and
- there is HREC (comprising ethical and scientific) approval (this approval may not be available on initial submission).

Health Services must ensure that RGOs are adequately resourced to conduct the assessment in an efficient and timely manner as some RGOs may be responsible for several sites within a Health Service. For clinical trials this includes reviewing any applicable insurance, indemnity and clinical trial research agreement documentation as soon as possible. RGOs will complete the governance review within a 60 calendar day timeframe, which allows for a 'stop clock' capability when additional input is required from the sponsor or investigator before consideration can continue. Following assessment, RGOs will make a recommendation to the Chief Executive or delegate regarding authorisation of the project.

Authorisation to commence a research project will only be granted when a HREC has recommended ethics approval and the SSA, following recommendation by the RGO, has



been approved by the Chief Executive/delegate. Investigators must receive a letter of authorisation (listing all approved documents) in writing from the Chief Executive/delegate prior to commencing a project.

2.5 Access Request Review

A human research project that requires support from a Health Service in the form of access to participants, tissue or data but does not involve the conduct of research at any facilities, locations or services under the control of that Health Service, is not required to undergo a governance review using a SSA form. However, a completed **WA Health Access Request Form**⁵, HREC approval and supporting documentation must be submitted to the responsible RGO for a research governance review and recommendation to the Chief Executive or delegate, to consider whether to support the project and sign a declaration of authorisation. The HREC approval must be from either a WA Health HREC (or Non-HREC level alternative) or a NHMRC certified HREC.

Access Request Review is required when the research project involves:

- participant recruitment through posters, leaflets, handouts, letters of invitation (but not recruitment through direct contact with potential participants or enrolment);
- distribution of surveys and questionnaires through personnel of the Health Service (but not collation and analysis of responses at the Health Service); and
- access to data or tissue held at the Health Service (but not processing or analysis at that Health Service).

The CPI responsible for the research project must complete a *WA Health Access Request Form* and supporting documentation for access authorisation. This supporting documentation includes:

1. A copy of the WA Health HREC (or Non-HREC level alternative) or NHMRC certified HREC letter of approval.
2. A copy of WA Health Ethics Application Form or NEAF plus WA-Specific Module (as relevant).
3. A copy of the WA Health Research Conflict of Interest Form for the CPI (if a conflict of interest exists).
4. All documents to be distributed through the sites within the Health Service, e.g. posters, leaflets or handouts; letters of invitation (on research site letterhead); and surveys and questionnaires.
5. Written confirmation of approval from personnel of the sites through which the CPI is seeking access to participants, tissue or data, for example:
 - Head of Department who agrees to personnel distributing posters and leaflets about the research project or letters of invitation to potential participants;
 - Head of Department who agrees to questionnaires or surveys to personnel by e-mail, in line with the Health Service policies; and
 - Relevant Senior Executive and/or Data Steward⁶ who agree to provide access to medical records, data or tissue held in collections or databases under their management, in line with ethical conditions imposed by the approving HREC.

⁵ This form is not applicable to the Department of Health WA HREC which has its own governance processes.

⁶ Access to data must be approved in accordance with the WA Health Information Disclosure Model outlined in the Department of Health ["Information Access and Disclosure Policy" 2012](#).



This form is available from the RGO and through the Research Governance Portal (when available). Only one Access Request Form for each RGO contained within a Health Service will be required for each research project, even if the project requires access from a number of sites covered by that RGO. The RGO has the discretion to request that the application be submitted for SSA if the project involves conduct of research at the site.

RGOs must review the application and confirm that:

- all relevant information is provided;
- all required supporting documents have been submitted (as outlined on the form);
- the research project has received ethical and scientific approval; and
- the Health Service’s sites have appropriate resources and have agreed to provide the access required by the project.

RGOs must conduct the review in an efficient and timely manner (i.e. within 60 calendar days) and make a recommendation to the Chief Executive/delegate regarding authorisation of the project. Investigators must receive authorisation in writing from the Chief Executive/delegate prior to commencing a project at that site.

2.6 Financial Management

Management of all research funds received by WA Health, whether identified as a fee-for-service, funded research (e.g. grants) or as a donation or bequest must be managed in line with the WA “[Health Accounting Manual](#)”, comply with WA Government policy and legislation ([Financial Management Act 2006 \(WA\)](#), [Hospitals and Health Services Act 1927 \(WA\)](#) and “[Treasurer’s Instructions](#)”) and adhere to the following:

- budgets for all commercial and non-commercial sponsored/funded research are to be developed by PIs, in consultation with their Business Manager and relevant Supporting Departments (e.g. pharmacy, pathology and imaging) and should be considered in the overall expenditure limit for the Health Service;
- the budget should document all the Health Service’s/site’s research activity costs for the project as defined by the Teaching and Research Cost Definitions in the Australian Department of Health & Ageing “[Australian Hospital Patient Costing Standards](#)” 2011⁷. This includes departmental, infrastructure costs and support department charges (including ‘in kind’ support) that form part of the research protocol which are secondary to the primary purpose of providing patient care;
- the budget should provide a comparison between the costs of the project and the funding that will be received from external funding/sponsorship;
- the PI should negotiate funding/sponsorship with sponsors utilising the fee structures within WA Health, with support provided by the RGO as required;
- research funds that are not restricted and will be managed in operating accounts will require a forward proposal (budget) to be submitted with the SSA prior to the research commencing, outlining the expenditure over various years (i.e. over the period of the

⁷ According to the “Australian Hospital Patient Costing Standards v 2.0” 2011 definition, research is an activity where the primary aim is the advancement of knowledge through:

- Observation, data analysis and interpretation, or other means that are secondary to the primary purpose of providing patient care; or
- Activities associated with patient care where additional components or tasks exist (for example, the addition of control group in a cohort study).

It excludes curriculum-based research projects. Indirect or by-product research is considered as part of normal patient care and is not included in the national standard.



research project). Funds in operating accounts that meet the requirements of restricted cash can be carried over across financial years whereas if not deemed restricted cash then monies should be expended in the financial year in which they are received;

- all research project funding and costs should be documented on the SSA form with additional supporting documentation (if required) for review and approval by the RGO;
- commercially sponsored research must demonstrate full cost recovery of all research-related costs (i.e. research costs must be matched by external funding/sponsorship);
- costs for non-commercial sponsored research or unfunded research will have to be met by the combination of the non-commercial funding (e.g. grants) and 'in kind' support or funding from the Health Service;
- ethics and research governance administrative fees will be levied for all commercially sponsored research. Fees for ethics review and research governance review conducted within WA Health are available from RGOs. These fees are reviewed annually. Standard WA Health fees will be charged in accordance with 18(2a) of the [Hospitals and Health Services Act 1927 \(WA\)](#) - The Minister for Health must give approval for the provision of services to a person or body, including payment for those services;
- contractual agreements should detail the amount, timing and method of any payments to WA Health. All costs are subject to Goods and Services Tax (**GST**) (10%) if the sponsor (or CRO) is registered as an entity in Australia. Payments from an overseas sponsor are not subject to GST; however, if an Australian CRO is making the payments on behalf of an overseas sponsor, payments will be subject to GST;
- payments or gifts intended to be provided by sponsors to participants in research undertaken within WA Health must be reviewed by the relevant HREC. Investigators should outline to the HREC the rationale for providing the payment or gift. Incentive payments or gifts should not be confused with reimbursement of participants (e.g. reimbursement of travel, parking or accommodation costs);
- invoices for payments from external entities can occur either by Direct Tax Invoice via Health Corporate Network or by Recipient Created Tax Invoice (Debtor generated invoice);
- reimbursement of costs to Supporting Departments for research related costs are to be promptly reimbursed by the investigator from the research project cost centre; and
- when a Health Service is providing a service, funded from a research grant held by an external administering organisation (e.g. NHMRC grant held by a university investigator), the external administering organisation must provide invoicing details to the Health Service, prior to the commencement of the project.

2.7 Account Management

In accordance with the [Financial Management Act 2006 \(WA\)](#), the “[Treasurer’s Instructions](#)” and the WA “[Health Accounting Manual](#)” (most recent version on the WA Health intranet site), research funds (including operating revenue, donations, bequests and grants) are managed in Health Entity operating accounts.

2.7.1 Operating Accounts

Operating accounts can hold funds that are either restricted or not restricted. Those funds that are deemed to be restricted cash can be set up and classed as ‘Special Purpose Accounts’ (refer to section [2.7.2 SPAs](#)) which are also operating accounts but are segregated out to permit funds to be carried forward from one financial year to the next.



Restricted funds are those funds that the Health Entity has an obligation to use in accordance with conditions imposed by the external donor/contributor.

Donations, bequests or grants that do not have specific conditions attached and where discretion can be exercised on how the money will be spent should be treated as operating revenues and credited to the operating account as unrestricted funds.

Research funding received that has an obligation to be used in accordance with conditions imposed by the donor/contributor must be utilised for its stated purpose (this must be stipulated in the research agreement). If funding is received from more than one source and not all funding is restricted then it can be separated into restricted and not restricted by the utilisation of different cost centres, i.e. restricted funds can utilise a 'special purpose account' cost centre and non restricted funds can utilise an operating cost centre. These funds should be identified appropriately and governed by the appropriate committee/individual, taking into account any specific directions applicable to the use of these monies.

Money credited to the operating account shall only be applied for the services and purposes detailed in the annual budget statements. In accordance with the [Financial Management Act 2006 \(WA\)](#) if the total amount of an appropriation for a financial year for a particular service/purpose of an agency is not charged to the operating account for the service/purpose by the end of that year, any unexpended amount of the appropriation lapses i.e. there is no carry over of funds.

2.7.2 Special Purpose Accounts

Note: These are internal Operating accounts

As a requirement under the [Financial Management Act 2006 \(WA\)](#) and the "[Treasurer's Instructions](#)", if research funds fit the criteria of money that must be spent in accordance with the conditions/restrictions specified/imposed by the donor/contributor, where there is an agreement imposing a legal requirement that funds be held in a separate account, then the money must be accounted for in a separate SPA established for that purpose. The balance of a SPA can only be applied for purposes for which the account was established. Expenditure will be specified in the Special Purpose Statement.

The Special Purpose Statement complements any agreement between the donor and the recipient and should therefore succinctly express the intent of the agreement i.e. what money can be received into the account and how the money is to be applied. Funds must only be dispersed in accordance with the purposes for which the SPA was established.

The Special Purpose Statement should document the terms and conditions regarding the distribution of funds remaining in the SPA should it be closed. These terms and conditions may derive from, *inter alia*, a deed or bequest or by arrangement with donors at the time the donation is made. If no provision is made, the direction of the Courts may be required. In the case of a parliamentary appropriation the balance is transferred to the Consolidated Account.

The WA "[Health Accounting Manual](#)" states the use of WA Health Special Purpose Accounts will only be permitted in the following very limited circumstances:

- when an external donor/contributor specifically states in their underlying agreement or legal instrument with the Health Entity, that they require a separate special purpose account to be created, that separately shows the financial transactions of that particular special purpose account in the financial statements of the Health Entity (this



will occur every year until the funds are exhausted and the trust statement is closed);
or

- where a parliamentary appropriation is made to a SPA for a specific purpose.

Restricted cash and cash equivalents are monies that the Health Entity is obliged to spend in accordance with the conditions or restrictions specified by the donor/contributor. The conditions/restrictions must be externally imposed or restricted under law. In this case the restricted cash should be placed in a SPA.

SPAs operate on a cash basis. When unspent money remains in a Health Entity SPA at the end of the financial year, the Health Entity has an obligation to maintain a commensurate balance of cash in its bank account for usage in the following financial year. The balance of the Health Entity SPA should be disclosed as restricted cash in the financial statements.

A Research Advisory Committee (or equivalent) may be established at each Health Service to oversee the annual allocation of general research SPA funds between research projects. If a committee is utilised, a responsible officer should be appointed to be accountable for overseeing and reporting on the SPA and distribution of funds.

2.7.3 Creation of Cost Centres

Business Managers should always be involved in the creation of cost centres and liaise with the investigator to determine the number of cost centres required (i.e. should several research projects be managed through one cost centre or multiple cost centres) and the type of account.

2.8 Contract Management

All research involving WA Health personnel, participants or resources conducted with an external sponsoring entity must be the subject of a written agreement. The type of research activity undertaken will determine the type of contractual agreement required.

A research contract is a legally enforceable agreement between two or more parties. It should contain all of the terms on which the parties have agreed to conduct the research project. Contractual terms must be appropriate and acceptable to WA Health and document the rights and obligations of the parties, reflect State laws, as well as ensuring the rights of the investigator, the participants and WA Health are protected. All research contracts are to be governed by WA law and any disputes will be dealt with by WA Courts.

The Minister for Health must give approval for the provision of services to a person or body, including payment for those services. Therefore all commercially sponsored research will require Ministerial/delegate endorsement, in regard to charges raised, prior to the contract being executed.

It is the responsibility of WA Health personnel involved in research projects to ensure that research contracts are reviewed prior to signing by the Chief Executive or delegate. These contracts must be reviewed by the Health Service RGOs under the direction of legal advice from the Department of Health Legal and Legislative Services prior to authorisation by the Chief Executive or delegate, who should be satisfied with the proposed contract before they sign. Refer to section [2.9](#) for review of CAs and section [2.11.3](#) for review of CTRAs/CIRAs.



WA Health standard clinical trial/investigation, research and confidentiality agreement templates are available on the Department of Health [Research Development](#) website and from site RGOs. They must be used wherever possible to reduce legal review. A separate contractual agreement is required for each Health Service/institution involved in the research project; investigators should contact the relevant RGO for details.

WA Health investigators and personnel involved in contract negotiations are not authorised to bind the State; therefore no contract can be executed unless it has been signed by the appropriate authorised WA Health delegate.

2.9 Confidentiality Agreement

Investigators are often asked to sign commercial Confidentiality Agreements by external entities relating to a proposed research project. The SSO recommends that WA Health employees do not sign commercial CAs. CAs are legally binding agreements that can give rise to legal liability.

If a CA is required by an external entity, WA Health has established a standard CA which is recommended for use in clinical trial research and data registries. Amendment to the standard CA can be negotiated with the external party by the RGO in consultation with the LLS. If a CA or non-disclosure agreement other than the endorsed WA Health version is required then the RGO should seek legal advice from the LLS prior to signing by the Chief Executive or delegate.

Investigators do not have the legal delegation to bind or sign agreements on behalf of the institution. Investigators may choose to sign a sponsor's CA in a personal capacity only. In such cases, the agreement must not refer to WA Health or the site in any way that might be construed as inferring that WA Health or the site is a party to that agreement.

2.10 Clinical Data Registry Agreement

External entities wishing to access data held in a WA Health clinical registry must enter into a Clinical Data Registry Agreement. Review and amendments must be processed by the RGO in line with the guidelines established for Clinical Trial/Investigation Research Agreements.

2.11 Clinical Trial/Investigation Research Agreements

Each clinical trial⁸ conducted in a Health Service involving an external entity such as a commercial sponsor, Contract Research Organisation or collaborative group must be governed by a CTRA/CIRA. A standard, system-wide approach to the agreements and indemnities applying to clinical trials conducted in WA Health is in place. These templates are available on the Department of Health [Research Development](#) website.

WA Health uses the [Medicines Australia](#) and [Medical Technology Association of Australia](#) template agreements. Each of these agreements provides for amendments to be made to the terms presented in the body of the agreement. WA Health has specified a number of amendments to be included in the relevant schedule (Special Conditions) to the agreement, in line with the SSO legal and legislative policy and guidelines. The Department of Health LLS will inform RGOs of Health Services when a new version of a CTRA/CIRA, approved by WA Health, becomes available.

⁸ References to clinical trials within this document also include clinical investigations.



2.11.1 Types of Clinical Trial/Investigation Research Agreements

2.11.1.1 Commercially Sponsored Pharmaceutical Clinical Trials

For all pharmaceutical industry-sponsored clinical trials, WA Health has endorsed the mandatory use of the following standard CTRAs:

1. Clinical Trial Research Agreement - Medicines Australia - Standard Form (Form A):

This bipartite CTRA is used by WA Health where the parties to the agreement are the Minister for Health (delegate) and the commercial sponsor. This can also be used where a pharmaceutical company uses a subcontractor (under clause 20 of the CTRA), but remains as the sponsor of that trial.

2. Clinical Trial Research Agreement - Standard Form B - For Studies Involving a Sponsor and a Contract Research Organisation (Form B):

This tripartite CTRA is used by WA Health where the parties to the agreement are the Minister for Health (delegate), the commercial sponsor and a CRO and is used in preference to Form A or D when three parties are involved in the management of the research project.

3. Clinical Trial Research Agreement - Medicines Australia Form: Contract Research Organisation acting as the Local Sponsor (Form D):

This bipartite CTRA is used by WA Health where the parties to the agreement are the Minister for Health (delegate) and a CRO. It should be used when a CRO, engaged by a foreign commercial company, is acting as the Australian sponsor. The sponsoring CRO must be an Australian entity.

2.11.1.2 Non-Commercially Sponsored Clinical Trials

For all non-commercial clinical trials WA Health has endorsed the mandatory use of the following Standard CTRAs:

1. Clinical Trial Research Agreement - Collaborative or Cooperative Research Group (CRG) Studies - Standard Form (Form C):

This bipartite CTRA is used by WA Health where the parties to the agreement are the Minister for Health (delegate) and a collaborative or cooperative research group.

2. Clinical Trial Research Agreement - Investigator-Initiated Trial (Form E):

This bipartite CTRA is used by WA Health where the parties to the agreement are the Minister for Health (delegate) with an entity that is providing funding and/or drug/medical device. Any IP arising from the project remains the property of WA Health or as negotiated on an individual basis.

2.11.1.3 Commercially Sponsored Clinical Device Trials

For all medical device industry-sponsored clinical projects WA Health has endorsed the mandatory use of the following standard MTAA Clinical Investigation Research Agreement:

1. MTAA Standard Clinical Investigation Research Agreement (CIRA):

This bipartite CIRA is used by WA Health where the parties to the agreement are the Minister for Health (delegate) and the sponsor.



2.11.2 Clinical Trial/Investigation Research Agreement Clauses

The template contracts include clauses covering the following:

2.11.2.1 Parties

The contract must be between parties that are legal entities and not individuals and must detail the parties' full legal name (including ABN if a company) and registered address. Affiliates should be identified and overseas sponsors providing an indemnity must be party to the Agreement.

WA Health must always be described as: "The Minister for Health is incorporated as the board of (insert name of Health Service/Institution), under s7 of the Hospitals and Health Services Act 1927 (WA) and has delegated all the powers and duties as such to the Director General of Health."

The signatory on legal documentation should read: "Signed on behalf of the Institution, for and on behalf of the Director General of Health as delegate of the Minister for Health, by its duly authorised representative."

2.11.2.2 Obligations, Roles and Responsibilities

The roles and responsibilities of each party in relation to the conduct of the research project must include compliance with all applicable Australian and WA laws and regulations, national research guidelines, standards and regulatory authorities. This must include the parties' responsibilities for reporting and management of adverse events, records management, provision of equipment or project products, completion of reports and retention and access requirements to project related materials.

WA Health personnel should be aware that amongst other things WA Health:

- cannot agree to "not violate any foreign laws" as it is not aware of, or subject to, such laws;
- is bound to comply with a variety of policies determined by government which may restrict their ability to assist commercial entities with investigations; and
- may be directed to retain a sample of an unused investigational product (e.g. in a civil or criminal legal action).

2.11.2.3 Confidentiality and Privacy

This details the requirements of the parties to protect information created, disclosed or acquired (directly or indirectly) during the course of the project. WA Health employees are subject to the Department of Health "[Practice Code for the Use of Personal Health Information](#)" 2009 and the [Public Sector Management Act 1994 \(WA\)](#) to keep information confidential. Regarding disclosure, WA Health personnel are subject to legal obligations. External parties to the CTRA/CIRA are required to comply with the provisions of the [Privacy Act 1988 \(Cwth\)](#).

2.11.2.4 Indemnity

WA Health must ensure that it does not assume liabilities attached to an external entity. In a commercially sponsored clinical trial the MA CTRA requires the sponsor or CRO to indemnify WA Health and WA Health HRECs against claims by participants involved in the trial in accordance with either the [Medicines Australia 'Standard' or 'HREC Only' Forms of Indemnity](#). The Indemnity Form should be inserted or referenced at Schedule 3 of the MA CTRA and RGOs must ensure that it is signed by both the sponsor/CRO and Chief Executive or delegate at the time of signing the CTRA.



In a commercially sponsored clinical investigation the MTAA CIRA requires the sponsor to indemnify WA Health against claims by participants involved in the device trial in accordance with the [MTAA Standard Forms of Indemnity](#). The Indemnity Form should be inserted or referenced at Schedule 3 of the MTAA CIRA and RGOs must ensure that it is signed by both the sponsor/CRO and Chief Executive or delegate at the time of signing the CIRA.

In clinical trials that are investigator-initiated, collaborative or funded from non-commercial organisations, the indemnity clauses should be mutual or specifically tailored to the risks and liabilities associated with the project; these should be documented in the CTRA/CIRA. Care must be taken in providing indemnity to a third party, as such an action may not be covered by RiskCover and/or contravene [Treasurer's Instruction 821](#).

Under the National Approach involving the conduct of clinical trials, WA Health must ensure that there are appropriate insurance and indemnity arrangements in place that provide the Department of Health and Health Services (and their associated HRECs) with appropriate protection in respect of any liabilities that might be incurred in relation to its research activities. This includes providing an ethical review outcome for a multi-centre research project, whether or not that research is occurring at the WA Health site. This does not preclude WA Health from requiring an indemnity from a third party (including another publicly funded health service outside WA Health) as part of their research governance process. In the instance of a commercially sponsored clinical trial the sponsor must provide indemnity to the certified HREC.

In regards to a clinical trial which has been reviewed externally to WA Health by a private HREC the following indemnity requirements must be adhered to:

- commercial trial – where the private HREC review concerns a commercial trial, the two MA forms of indemnity would need to be provided by the sponsor (one to cover the private HREC and one to cover the WA Health institution for the conduct of the trial). Along with the HREC approval, the CPI would need to provide the RGOs with a copy of the HREC indemnity, so that the RGOs would have copies of both indemnities on file; and
- non-commercial trial - where the private HREC review concerns a non-commercial trial, the private HREC would need to provide evidence that it holds sufficient and appropriate insurance. In terms of WA Health's duty of care to participants, the institution should ensure that the HREC's insurance cover would respond to a claim, alleging negligence in the review, made by a participant against the HREC.

2.11.2.5 Insurance

The contract must include a clause requiring any party who is providing an indemnity under the contract to have and maintain appropriate insurance. The CTRA/CIRA requires the sponsor or CRO to provide an insurance Certificate of Currency or full policy to demonstrate their ability to meet their liability obligations. The insurance requirements are outlined in Schedule 4 of the commercial CTRA/CIRA.

RGOs must review the insurance Certificates of Currency in consultation with RiskCover as documented in the Health Services' Standard Operating Procedures, to ensure the insurance will meet any liabilities. RGOs, in consultation with RiskCover, should ensure policies meet the requirements as outlined in Schedule 4 of the commercial CTRA/CIRA.

Consideration must be given to clinical trial, product and public liability cover, the availability of legal liability cover and whether the commercial insurer is [Australian Prudential Regulation](#)



Authority approved. During the course of the required research liability cover, updated insurance policies should be reviewed and approved by RGOs.

2.11.2.6 Term and Termination

This details the circumstances in which a party may terminate the contract. The ability to terminate the CTRA/CIRA if at any time participant safety necessitates the cessation of the research project is critical. Clauses should also be included regarding the consequences of termination (e.g. obligations to finalise/submit reports, payment of all funds due and owing up until the date of termination and arrangements for ongoing medical care of participants).

2.11.2.7 Additional Clauses

These may involve Disputes, Waiver, Variations, Assignment, Entire Agreement, Severance, Relationship of Parties and Force Majeure. In respect to commercial disputes, it is the experience of the State that if the parties can't reach an agreement, then mediation has little prospect of success and merely adds to costs and time. In respect to the Severance clause, it is the opinion of the SSO that, if a clause is severed from the Agreement, that clause may go to the heart of the Agreement (e.g. Indemnity) which may be prejudicial to WA Health.

2.11.2.8 Schedule 7 (Commercial)/Schedule 4 (Non-commercial)

All CTRAs/CIRAs allow for the parties to include amendments in Schedule 7 for commercial agreements and Schedule 4 for non-commercial agreements, these are known as **Special Conditions**. WA Health has agreed with a number of individual commercial and non-commercial entities to use a negotiated form of the CTRA/CIRA between WA Health and that particular entity, for multiple sites on an on-going basis. These are either in the form of a standard CTRA/CIRA template; or a set of clauses to be included as Special Conditions in Schedule 7 or 4 (as appropriate). RGOs of Health Services will be notified of clauses that have been reviewed and pre-approved by the Department of Health LLS.

2.11.3 Review of Clinical Trial/Investigation Research Agreements

The following processes must be adhered to when reviewing CTRA/CIRAs:

- where an external entity uses the WA Health standard CTRA/CIRA for a clinical trial without alteration, the Health Service should accept this agreement without further legal review;
- where an external entity uses the WA Health Standard CTRA/CIRA with the addition only of clauses under Special Conditions in Schedule 7 or 4 (as appropriate) that have been reviewed and pre-approved by WA Health for that particular entity, the Health Service should accept this agreement without further legal review;
- RGOs should contact LLS to check if that external entity has a standard set of pre-approved Special Conditions in Schedule 7 or 4 (as appropriate);
- Health Services retain the ability for RGOs to negotiate specific additional operational terms and conditions for a particular CTRA/CIRA with the sponsoring external entity;
- Health Services must obtain legal advice from LLS where an external entity insists on using their own contract or uses the WA Health Standard CTRA/CIRA but makes significant alterations or additions to it, other than the addition of pre-approved Special Conditions clauses;
- where legal review of the non-standard CTRA/CIRA is required, the external entity should be informed that this advice (if it involves external legal fees) may be at the expense of the sponsor and the undertaking may cause significant delays to the approval process;
- new or revised amendments to Special Conditions clauses in Schedule 7 or 4 (as appropriate), intended for general use for all research projects, should be submitted to LLS to enable legal review and pre-approval; and



- project specific amendments to Special Conditions clauses in Schedule 7 or 4 (as appropriate), are approved only for that project and do not affect current approved Special Conditions clauses for that external entity.

2.12 Non Standard Research Agreements

2.12.1 Agreements

WA Health does not mandate the use of a particular research template for research projects that do not involve clinical trials, clinical investigations or registries. The following agreements are available for use in other research projects as required:

- **Material Transfer Agreement;**
- **Study Funding Agreement;**
- **Agreement for Clinical Equipment on Loan or Trial; and**
- **Service Agreement.**

Research projects may require a research agreement to be specifically tailored to reflect the particular arrangements for the project, with clauses specifically drafted to deal with unique issues. This may include ownership and use of pre-existing and new Intellectual Property (with respect to protecting or commercialising), or if one of the investigators is a joint-appointee of the parties to the contract. Legal advice should always be obtained on the terms of any research agreement for a research project that falls within this category.

2.12.2 Indemnity

In research projects that are not commercial clinical trials, the indemnity clauses should be mutual or specifically tailored to the risks and liabilities associated with the project; these should be documented in the agreement as required. Care must be taken in providing indemnity to a third party, as such an action may not be covered by RiskCover and/or contravene [Treasurer's Instruction 821](#).

Under the National Approach, WA Health must ensure that there is appropriate insurance in place that provides the Department of Health and Health Services (and their associated HRECs) with appropriate protection in respect of any liabilities that might be incurred in relation to its research activities. This includes providing an ethical review outcome for a multi-centre research project, whether or not that research is occurring at the WA Health site. This does not preclude WA Health from requiring an indemnity from a third party (including another publicly funded health service outside WA Health) as part of their research governance process.

In regards to a research project, that is not a clinical trial, which has been reviewed externally to WA Health by a private HREC the following indemnity requirements must be adhered to:

- commercial research project – where the private HREC review concerns a commercial project, two types of indemnity would need to be provided by the sponsor (one to cover the private HREC and one to cover the WA Health institution for the conduct of the research project). Along with the HREC approval, the CPI would need to provide the RGOs with a copy of the HREC indemnity, so that the RGOs would have copies of both indemnities on file; and
- non-commercial research project - where the private HREC review concerns a non-commercial project, the HREC would need to provide evidence that it holds sufficient and appropriate insurance. In terms of WA Health's duty of care to participants, the



institution should ensure that the HRECs insurance cover would respond to a claim, alleging negligence in the review, made by a participant against the HREC.

2.13 Intellectual Property

Intellectual Property is the tangible representation of intellect and creativity. There is wide diversity in the type of IP that is being generated in the State health system. For example, new treatments, data, software, training materials or business improvement processes are all innovations that can arise as a consequence of the activities of the health sector and, if value is to be added, require some form of protection. Refer to the Australian Research Council [“National Principles of Intellectual Property Management for Publicly Funded Research” 2001](#).

The Department of Health [“Code of Conduct” 2008](#) states that WA Health personnel will "Protect and responsibly manage the Intellectual Property developed in, or used by, WA Health. The Intellectual Property we create in the course of our employment may remain the property of WA Health". The ability to provide innovative Government employees with rewards for developing or creating commercially valuable IP assets in the course of their work is discussed in the document WA Government [“Encouraging Innovation by Government Employees” 2003](#).

Research conducted in WA Health must comply with the [WA “Intellectual Property Policy and Best Practice Guidelines” 2003](#), and Department of Health [“Intellectual Property Management in WA Health” 2006](#). Research agreements must state the arrangements for use of existing IP and the parties' rights in relation to ownership and use of all new IP developed through the research project. For further information and assistance from the Department of Health IP Coordinator refer to Department of Health [Intellectual Property Management](#) website. Refer any IP issues to the RGO or Department of Health IP Coordinator.

2.14 Authorship

It is the responsibility of the investigators to be aware that minimum requirements for authorship of scientific publications will accord with the International Committee of Medical Journal Editors (ICMJE), [“Uniform Requirements for Manuscripts Submitted to Biomedical Journals” 2010](#).

An individual must meet all of the following conditions to be included in the authorship manuscript list:

- substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content; and
- final approval of the version to be published.

A person who does not fulfil these criteria should not be included as an author of a publication. Acquisition of funding, collection of data, or general supervision of the research group does not constitute authorship.

Authorship should be decided early in the planning process of a research project, specifically who will be credited as authors, contributors and who will be acknowledged. This should be reviewed and documented whenever there are changes in participation.



2.15 Publication

All those involved in research have a duty to ensure that research results are disseminated and communicated, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding. Investigators have a responsibility to their colleagues and the wider community to disseminate a full account of their research, including results contrary to their hypotheses, as broadly as possible.

A clear agreement between all parties, describing the method of disseminating results and protection of IP rights, should be reached and documented at the planning stage of any research. This should be incorporated into the research protocol and any relevant CTRA or CIRA.

The investigator should be afforded reasonable rights to publish papers related to the results of the project in a reasonable amount of time following the project completion, subject only to short delays to allow for a party to seek protection of IP or remove any confidential information. The maximum delay in publication should be stated in the protocol and CTRA or CIRA and investigators should ensure that they are aware of these arrangements. The parties are required to obtain the prior written permission of the other party for use of a party's name in any publications or promotional material.

With respect to personal health information provided by the Department of Health, guidelines about the publication of results based on the analysis of information provided by the Department of Health are outlined in the Department of Health ["Practice Code for the Use of Personal Health Information" 2009](#). The responsibilities of the investigator with respect to proposed publications using information provided by the Department of Health are also outlined in the document.

2.15.1 WA Health Permission to Publish Professional or Scientific Papers

It is a responsibility of WA Health employees involved in the publication of professional or scientific papers on behalf of WA Health, to inform their Manager or the relevant delegated authority. WA Health should be acknowledged in all publications by WA Health employees. Further information regarding the format of WA Health publications can be found in the Department of Health ["Style Guide for Corporate Visual Identity" 2011](#).

WA Health employees should be aware of the Department of Health ["Policy on Use of Official Information and Public Comment" 2011](#) that states when delivering conference papers or discussing issues related to WA Health or on their professional, scientific or technical findings, it is acceptable for personnel to use official information that is not confidential. However, in doing so, employees must issue public disclaimers stating that the views are their own and are not necessarily those of the State Government or WA Health.

2.15.2 Manuscripts

Unless IP assignment is required by the journal publisher, any publication, whether in print or electronic form, arising from WA Health activities should carry the copyright disclaimer available on the Department of Health [IP Management](#) website.

A manuscript should acknowledge the host institution; include information on all sources of financial and in-kind support for the research and any potential conflicts of interest. Manuscripts should include a statement that the project has undergone ethical review by a HREC prior to commencement of the project as research projects must not be ethically approved by a HREC retrospectively. This statement should acknowledge whether the



project has undergone ethical review by a full HREC or non-HREC level alternative (or has been exempted from ethical review).

Authors planning to submit manuscripts may refer to the research ethics and publications ethics guidelines provided in:

- [National Statement](#);
- [The Code](#);
- Australasian Evaluation Society “[Guidelines for the Ethical Conduct of Evaluations](#)” 2010; and
- International Committee of Medical Journal Editors “[Uniform Requirements for Manuscripts Submitted to Biomedical Journals](#)” 2010.

2.15.3 Public Clinical Trials Registry

In accordance with the World Medical Association “[Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects](#)” 2008, every clinical trial must be registered in a publicly accessible database before recruitment of the first participant. [The Code](#) requires investigators to register clinical trials with a recognised register to promote access to information about all clinical trials.

The ICMJE member journals now require registration in a publicly accessible clinical trials registry as a condition of consideration for publication. Investigators, who plan on publishing their project, should consider whether the research fits the ICMJE definition of a clinical trial. Registries recognised by ICMJE include, but are not limited to:

- [Australian New Zealand Clinical Trials Registry](#);
- [ClinicalTrials.gov](#); and
- [International Standard Randomised Controlled Trial Number \(ISRCTN\) Register](#).

Investigators conducting clinical trials must provide information to the RGO, on the SSA form, that the clinical trial has been/or will be registered on a recognised clinical trials registry (including the name and the reference number, if available), prior to recruitment of the first participant.

2.16 Human Research with Specific Regulatory Requirements

As part of research governance all external regulatory requirements for research including licensing, registration and accreditation must be met by the Department of Health and Health Services. This may involve reporting and/or registration to the following:

- Department of Innovation Industry, Science and Research (AusIndustry) - registration and annual report as an Australian Research Agency;
- NHMRC – registration and annual report as an Australian NHMRC registered HREC;
- Office of Gene Technology Regulator – registration as an Institutional Biosafety Committee and annual reporting;
- TGA – registration and regulation of therapeutic goods in Australia;
- United States of America (USA) Federalwide Assurance (FWA) for the Protection of Human Subjects for International (Non-USA) Institutions – registration of an institutional review board (IRB) with the [Office for Human Research Protections](#); and the obtaining of a FWA in order to receive US Department of Health and Human Services support for research involving human subjects. These are related but separate processes - tri-annual renewal of both IRB registration and the FWA is required; and



- USA Food and Drug Administration (**FDA**) – WA Health personnel using electronic signatures/electronic records are required to file a one-time certification document with the FDA according to the Electronic Records: Electronic Signatures Regulations, 21 C.F.R. Part 11. It is a declaration that electronic signatures affixed on their electronic records are legally binding equivalents for handwritten signatures. The Office of Regional Operations is designated as the administrator of filing and maintenance of the certification information. WA investigators should be aware that S.10 (1) (a) of the [Electronic Transactions Act 2011 \(WA\)](#) states that if “the signature of a person is required, that requirement is taken to have been met in relation to an electronic communication if a method is used to identify the person and to indicate the person’s approval of the information communicated”.

2.17 Conflict of Interest

Although the NEAF (Section 3) asks about potential competing interests, it is a requirement for WA Health under the WA Public Sector Commission [“Code of Ethics” 2012](#) that employees will disclose any personal or professional matters that may lead to actual or perceived conflicts of interest. In addition, it is a requirement of WA Health that all investigators must indicate any perceived conflicts of interest. Any conflicts of interest must be outlined by the investigators in the standard *WA Health Research Conflict of Interest Form* and submitted with the SSA to the RGO for review prior to authorisation of the project.

The types of conflicts of interest are related to either:

- financial and material interests – where an investigator could gain or lose financially because of the way the investigator conducts a project e.g. business partnerships, travel and gifts; and
- non-financial and partiality interests – where an investigator’s personal involvement, relationships or values may influence the way they conduct a project e.g. membership of associations, relationships.

Conflicts of Interest must be managed in accordance with the Department of Health [“Managing Conflict of Interest Policy and Guidelines” 2010](#). This may involve registering the conflict of interest; restricting or removing the investigators involvement in a project; or the investigator relinquishing their private interest that prompted concerns about a conflict of interest.

2.18 Complaints Handling and Misconduct

WA Health recognises the right of persons to report or complain about matters relating to research undertaken within WA Health and breaches of the Department of Health [“Code of Conduct” 2008](#). The institution has overall responsibility for ensuring the quality of research conducted at its site. With respect to management of complaints and research misconduct allegations, institutions have the responsibility to investigate and take action in response to any complaints or allegations of misconduct. Complaints from research participants will be initially referred to the institution’s RGO. However, HRECs should be informed of complaints or allegations and the action taken by the institution to address the concerns.

Complaints involving allegations of research misconduct involving WA Health employees should be addressed according to the Department of Health [“Misconduct & Discipline Policy and Guidelines” 2011](#). Where the complaint concerns a matter other than the conduct of a research project, the complaint must be managed according to Department of Health [“WA Health Complaint Management Policy” 2009](#) and be referred to the complaint coordinator located within the Health Service/institution or the Department of Health (as applicable).



2.19 Project Monitoring

The [National Statement \(Chapter 5.5\)](#) refers to monitoring as the process of verifying that the conduct of the research conforms to the approved proposal. The parties responsible for the monitoring of a research project include the investigator, institution, reviewing HREC and the sponsors of research, including any expert committees and regulatory agencies for complex research. The investigator is responsible for reporting to the reviewing HREC, institution or sponsor. The reviewing HREC, institution or sponsor are responsible for receiving, processing and disseminating information to relevant parties. In a few cases, principally safety reporting, there are reports flowing in two or more directions.

With the advent of single ethical review some of the monitoring roles that were previously undertaken by the HREC are now the responsibility of the institution, as part of their research governance framework. This is consistent with the [National Statement](#) which indicates that the responsibility for the monitoring of research lies with the institution under whose authority the research is conducted.

2.19.1 Guidance and Regulation

Requirements for the monitoring of research are outlined in the:

- NHMRC documents including the [National Statement](#), [The Code](#); and [“Value and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research” 2003](#);
- AHEC position statement [“Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products”](#), 2009; and
- TGA documents including the [“The Australian Clinical Trials Handbook” 2006](#); [“Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)” 2000](#); [“Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting \(CPMP/ICH/377/95\)” 2000](#); [“Access to Unapproved Therapeutic Goods – Clinical Trials in Australia” 2004](#); [“Human Research Ethics Committees and the Therapeutic Goods Legislation” 2001](#); [Therapeutic Goods Act 1989](#), and [Therapeutic Goods Regulations 1990](#).

Although these documents differ slightly in emphasis they attribute the broad responsibility for monitoring research to the institution where the research is conducted, with the added responsibility for unapproved therapeutic goods assigned to sponsors of clinical trials. Oversight of conformance to a research protocol is primarily the responsibility of the reviewing HREC.

2.19.2 Monitoring Role of the Institution

Each institution under which the research is conducted has the ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored. Where an institution decides to rely on ethical review by a body it has not established, it should undertake to establish the roles, if any, the institution and the review bodies may have in monitoring the research.

The institutional responsibilities for monitoring the conduct of approved research are outlined in the [National Statement \(Chapter 5.5\)](#) and the [“Framework for Monitoring: Guidance for the National Approach to Single Ethical Review” 2012](#). The Department of Health and Health Services must ensure they establish research governance measures to incorporate the components of monitoring which are institutional requirements.



The institutional components of monitoring include:

- registration of a research project on an approved registry or database;
- conduct of the project in accordance with the approved protocol including project design, recruitment, consent, safety monitoring and reporting;
- special conditions of approval for site authorisation;
- changes to the protocol including amendments with resource implications;
- compliance with policy, conformance with contracts and agreements;
- financial management;
- quality control including record keeping, and data integrity and management;
- management of complaints/misconduct or conflicts of interest;
- reporting including progress, safety and annual reporting;
- project closure including administrative processes, safety updates, device tracking and final reporting;
- communication of individual research results; and
- publication of outcomes.

As part of the institutional responsibility for oversight of research projects Health Services must ensure RGOs are adequately resourced to conduct their responsibilities related to the monitoring of research; which include:

- monitoring the conduct of research within the institution through review of annual and final progress reports submitted by the CPI (single-centre research) or PI (multi-centre research);
- monitoring special conditions imposed on the conduct of research;
- conducting or coordinating audits of research projects, where required;
- reviewing and managing amendment documentation related to authorised research projects that have implications for the site (e.g. resourcing);
- processing complaints relating to the conduct of research at the institution in accordance with institutional complaints policy and processes;
- receipt and investigation of allegations of research misconduct;
- review of required reports, and receipt and investigation of conflict of interest allegations;
- completion of requirements for project closure; and
- review of annual and final reports for the publication of research outcomes.

Institutions should not delegate these monitoring responsibilities to members of the institution's HREC.

2.19.3 Monitoring Role of the Reviewing HREC

Refer to [Section 3.4 Project Monitoring by the Reviewing HREC](#) for information on the monitoring role of the reviewing HREC.



2.19.4 Monitoring Role of Investigators

The investigator's responsibility covers all aspects of the research project; sometimes requiring monitoring activity long after the project is closed. This responsibility is principally met by reporting to other parties or by forwarding reports provided to the CPI by sponsors of the research. It is the role of the PI to complete and submit the reports. In the case of single ethical review, it is the responsibility of the CPI to communicate with the reviewing HREC. The CPI may serve as a conduit for information from the PIs or may consolidate multiple reports from the sites into a summary report for the HREC.

The monitoring role of the CPI includes:

- monitoring the conduct of research through project coordination; submission to HREC of amendments, protocol violations, requests for waiver of protocol requirement and required annual reports; and submission to sponsor of required reports;
- monitoring special conditions imposed on the conduct of research;
- reporting to the HREC any complaints, allegations of research misconduct, conflicts of interest based on institutional recommendations;
- submission of final notification to the HREC for closure of the project; and
- submission of final report for communication of results to research participants.

The monitoring role of the PI includes:

- monitoring the conduct of research through project management at the site; communication with the CPI as necessary; referral of approved amendments or submission to the institution of required reports;
- monitoring special conditions imposed on the conduct of research;
- reporting to the HREC (through the CPI) any complaints, allegations of research misconduct, conflicts of interest based on institutional recommendations;
- completion of requirements for closure of the project; notification to CPI of closure;
- submission of annual report to CPI for communication of results to research participants; and
- submission of annual and final reports to institution for the publication of research outcomes.

2.19.5 Monitoring of Approved Clinical Research

The monitoring of approved clinical research is outlined in the [National Statement \(Chapters 3.3 and 5.5\)](#). In clinical research, and especially clinical trials, in addition to the institution, the research sponsors also have some monitoring responsibilities. Health Services must maintain appropriate standards of research governance in their role as the sponsor of investigator-initiated research.

Institutions responsible for monitoring of industry sponsored and investigator-initiated clinical research must ensure there are mechanisms for reporting and reviewing serious adverse events (SAEs), serious adverse drug reactions (ADRs), serious unexpected suspected adverse reactions (SUSARs), serious adverse device events and Data Safety Monitoring Board reports from any site for which the institution is responsible. The HREC should review approved projects taking into account this information in accordance with their reporting guidelines. In multi-centre research the CPI must coordinate the submission of these reports to the approving HREC and the PI reports to their institution.



For trials with implantable medical devices, WA Health investigators must ensure that they establish or confirm the existence of systems for:

- tracking the participant, with consent, for the lifetime of the device; and
- reporting any device incidents to the TGA.

The TGA publication [“Human Research Ethics Committees and the Therapeutic Goods Legislation” 2001](#) describes the role of HRECs in relation to the supply of unapproved therapeutic goods in connection with the operation of the Clinical Trial Notification Scheme, the Clinical Trial Exemption Scheme, the Special Access Scheme, and the endorsement of Authorised Prescriber applications to the TGA. For monitoring of clinical trials the TGA recommends that HRECs have clearly defined mechanisms that require investigators to advise the Lead HREC of:

- any serious unexpected adverse events that occur during the trial, including those that have occurred at other sites involved in the project;
- new information from other published or unpublished projects which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol or participant information sheet and consent form (**PICF**); and
- deviations from, or changes to, the protocol that either eliminate immediate hazards to trial participants, significantly affect the conduct of the trial, or increase risks to participants.

It is also recommended by the TGA that any such information be accompanied by comment from the investigators on what implications, if any, they believe the new information has for the trial.

The CPI/PI must be cognisant of the above TGA reporting requirements as well as those outlined in the TGA [“Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)” 2000](#) and the NHMRC AHEC position statement [“Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products”, 2009](#). A large multi-centre trial should have a DSMB to inform the HREC of any relevant emerging data from the DSMB. If an investigator-initiated clinical trial does not have a DSMB, then the CPI should outline to the HREC the process for ensuring adequate independent monitoring of efficacy and safety for the duration of their project. Investigators should contact the HREC to establish whether there are guidelines in place for reporting requirements.

In industry sponsored research, monitoring specified in the CTRA or Protocol may include periodical sponsor monitoring, inspections by regulatory bodies (both national and international) as well as sponsor initiated audits. All Health Services must comply with the requests of the monitoring body.



3. ETHICAL AND SCIENTIFIC REVIEW

Human research ethical and scientific review enables WA Health to ensure that a proposed research project complies with appropriate ethical and scientific standards through an effective and efficient system of review. All human research conducted in WA Health, or requesting personal health information from the Department of Health data collections, must undergo ethical and scientific review, approval and monitoring by a HREC registered with the NHMRC's Australian Health Ethics Committee and operating in accordance with the [National Statement](#). HREC approval must be obtained and form part of the governance review, prior to a request for authorisation to either the Chief Executive or delegate for Health Services, or Data Steward for the Department of Health data collections.

All research should comply with regulatory requirements for, *inter alia*, gene technologies and related therapies, embryos, coronial tissue, ionising radiation, unapproved therapies and devices. Specific consideration should be given for the ethical review of research involving adults considered incompetent to consent, the recruitment of Aboriginal people and minors, access to the Department of Health data collections and use of post-mortem tissue.

The composition of a reviewing HREC or the scientific advisory panel to the reviewing HREC must be appropriate for review of the specific project, by having access to the expertise necessary, to enable it to address the ethical issues arising from research. This may necessitate going outside the HREC membership.

WA Health HREC approval processes must be timely and transparent, and appropriate risk assessment and monitoring must be established for all research. HRECs will complete the ethical and scientific review within a 60 calendar day timeframe, which allows for a 'stop clock' capability when additional input is required from a sponsor or investigator before consideration can continue. All investigators must comply with the guidelines set by the relevant HREC and requests by a HREC to an investigator for additional information or amendments. Delays in providing information to a HREC may result in a project being withdrawn from a HREC review.

Investigators conducting single-centre research within WA Health should apply to that site's local HREC for ethical approval. For multi-centre research there are alternative pathways; refer to section [3.2](#). In both single-centre and multi-centre projects, once a HREC has recommended ethical approval of a research project a HREC approval letter will be sent to the CPI to forward to the RGO (via the PI in multi-centre) as part of the SSA. HREC and research governance review can occur concurrently but the SSA cannot receive final authorisation until the HREC approval letter is received.

The HREC approval applies for a maximum of three (3) years with option for five (5) years if justified, except where action is taken to suspend or terminate the decision. The HREC has the capacity to set a shorter approval period dependant on the risk and complexity of the project. The request to extend the duration of the research project is submitted by the CPI as an amendment for review by the HREC. HREC approval for an extension of approval is limited to one period of three (3) years, except where action is taken to suspend or terminate the decision. Subsequent requests for extension should undergo a resubmission and be considered at the discretion of the HREC.



WA university investigators (including students) conducting research within WA Health require HREC approval from both the university and WA Health if there is no reciprocal single ethical review process in place (refer to section [3.3.2](#)). The WA Health Ethics Application Form or NEAF/WA-Specific Module must be used for WA Health HRECs.

To ensure university student applications are of a high standard, students are encouraged to submit an application to their university HREC prior to submission to the WA Health HREC, but this is not mandatory. University students must have an on-site WA Health Research Supervisor, who must discuss with the student the logistics of conducting the research at the site, prior to submission of the ethics application.

3.1 Quality Improvement Projects

Quality improvement is a systematic process that monitors, evaluates and seeks to improve health service delivery and efficiencies. It may involve clinical audit, practice review, satisfaction surveys, service improvement and program evaluation. All QI that is conducted with or about people should be registered and requires ethical consideration. The [National Statement](#) provides a basis for this ethical review.

Under NHMRC guidelines, QI projects require ethical review by a full HREC if the QI activity:

- is more than low risk (as defined by the [National Statement](#)); and
- requires waiver of consent for the use of existing data where the secondary use of the data is not consistent with the primary purpose for which the data was collected.

QI projects that require the disclosure of personal health information from the Department of Health data collections require Department of Health WA HREC approval (refer to [3.7.2](#)).

Within Health Services there are established alternative non-HREC levels of ethical review processes for QI projects (including QI audit projects) that are exempted from ethical review or do not require full HREC review. These include QI committees and delegated personnel. QI projects that do not require full HREC approval should be approved through these established QI approval processes, who will consider the ethical and governance merits of the project (refer to the approval pathways in [Annexure 1](#)).

WA Health institutions may choose to exempt from ethical review QI that:

- is negligible QI; and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

Research projects may sometimes be misclassified as clinical audits because the study method may encompass similar criteria. WA Health personnel should ensure that they correctly classify audits and research and seek the appropriate HREC review or QI registration of the project. Investigators who are uncertain about the correct classification of an activity should contact the relevant Ethics Executive Officer or Safety, Quality and Performance Office (or equivalent) personnel. Contact details for Ethics Offices are available on the Department of Health [Research Development](#) website.

Academic journals often require evidence of ethical review and approval of a QI project from a HREC, prior to publication. This process acknowledges that the project has under gone ethical review either by a full HREC or non-HREC level alternative (or has been exempted from ethical review). On request from the institutional Safety, Quality and Performance Office (or equivalent), the Ethics Executive Officer will provide investigators with a letter acknowledging the relevant ethical review process the project has under gone.



3.2 Types of Ethical and Scientific Review

There are two pathways for ethical and scientific review involving either 'Full HREC Review' or 'Ethical Review for Low or Negligible Risk Research'. The Department of Health and Health Services must have processes in place to ensure that the level of ethical review will be commensurate with the level of risk to which participants and investigators are exposed.

Only research applications ethically and scientifically approved by a full HREC (either local or Lead HREC/Lead WA Health HREC), alternative Non-HREC level of review (e.g. sub-committee), or exempted from ethical review will be considered (following a governance review) for authorisation by the Chief Executive or delegate. A summary of routes to obtain authorisation from WA Health and how they relate to ethical, scientific and governance approval is outlined in [Annexure 1](#).

Research applications involving the release of personal health information from the data collections held by the Department of Health will only be considered for authorisation by the Data Steward if the application has been ethically and scientifically approved by the Department of Health WA HREC and includes a completed Application for Data form.

Health Service investigators must utilise their own local HREC for single-centre research. In the case of multi-centre research the Health Service investigator must use one of the following options:

- review by a Lead WA Health HREC (which may, or may not, be their local HREC) utilising the WA Health Single Ethical Review process; or
- review by a NHMRC certified Lead HREC utilising the National Approach process (refer to section [3.3.1](#)).

The ethical and scientific review is carried out using an ethics application form. Ethics application forms used within WA Health include:

1. *National Ethics Application Form (NEAF)*

The [NEAF](#) (plus WA-Specific Module) can be used for ethical and scientific review irrespective of risk for both single-centre and multi-centre research projects involving humans. It is mandatory for ethics applications utilising the National Approach.

2. *The WA-Specific Module*

This form must accompany ethics applications using the NEAF. This module addresses additional ethical issues, specific to WA that are not addressed in the NEAF and must be considered when conducting both single-centre and multi-centre research in WA.

The module covers areas including:

- Recruitment of adults (18 years and over) who may lack the capacity to give consent;
- The use of health information from the Department of Health data collections and/or WA Health Biobanks;
- Recruitment of Aboriginal people;
- Recruitment of minors (aged less than 18 years of age);
- The use of human tissue from persons who were the subject of a post-mortem;
- A WA institution which functions in accordance with the Catholic Health Australia's "Code of Ethical Standards for Catholic Health and Aged Care Services in Australia" 2001; and
- Human research in WA schools.



3. **WA Health Ethics Application Form (for research conducted within WA Health)**

This form is available for use by investigators⁹ who are conducting human research projects within WA Health or accessing WA Health participants, their tissue or data. This is an alternative to completing the NEAF plus WA-Specific Module. It can be used for ethical and scientific review, irrespective of risk, for both single-centre and multi-centre research projects (except when using the National Approach). For the National Approach, you must complete a NEAF plus WA-Specific Module.

Ethics application forms are available through the RGP (when available), which provides guidance on completing the forms and supporting documents required for making an application. In addition, ethics forms, except for the [NEAF](#), are available from the Ethics Office or their website, as well as the Department of Health [Research Development](#) website. The NEAF is available from the NHMRC's [NEAF](#) website.

3.2.1 Full Human Research Ethics Committee Review

In accordance with the [National Statement](#), the following types of human research must be ethically and scientifically reviewed and approved by a HREC before they take place in WA Health:

1. Research that involves more than low risk to participants.
2. Research that includes any of the following, irrespective of risk:
 - interventions and therapies, including clinical and non-clinical trials and innovations or new treatment modalities;
 - Aboriginal people;
 - limited disclosure that involves active concealment or planned deception of participants;
 - limited disclosure that aims to expose illegal activities; and
 - waiver of consent for research using personal information in medical research, or personal health information (refer to section [3.5](#))¹⁰
3. Research that includes any of the following, irrespective of risk (except where the project uses existing collections of non-identifiable data and involves only negligible risk, and may therefore be exempted from ethical review):
 - human genetics;
 - human stem cells;
 - women who are pregnant and the human fetus;
 - people highly dependent on medical care who may be unable to give consent;
 - people with a cognitive impairment, intellectual disability or a mental illness; and
 - people who may be involved in illegal activities.

Note: In WA Health, paediatric research that involves direct interaction with children, is not considered low risk and therefore, must undergo full HREC review. Within the Child and Adolescent Health Service (**CAHS**) and the Women and Newborn Health Service (**WNHS**) all research projects on children, pregnant women, fetuses and neonates, regardless of risk, must undergo a full HREC review.

⁹ Investigators conducting research at sites within WA Health do not have to be WA Health employees but must have an agreement in place between WA Health and their employing organisation.

¹⁰ The use or disclosure of personal information from the Department of Health data collections and data linkage, irrespective of risk, requires full HREC approval by the Department of Health WA HREC.



In accordance with the “[Non-Coronial Post-Mortem Examinations Code of Practice](#)” 2007 made under the [Human Tissue and Transplant Act 1982 \(WA\)](#), all research using organs or tissues derived from post-mortems must have the approval of a properly constituted ethics committee.

All full HREC applications must be made by the CPI using the:

- NEAF plus the WA-Specific Module (contains information specific to WA that is not covered by the NEAF); or
- WA Health Ethics Application Form.

The completed HREC application form and supporting documents must be submitted to the applicable Ethics Executive Officer. WA Health Ethics Executive Officers’ contact details are available on the Department of Health [Research Development](#) website. Ethics Executive Officers must use the WA Health RGS IT system for the management of all applications for full HREC review for research projects involving WA Health sites.

3.2.2 Ethical Review for Low or Negligible Risk Research

Under the [National Statement \(Chapter 2.1\)](#), for low or negligible risk research (which does not involve specific methodologies or participants or research, refer to [3.2.1](#)), institutions, may establish an alternative Non-HREC level (e.g. sub-committee, delegate) ethical review process or exempt research from ethical review. Investigators should check with their Ethics Office to see if an alternative Non-HREC level ethical review process is available for their site, as not all WA Health HRECs have these processes in place.

The [National Statement \(Chapter 2.1\)](#) describes low risk or negligible risk research as:

- **Low Risk** - where the only foreseeable risk is one of discomfort e.g. minor side-effects of medication, measuring blood pressure or anxiety induced by an interview; and
- **Negligible Risk** - where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is the least form of harm that is possible for human participants in research e.g. filling in a form, participating in a survey or giving up time to participate in a research activity.

The [National Statement \(Chapter 5.1\)](#) specifies that institutions may establish Non-HREC levels of ethical review for research that carries only low risk and does not fall under any of the full HREC review categories listed in [3.2.1](#). The levels of ethical review may include, but need not be limited to:

- review or assessment at departmental level by the Head of Department;
- review or assessment by a departmental committee of peers (with or without external or independent members);
- delegated review with reporting to a HREC; or
- review by a subcommittee of a HREC.

For low or negligible risk research that does not require full HREC review, applicants should contact their local Ethics Office to discuss the proposed research and identify whether the project is suitable for an alternative review pathway rather than a submission to a full HREC. That is:

- For low risk research (i.e. only foreseeable risk is one of discomfort) the review process in WA Health is not standardised and may be in the form of an application to



a full HREC or using an alternative Non-HREC level of review (e.g. HREC sub-committee or Delegate of the Chair).

- For negligible risk research (i.e. involving only the risk of inconvenience), the Department of Health and Health Services may offer the review process as for low risk research or grant exemption from ethical review as outlined in section [3.2.3](#).

The Executive Officer and HREC Chair have the discretion to request that the research project is submitted for a full HREC review using the appropriate application form if they consider the risk to participants to be greater than low risk.

All HREC applications for review of research with low or negligible risk to participants (that does not fall under any of the full HREC categories in [3.2.1](#)) must be made by the CPI using the WA Health Ethics Application Form or the NEAF plus the WA-Specific Module. These forms can be accessed through the RGP (when available). They are also available from the Ethics Office (except for the NEAF). Under the National Approach, low or negligible risk research will have to undergo ethical review by a certified HREC and use the NEAF plus the WA-Specific Module.

Only a full HREC can grant waiver of consent for low risk research using personal information in medical research, or personal health information (refer to section [3.5](#)).

The completed forms and supporting documents must be submitted to the applicable Ethics Executive Officer. Ethics Executive Officers must use the RGS IT system for the management of all applications for low or negligible risk HREC review for research projects involving WA Health sites.

Low or negligible risk research (that does not fall under any of the full HREC categories in [3.2.1](#)) requires a WA Health Site Specific Assessment Form for Low and Negligible Risk Research to be completed for governance review at WA sites.

3.2.3 Exemption from Ethical and Scientific Review

In accordance with the [National Statement \(Chapter 5.1\)](#), WA Health provides the discretion to exempt from ethical review research that:

- is negligible risk research; and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

The Department of Health and Health Services must recognise that in exempting research from ethical review, they are determining that the research meets the requirements of the [National Statement](#) and is ethically acceptable. Investigators with a research project that fulfils the above criteria should consult the Ethics Executive Officer/Chair to ensure that the project is exempt from ethical and scientific review.

Academic journals often require evidence that a research project has undergone ethical review and approval or that it has been exempted from ethical review. The Ethics Executive Officer can provide a relevant letter as required. Refer to section [3.1](#) regarding exemption from ethical review for Quality Improvement projects.



3.3 Single Ethical Review of Multi-centre Research

In line with the [National Statement \(Chapter 5.3\)](#) requirement to minimise duplication of ethical review, WA Health supports the concept of single ethical review for all human research carried out in Australia. Notwithstanding the special or specific HREC review requirements stipulated by WA Health, under this system a research project which is conducted at a site under the jurisdiction of WA Health will be ethically and scientifically reviewed only once, irrespective of the number of Australian sites involved in the project. This can be achieved through either the National Approach¹¹ or WA Health Single Ethical Review processes.

Research involving Department of Health data collections, Aboriginal people and coronial material that require additional HREC approval, are an exception to the once only review for multi-centre research and applications must be referred to the relevant ethics committees. Contact details for these HRECs are available on the Department of Health [Research Development](#) website.

3.3.1 National Approach to Single Ethical Review of Multi-centre Research

Under the NHMRC's Harmonisation of Multi-centre Ethical Review ([HoMER](#)) system a designated NHMRC certified Lead HREC will conduct the full ethical and scientific review of a multi-centre research protocol. This process is known as the National Approach. Under this process, all multi-centre research projects being conducted at sites within Australia (participating in the National Approach)¹² must be ethically and scientifically reviewed only once, except for those that require additional specialist review. The specialist HRECs within WA are outlined in the WA-Specific Module.

Certain research projects conducted within WA Health will require additional review by specialist HRECs regardless of whether or not they have been, or are to be, reviewed by a Lead HREC. These include:

- the Western Australian Aboriginal Health Ethics Committee for health and medical research projects where Aboriginality is a key determinant or explicitly directed at Aboriginal people;
- the Coronial Ethics Committee WA for research projects that require access to coronial samples, data or information; and
- the Department of Health WA HREC for all research projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage (refer to section [3.7.2](#)).

The National Approach involves all categories of human research, irrespective of risk, including clinical trials, interventional clinical research, population/public health, paediatric, Aboriginal and justice health. Further information regarding the National Approach can be found on the NHMRC Human Research Ethics Portal ([HREP](#)).

WA Health institutions' ethical review processes that are certified by the NHMRC under the National Approach can participate in this process as either a Lead HREC or an 'accepting

¹¹ Public health organisations within Australia have implemented a version of the National Approach which only involves public health organisations and the single ethical review of clinical trials. The procedures relating to the National Approach can be applied to clinical trials and all human research once approval has been granted by the Director General for WA Health to participate in this process.

¹² Institutions participating in the National Approach can be from public or private organisations, including universities.



institution' once approval has been granted by the Director General of Health. Institutions with certified HRECs must accept the ethical and scientific review undertaken by their own HREC, or where relevant, another certified Lead HREC, as sufficient review for the purposes of the multi-centre projects conducted at sites under their control. Lead HRECs should ensure they are aware of legislation related to specific jurisdictions as outlined in the NHMRC [“National, State & Territory Legislative Framework for ethical review of multi-centre research” 2012](#).

WA Health institutions that are not certified will become 'accepting institutions' (but cannot be Lead HRECs) under the National Approach, once approval has been granted for this process by the Director General of Health. An 'accepting institution' must accept the ethical and scientific review undertaken by another certified Lead HREC as sufficient review for the purposes of the multi-centre projects conducted at sites under their control.

WA Health certified and 'accepting institutions' should ensure that they are aware of the liabilities attributed to certified HRECs and 'accepting institutions' as outlined on the NHMRC [HREP](#) and ensure they have adequate research governance measures in place (refer to section [2.11.2.4](#) and [2.12.2](#)).

According to the [National Statement \(Chapter 5.3\)](#), where a WA Health site decides to rely on the ethical review by a HREC it has not established, the institution (through the site PI), should undertake to identify any local circumstances relevant to the ethical review of the research, disclose these circumstances to the review body (through the CPI), and provide for their management. The local circumstances relevant to the ethical review of the research must be outlined in the NEAF and the WA-Specific Module and be included in the application by the CPI on behalf of the PI to the Lead HREC. The CPI must provide a copy of the NEAF/WA-Specific Module to the PI and maintain ongoing dialogue regarding the research as needed. The CPI must communicate the outcome of the ethical review to the PI to include in the SSA application. This process is outlined in the NHMRC [“Flowchart of Single Ethical Review Process for Multi-centre Research”](#).

The site-specific governance aspects of the project must be conducted by each site's PI in accordance with the research governance processes of each Health Service as outlined in their Standard Operating Procedures. At each WA Health site where the multi-centre project is being conducted, a SSA/Access Request Form must be completed by the PI and submitted to the RGO, who will determine what resources are required for the support and successful completion of the research at that site according to the research governance requirements (refer to section [2.4](#)).

Once the research is authorised the PI must inform the CPI when the research commences at the site, so that the CPI can inform the Lead HREC Ethics Office when the research has commenced. Both the institution and the Lead HREC must implement monitoring of the research. All multi-centre protocols must have an Australian CPI who will coordinate the Lead HREC review of the project and/or any amendments; progress reporting requirements as specified by the approving HREC; report any serious adverse events; and communicate with all the site PIs, funders or sponsors.



3.3.2 WA Health Single Ethical Review of Multi-centre Research

All multi-centre research projects being conducted at sites under the control of WA Health or involving participants, their tissue or data accessed through WA Health must be ethically and scientifically reviewed only once, by a Lead WA Health HREC¹³. The exception is those projects that require additional specialist HREC review. WA Health sites must accept the ethical and scientific review undertaken by their associated HREC or where relevant, another Lead WA Health HREC as sufficient review for the purposes of the multi-centre projects conducted at sites under their control.

The WA Health Single Ethical Review of Multi-centre Research process applies to:

- all multi-centre research projects (i.e. conducted under the authority of more than one WA Health HREC);
- research projects being conducted at sites under the jurisdiction of WA Health or involving participants, their tissue or data accessed through WA Health; and
- all categories of human research, irrespective of risk, including basic, clinical, health services and public health research.

The WA Health Single Ethical Review of Multi-centre Research should be utilised when it is not applicable to use the National Approach. That is, when it involves a multi-centre project which is:

- conducted at sites only within WA Health; or
- conducted at sites within Australia which are not participating in the National Approach.

The Lead WA Health HREC should be selected according to the following criteria in descending order. That is, the HREC:

- has expertise in the relevant category of research¹⁴ as outlined in the WA Health Single Ethical Review Standard Operating Procedures; and
- is associated with the site¹⁵ at which the CPI¹⁶ will be conducting the research.

Certain research projects will require additional review by specialist HRECs regardless of whether or not they have been, or are to be, reviewed by a Lead WA Health HREC. These include:

- the Western Australian Aboriginal Health Ethics Committee for health and medical research projects where Aboriginality is a key determinant or explicitly directed at Aboriginal people;
- the Coronial Ethics Committee WA for research projects that require access to coronial samples, data or information; and
- the Department of Health WA HREC for all research projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage (refer to section [3.7.2](#)).

¹³ A Lead WA Health HREC is a WA Health HREC registered with the NHMRC's AHEC and identified in the WA Health Single Ethical Review Standard Operating Procedures to conduct the ethical and scientific review of multi-centre human research on behalf of WA Health. A WA Health HREC does not require certification under the National Certification Scheme to be a Lead WA Health HREC.

¹⁴ Research categories are based on The National Certification Scheme research categories available on [HREP](#).

¹⁵ Lead WA Health HRECs and associated sites are listed on the Department of Health [Research Development](#) website.

¹⁶ If the CPI is from outside WA Health, the site should be chosen where the WA Health Principal Investigator is conducting the research.



If the WA Health Single Ethical Review process is extended to organisations external to WA Health (e.g. WA universities) through a reciprocal approval process, then the arrangement must be documented in a written Agreement.

According to the [National Statement \(Chapter 5.3\)](#) where a WA Health site decides to rely on the ethical review by a HREC it has not established, the institution (and the site PI), should undertake to identify any local circumstances relevant to the ethical review of the research, disclose these circumstances to the review body (through the CPI), and provide for their management. The local circumstances relevant to the ethical review of the research must be outlined in the ethics application form and be included in the application to the Lead HREC.

The site-specific governance aspects of the project must be conducted by each site's PI in accordance with the research governance processes of each Health Service as outlined in their Standard Operating Procedures. At each WA Health site where the multi-centre project is being undertaken, the relevant SSA form or Access Request Form must be completed by the PI and submitted to the RGO, to assess the suitability of the research project to be conducted at that site (refer to section [2.4](#)).

3.4 Project Monitoring by the Reviewing HREC (NEAF Section 5)

The responsibility for the monitoring of approved human research projects lies with the investigator, institution, reviewing HREC and sponsor. All reviewing HRECs have a clearly defined responsibility for monitoring the conduct of a research project in accordance with the approved protocol. Components of monitoring include:

- ensuring the project is conducted in accordance with the approved protocol including project design, recruitment, consent, safety monitoring and reporting, and data integrity and management;
- review of safety reports;
- consideration of changes to the protocol including amendments, waivers and violations;
- ensuring special conditions of approval or authorisation are met; and
- ensuring research results are communicated to research participants as required.

HRECs require a structured compliance monitoring program, reflecting the degree of risk, of the research. Compliance monitoring methods are to include review of:

- annual reports on the progress to date from the CPI (including compliance with the approved proposal, compliance with any special conditions of approval, extension of the project, maintenance and security of records, communication of results to research participants);
- progress reports on instances where there is any significant deviation from, or violation of, the project protocol;
- reports on instances where the project is withdrawn, terminated or suspended before the expected date of completion;
- safety reports of serious adverse events/serious unexpected events;
- protocol amendments, or changes to informed consent documents; and
- a final report on completion from the CPI when all sites are closed (including the outcome, a copy of the research results to facilitate communication to research participants, as required).

In multi-centre research the CPI has the responsibility to report to the HREC (with information provided by the PI) and the PI has the responsibility to report to the institution.



3.5 Participant Information and Consent (NEAF Section 6)

Informed consent will be required for all research unless waived by a HREC according to NHMRC standards (see below). Informed consent is an important part of the research process and the HREC (or Non-HREC level alternative) review must scrutinise all participant informed consent documents to ensure that they are in accordance with national and State requirements (e.g. [National Statement](#), the TGA “[Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)](#)” 2000 and the Department of Health “[Consent to Treatment Policy for the Western Australian Health System](#)” 2011).

Investigators must notify the HREC of any deviation from, or violation of, the project protocol, as amendments to the protocol may require changes to the PICFs in accordance with local HREC guidelines. Template versions of PICFs are available from the NHMRC [HREP](#) but are not mandatory to use.

All research must have participant informed consent, except where:

- there is an adult who lacks the capacity to consent (refer to section [3.6.2](#)); and
- the investigators have obtained approval from a HREC (or non-HREC level alternative) for limited disclosure or a waiver of consent according to the [National Statement \(Chapter 2.3\)](#). Investigators seeking waiver of consent should specifically address the points outlined in the [National Statement \(Chapter 2.3.6\)](#) in their application.

Only a full HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Non-HREC level alternative review bodies may grant waiver of consent for research not involving the use of personal information. Given the importance of maintaining public confidence in the research process, it is the responsibility of the Department of Health and Health Services to make publicly accessible (for example in annual reports) summary descriptions of all its research projects for which consent has been waived.

In research involving those with a cognitive impairment, an intellectual disability or a mental illness, the capacity of that person to consent should be assessed and the process of how this is to be done advised to the HREC reviewing the project (refer to section [3.6.2](#)). Regarding research involving mental health, investigators and their institutions should respect the privacy and confidentiality sensitivities of the participants and consent should be obtained prior to accessing personal health information.

In relation to the establishment of databanks/databases investigators should seek consent from participants to ‘bank’ their data for possible use in future research projects.

3.6 Participant Specific Requirements (NEAF Section 7)

The [National Statement \(Section 4\)](#) identifies the need to pay additional attention to ethical issues associated with research involving certain specific populations.

3.6.1 Recruitment of Minors (aged less than 18 years of age) in Research

Investigators involved with direct contact with participants under 18 years of age ([Age of Majority Act 1972 \(WA\)](#)) must have, or obtain a WA Government “[Working with Children Check](#)” ([Working with Children \(Criminal Record Checking\) Act 2004 \(WA\)](#)). If there is to be recruitment of minors, details must be outlined for review by the HREC either in the WA Health Ethics Application Form or the WA-Specific Module if the NEAF is used.



Investigators should check with the relevant WA Health HREC to assess whether there is a requirement that age appropriate child information sheets as well as parent/guardian information sheets and a signed child assent form are required for research projects requiring participation of children. The exact age at which these information sheets and assent forms should be required (i.e. about 7 or 10 years) may be dependent on the type of project being proposed, and the patient group being recruited. The CAHS recommends assent from the age of 7 years.

If the research may increase the body of knowledge in a clinical area, but will not be of direct benefit to the participant, the project should not be conducted if the parent is unwilling for their child/infant to participate (all ages); and/or the child has not provided signed assent (i.e. about 7 or 10 years). If a child or young person has the capacity to consent and is unwilling to participate in research, their refusal to participate should be respected. Where a child or young person lacks the capacity to consent, their refusal may be overridden by the parents' judgement as to what is in the child's best interest. Refer to the [National Statement \(Chapter 4.2\)](#) for further clarification.

The [National Statement](#) states that an ethical review body may approve research to which only the young person consents if it is satisfied that he or she is mature enough to understand and consent, and not vulnerable through immaturity in ways that would warrant additional consent from a parent or guardian.

Investigators intending to obtain consent from mature minors should refer to the Department of Health "[Consent to Treatment Policy for the Western Australian Health System](#)" 2011 which states that where a child is a mature minor and able to make a treatment decision, the consent of the child's parent is not necessary. The law in Australia considers that a mature minor is a person under the age of 18 years of age who is, by reason of their maturity, capable of giving (or refusing) effective consent to a medical procedure.

In determining whether a child is capable of providing consent, health professionals should consider the:

- age and maturity of the child;
- child's ability to understand fully the medical advice being given;
- nature, consequences and implications of the proposed treatment and their capacity to understand them;
- potential risks to health; and
- emotional impact on the child of either accepting or rejecting the advised treatment.

If it is intended to assess the capacity of minors to provide consent as mature minors the investigators must provide details of the person(s) assessing the capacity of the minor and how this assessment will be done. Investigators, as appropriate, should consider whether parental acknowledgment is desirable. In doing so, they should be guided by the opinion of the mature minor.

It is a requirement of WA Health HRECs that where recruitment of minors for research is through consent of a parent/guardian, then once the minor has reached the age of 18 years, within reason, consent must be re-established for that individual to continue/resume in the research.

In WA Health paediatric research that involves direct interaction with children/infants is not considered low risk and therefore must undergo full HREC review. Within the CAHS and the



WNHS all research projects involving children, pregnant women, fetuses and neonates, regardless of risk, must undergo a full HREC review.

The composition of the reviewing HREC, or the scientific advisory panel to the reviewing HREC, must be appropriate for review of paediatric projects, by having access to the expertise necessary, to enable it to address the ethical issues arising from research involving minors. This may necessitate going outside the HREC membership. Depending on the risk, it may not be sufficient to include one paediatrician on the HREC or scientific advisory panel; rather, there should be a number of paediatricians included, representing the major sub-specialities. WA Health institutions reviewing paediatric applications should contact the relevant CAHS or WNHS HRECs to seek input from a specialist in this area.

3.6.2 Recruitment of Adults Who May Lack the Capacity to Give Consent

According to the [National Statement \(Chapters 4.4 and 4.5\)](#) adults who may lack the capacity to give consent includes people highly dependent on medical care who may be unable to provide consent and people with a cognitive impairment, an intellectual disability, or a mental illness.

In WA, in contrast to other Australian jurisdictions, the [Guardianship and Administration Act 1990 \(WA\)](#) does not include a provision for responsible persons (i.e. nearest relative/guardian) to give consent for inclusion of their relative who is assessed as incapable of providing informed consent in medical research.

Investigators must therefore only include such a person in a research project if they consider it to be not against the best interests of the person to be a participant. In practice this means that in WA it is not possible to enrol people unable to provide consent in projects comparing an untried treatment or a treatment with unknown or potential risk compared with a known best standard of care. That is, only in observational projects or those in which an established best practice is not known and the intervention is believed to be an important part of treatment for the person, will participation in research be possible.

The senior responsible person (nearest relative/guardian) should be asked to sign a form that provides information about the proposed project and asks them to record whether they believe that the person for whom they have a duty of care has not previously expressed an objection or would not be likely to object to inclusion.

It should be noted that more than one information and consent document may need to be drafted and approved by the HREC to accommodate all potential participants (e.g. participants who have had a stroke and may comprehend the information provided but may physically not be able to sign a form. In this case, ways of obtaining consent from the participant may need to be explored that do not include the nearest relative providing consent but may involve the participant in the consent process).

If the research involves people in this category the investigator will have to provide the HREC with sufficient details to make an assessment of whether participation of such people can be ethically supported. This must be documented in either the WA Ethics Application Form or the WA-Specific Module if the NEAF is used.

In research involving people with a mental illness, cognitive impairment or intellectual disability, the participant's responsible medical practitioner should make a judgement on their capacity to give informed consent to participate in the research.



3.6.3 Recruitment of People in Dependent or Unequal Relationships

Pre-existing relationships between participants and investigators or between participants and others involved in facilitating or implementing the research may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. In the consent process investigators should, wherever possible, invite potential participants to discuss their participation with someone who is able to support them in making a decision. Where potential participants are especially vulnerable or powerless, consideration should be given to the appointment of a participant advocate. Refer to the [National Statement \(Chapter 4.3\)](#).

3.6.4 Aboriginal People

Research involving Aboriginal people should refer to the [National Statement \(Chapter 4.7\)](#) and the NHMRC "[Value and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research](#)" 2003.

The WA Aboriginal Health Ethics Committee (**WAAHEC**) exists to promote and support ethically based research which will benefit Aboriginal people. In addition to the local or Lead HREC/Lead WA Health HREC approval it is a requirement of WAAHEC to approve the conduct of health and medical research in WA where the research project involves the following categories:

- Aboriginality is a key determinant;
- data collection is explicitly directed at Aboriginal people;
- Aboriginal people, as a group, are to be examined in the results;
- the information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

Refer to the "[Western Australian Aboriginal Health Ethics Committee \(WAAHEC\) Values and Ethics Statement](#)" for further information. The WAAHEC application form is available at the [Aboriginal Health Council of WA](#) website. Research involving Aboriginal people must be documented in the WA Ethics Application Form or the WA-Specific Module if the NEAF is used for review by the HREC.

Investigators are encouraged to notify the Kimberley Aboriginal Health Planning Forum, a research sub-committee of the [Kimberley Aboriginal Medical Services Council](#), of research projects involving Aboriginal people located in the WA Kimberley region.

3.7 Confidentiality and Privacy (NEAF Section 8)

WA Health personnel who are involved in research must comply with all policies and guidelines, governing the collection, storage/retention, access/disclosure, use and disposal of information (data). This process is outlined in the Department of Health "[Information Lifecycle Management Policy](#)" 2012.

The [National Statement \(Chapter 3.2\)](#) states that data may be collected, stored or disclosed in three mutually exclusive forms:

- **individually identifiable data**, where the identity of a specific individual can reasonably be ascertained e.g. the individual's name, image, date of birth or address;
- **re-identifiable data**, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual e.g. using the code or linking different data sets; and



- **non-identifiable data**, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.

Information for consumers and/or participants regarding the Department of Health data collections, the use and access to health data, and privacy and security of data is contained within the Department of Health ["Information about your Health Data" Booklet 2009](#).

3.7.1 Data Access, Disclosure and Use

The [Privacy Act 1988 \(Cwth\)](#) requires personal identifiable information (which includes identifiable patient information) held by Commonwealth government bodies (listed at the [Australian Government Directory](#)) and private sector organisations to be kept private. Investigators who intend using data held by Commonwealth government bodies or private sector organisations in their research must comply with the requirements of the *Privacy Act* and should be familiar with the NHMRC documents:

- ["Guidelines Under section 95 of the Privacy Act 1988" 2000](#) which provides a framework for the conduct and ethical review of research, involving the collection, use or disclosure of personal health information by Commonwealth agencies without the consent of the individual(s) involved; and
- ["Guidelines approved under Section 95A of the Privacy Act 1988" 2001](#) which provides a framework for the conduct and ethical review of research, involving the collection, use or disclosure of personal health information by private organisations without consent from the individual(s) involved.

In addition, WA Health personnel are subject to the [Public Sector Management Act 1994 \(WA\)](#) to keep information confidential. All WA Health personnel and those applying for access to WA Health data must comply with the Department of Health ["Practice Code for the Use of Personal Health Information" 2009](#) to maintain information security and confidentiality.

The WA Health policy on disclosure of patient health information is outlined in the Department of Health ["Information Access and Disclosure Policy" 2012](#) which states that as a general rule, no information concerning a patient should be released to another person without the consent of the patient. Disclosure in such circumstances should be provided strictly in accordance with the common law duty of confidentiality as well as the National Privacy Principles under the [Privacy Act 1988 \(Cwth\)](#).

There are exceptional situations where consent is not required in order to disclose a patient's personal identifiable health information. They include:

- a court order to produce a patient's personal health information;
- it is required or authorised by or under law (e.g. mandatory reporting of child sexual abuse);
- where the health professional believes that the disclosure is necessary to prevent a serious threat to public health or public safety (e.g. [Mental Health Act 1996 \(WA\)](#));
- statutory medical notifications (e.g. notifiable communicable diseases, anaesthetic deaths, cervical cancer testing); and
- mandatory reporting under the National Health Care Agreement.



Where information is disclosed in strict compliance with the relevant statutory provision, no breach of confidentiality is involved.

The Department of Health [“Patient Confidentiality and Divulging Patient Information to Third Parties” 2006](#) details the general circumstances in which confidential patient information may be disclosed to third parties under the common law.

In accordance with the Department of Health [“Information Access and Disclosure Policy” 2012](#) all research projects, both internal and external to WA Health, involving the use or disclosure of personal health information for research purposes from WA Health data collections must have the approval of a WA Health HREC. For research projects requiring the release of information from the Department of Health data collections refer to section [3.7.2](#).

Investigators who require access to personal identifiable health information held by Health Services or other health service providers, which are separate from the Department of Health data collections, must apply for approval from the relevant HREC responsible for that Health Service/site.

Investigators who require access to data from the Commonwealth Electoral Roll for the purposes of research must review the information provided by the Australian Electoral Commission [“Supply of Elector Information for Use in Medical Research” 2011](#).

Data must only be used in line with the Department of Health [“Information Lifecycle Management Policy” 2012](#).

3.7.2 The Department of Health Data Collections and Data Linkage

The Department of Health¹⁷ is responsible for the statewide health data collections that contain summaries of personal health information collected from WA Health patients. Personal health information includes information or opinions that relate to the health of a person where the identity of a person is apparent or can reasonably be ascertained from the information.¹⁸ The personal health information can be used by investigators internal and external to WA Health for health related research. Further details and information about the statewide health data collections are available from the Department of Health [Information About Health Data](#) website.

The Department of Health Data Linkage Branch maintains the Western Australian Data Linkage System (**WADLS**), which comprises a system of linkages connecting data about the health events of Western Australians. The WADLS is used to link the statewide health data collections held by the Department of Health and some other organisations. The WADLS can be used for ethically approved research, planning and evaluation projects that aim to improve the health of Western Australians. Further details about the WADLS are available from the [Data Linkage WA](#) website and the Department of Health [“Data Linkage Branch Access Policy” 2010](#).

Investigators wishing to access personal health information from the Department of Health data collections must consult with the relevant Data Custodian or with the Data Linkage

¹⁷ Department of Health – In this context does not include the Health Services or other health service providers.

¹⁸ For more detailed explanation see the Department of Health [“Practice Code For the Use of Personal Health Information” 2009](#)



Branch Project Officer about the data application process (including relevant forms and supporting documentation) before applying for the data or requesting Department of Health WA HREC approval. The application will be formally reviewed by the Data Custodian in order to provide advice to the Data Steward on the release of the data. Further details about the data application, ethics and governance approval processes are available from the [Data Linkage WA](#) website and the Department of Health WA HREC “[Application Process for Personal Health Information](#)” guidelines on the Department of Health [Information About Health Data](#) website.

The release of information from the Department of Health data collections for use in research must be approved by the Data Steward. The Data Steward will not approve the use or disclosure of personal information from the Department of Health data collections for research unless the research project has been approved by the Department of Health WA HREC. The Department of Health WA HREC has special responsibility for oversight of the use and disclosure of personal health information held in the Department of Health data collections.

An investigator must have ethics approval from the Department of Health WA HREC, regardless of approval by another reviewing HREC, if they are applying for:

- personal health information from the data collections held by the Department of Health;
- the establishment of any new linkages with data collections held by the Department of Health;
- the disclosure of personal health information from data collections held by the Department of Health¹⁹ for projects that involve the funding, management, planning, monitoring, improvement or evaluation of Health Services; and
- other research projects as outlined in the Department of Health HREC ‘Terms of Reference’ available from the Department of Health [Information About Health Data](#) website.

As part of the Department of Health WA HREC application process, investigators conducting research within WA Health, must document that they have also applied for ethics and governance approval to undertake the research within their Health Service. In addition, institutions internal and external to WA Health which are accepting the ethical review by the Department of Health WA HREC must accept the legal liability for the conduct of the research project at their sites.

3.7.3 Data Collections and Repositories

In addition to those documents relating to data access and disclosure (refer to section [3.7.1](#)) and records management (refer to section [3.7.4](#)), WA Health personnel must comply with the following data management documents governing data collections and repositories:

- [National Statement \(Chapter 3.2\)](#);
- Department of Health “[Information Classification Policy](#)” 2010; and
- Department of Health “[Data Stewardship and Custodianship Policy](#)” 2011.

When third parties are collecting data on WA Health’s behalf an agreement must be in place to ensure confidentiality and security of data.

¹⁹ Except where information is required to meet clinical patient management requirements or mandatory reporting obligations such as the National Health Care Agreement or any other funding agreements, and reporting required by legislation.



3.7.4 Data Storage and Disposal

All records of research projects received and reviewed must be maintained in accordance with the [National Statement](#), [The Code](#), TGA “[Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\)](#)” 2000 and the Department of Health “[Recordkeeping Plan](#)” which has been established under the [State Records Act 2000 \(WA\)](#). The classification of data will determine how the information must be stored as outlined in the Department of Health “[Information Classification Policy](#)” 2010.

Administrative records should be managed using the Department of Health “[Retention and Disposal Schedule for Administrative and Functional Records 2007](#)” and electronic records should be managed according to the Department of Health “[Long Term Management of Electronic Records Policy](#)” 2004. Investigators within WA Health must retain and archive records in accordance with the above policies and when dealing with patient records, the current version of the Department of Health “[Patient Information Retention and Disposal Schedule](#)” 2008.

In general, the minimum recommended period for retention of research data is 5 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:

- for short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient (students should check with their university policies);
- for most clinical trials, retaining research data for 15 years or more may be necessary;
- for areas such as gene therapy, research data must be retained permanently (e.g. patient records); and
- if the work has community or heritage value, research data should be kept permanently at this stage, preferably within a national collection.

3.8 Project Specific Requirements (NEAF Section 9)

Investigators applying for ethical approval should consider the following project specific requirements as documented in the [National Statement \(Section 3 and 4\)](#).

3.8.1 Clinical Trials

Research in WA Health that involves the use of approved or unapproved medicines, medical devices, blood, tissues and chemicals must be compliant with the legislation, regulations and guidelines of the TGA (refer to the TGA “[Access to Unapproved Therapeutic Goods – Clinical Trials in Australia](#)” 2004). The TGA administers two schemes under which clinical trials involving therapeutic goods may be conducted: The Clinical Trial Notification Scheme and the Clinical Trial Exemption Scheme. For further information refer to the [TGA](#) website.

A notification or application to the TGA is required for all clinical investigational use of a product in Australia, where that use involves:

- a product not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or
- use of a registered or listed product outside the conditions of its marketing approval.

The CTN form is called the “Notification of Intent to Supply Unapproved Therapeutic Goods under the Clinical Trial Notification Scheme” and is available from the [TGA](#) website. Under



the scheme the HREC reviews all material relating to the proposed trial. Approval must be given from the Lead HREC and final authorisation from the site Chief Executive/delegate before conducting the clinical trial at the site. A CTN is required for each site involved in a clinical trial and the sponsor (or CRO) of the clinical trial must be an Australian entity.

The CTX form is used to make an application to the TGA under the Clinical Trial Exemption scheme and is available from the [TGA](#) website. Under the CTX scheme the TGA conducts an evaluation of the clinical trial and provides written advice to the reviewing HREC. Approval must be given from the Lead HREC and final authorisation from the site Chief Executive/delegate before conducting the clinical trial at the site. Before the CTN/CTX form can be lodged with the TGA, it needs to be signed by the Lead HREC Chair and then submitted to the RGO as part of the SSA for signing by the site Chief Executive/delegate.

In accordance with the World Medical Association “[Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects](#)” 2008, every clinical trial must be registered in a publicly accessible database before recruitment of the first participant.

3.8.2 Ionising Radiation

All research involving any form of radiation should comply with relevant national and State legislation ([Radiation Safety Act 1975 \(WA\)](#)), codes and standards of practice as listed by the NHMRC and the [Australian Radiation Protection and Nuclear Safety Agency](#). All research involving exposure of participants to ionising radiation must be reviewed by the institutions’ Radiation Safety Officer (**RSO**) who shall provide the RGO (and WA Health HREC if it conducts the ethical review) with a written report. Submission of the application to the RSO must be documented on the SSA form as part of the site authorisation.

Research that involves participant radiation exposure greater than 5mSv will generally be required to be submitted to the Radiological Council for approval. The institution’s RSO will decide if this is required and will advise the investigators and RGO (and WA Health HREC if it conducts the ethical review) accordingly, and will submit the application to the Radiological Council. If Radiological Council approval is required, the RGO will not recommend to the Chief Executive/delegate to authorise the research until the approval is received.

3.8.3 Human Embryos or Gametes

Research involving the use of gametes or embryos is governed by the [Research Involving Human Embryos Act 2002 \(Cwth\)](#) and the NHMRC “[Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research](#)” 2007, which requires that research on certain human embryos may only be conducted under licence issued by the NHMRC Licensing Committee once the project has been approved by a HREC.

Under the [Human Reproductive Technology Act 1991\(WA\)](#) clinics in WA providing infertility treatment are required to be licensed. Any research carried out by or on behalf of a licensee on eggs, sperm or participants, is required to have general or specific approval from the Department of Health [Reproductive Technology Council](#). Applications can occur prior to HREC approval but preference is for HREC approval to be obtained prior to consideration by the Council. Research involving human embryonic stem cell lines should refer to the [Human Tissue and Transplant Act 1982 \(WA\)](#).



3.8.4 Human Tissue Samples

Research involving human tissue samples should comply with the [National Statement \(Chapter 3.4\)](#) and the [Human Tissue and Transplant Act 1982 \(WA\)](#). Research projects involving the human fetus or human fetal tissue should comply with the NHMRC [“Statement on Human Experimental and Supplementary Notes” 1972](#).

Some WA Health sites have specific requirements relating to the storage and use of tissue samples (tissue, blood and other body fluids) taken for future research; investigators should contact the relevant RGO for further information. Tissue samples requiring shipment should be packaged and transported according to International Air Transport Association regulations.

3.8.5 Coronial and Non-Coronial Post-mortem Material

Research involving samples from a non-coronial post-mortem must be reviewed by a HREC after consideration of the Department of Health [“Non-Coronial Post-Mortem Examinations Code of Practice” 2007](#), enacted under the [Human Tissue and Transplant Act 1982 \(WA\)](#).

Research involving access to coronial material and information must comply with the [Coroners Act 1996 \(WA\)](#) and be referred to the Coronial Ethics Committee for ethical and legal approval, contactable through the WA Government [Coroner’s Court of WA](#). This must be documented in the WA Ethics Application Form or the WA-Specific Module if the NEAF is used.

3.8.6 Human Genetic Technologies and Biobanks

WA Health investigators are required by law to abide by the legislation for the regulation of genetically modified organisms (**GMOs**) in Australia as defined in the [Gene Technology Act 2000 \(Cwth\)](#) and the [Gene Technology Regulations 2001 \(Cwth\)](#) as well as the [Gene Technology Act 2006 \(WA\)](#). Organisations involved in using or undertaking dealings with gene technology are strongly encouraged to obtain accreditation by the [Gene Technology Regulator](#) and maintain, or have an established link with, a properly constituted Institutional Biosafety Committee (**IBC**) who must be consulted for any activity involving GMOs.

All research protocols involving human genetics and related technologies should be assessed and comply with recommendations made by the NHMRC’s [Human Genetics Advisory Committee \(HGAC\)](#) and the IBC prior to the review and approval from a HREC.

Health professionals involved in genetic testing should refer to the NHMRC [“Medical Genetic Testing: Information for Health Professionals” 2010](#) which identifies key issues that should be considered in relation to genetic testing, and identifies relevant resources, guidelines, standards, and requirements that are pertinent for the delivery of genetic testing in Australia. Genetic Research Registers should be established and managed in accordance with the NHMRC [“Guidelines for Genetic Registers and Associated Genetic Material” 1999](#) which identifies matters for ethical consideration that relate to the establishment and operation of a genetic register.

Biobanks should be established, managed and governed in accordance with the NHMRC [“Biobanks Information Paper” 2010](#). In WA, government and non-government organisations must comply with the Department of Health [“Guidelines for human biobanks, genetic research databases and associated data” 2010](#) which form part of an overarching governance and regulatory framework for biobanks in WA and should be used in conjunction with existing guidelines, laws and regulations. The Guidelines are intended for use by



organisations and research personnel to assist in the establishment, governance, management and use of all human biobanks, within the custodianship or held under the auspices of WA Health and used for research purposes. This includes but is not restricted to biobanks:

- established through collaborations between WA Health and universities or research institutions;
- established by investigators with joint appointments between WA Health and universities or research institutions;
- established using samples and/or information obtained from WA Health participants;
- established with funding in part or in full from WA Health; and
- for which investigators wish to link the biobank's data with the WA Health data collections.



4. ROLES AND RESPONSIBILITIES

Position	Responsibilities	Accountability Criteria
<p>Department of Health Research Development Unit</p>	<p>This Unit is responsible for:</p> <ul style="list-style-type: none"> • undertaking a review of the WA Health Research Governance Policy and Procedures every 5 years in line with national guidelines and relevant legislative requirements; and • facilitating implementation of the WA Health RGS IT system, and training in its use throughout WA Health. 	<p>WA Health Research Governance Policy and Procedures implemented and maintained across WA Health.</p> <p>RGS IT system implemented and maintained across WA Health.</p>
<p>Health Service or Department of Health Chief Executive (or Delegate i.e. Site Executive Director)</p>	<p>This position is responsible for ensuring:</p> <ul style="list-style-type: none"> • authorisation (delegated) is issued to conduct research at the relevant WA Health site, contingent upon receiving ethics and research governance approval; • the requirements and procedures related to the policy are communicated to research personnel; • structures and support are provided for the implementation of the WA Health Research Governance Policy and Procedures, ethics and governance forms; • sufficient resources are provided for effective and efficient processing of site authorisation applications by the RGO; • sufficient resources are provided for effective and efficient processing of applications for ethical and scientific review by the HREC; • delegation for research authorisation is documented; • the research conducted at the site is monitored for compliance with policy and procedures; • systems are in place for the management of complaints about research, including research misconduct and fraud; and • funds are allocated for education and training of HREC members, governance and research personnel. 	<p>Annual report of research activity, revenue and timeliness of ethics and governance reviews.</p> <p>Annual report of research complaints, including research misconduct and fraud.</p> <p>Annual report on training attended by WA Health HREC members, ethics/governance and research personnel.</p> <p>Research organisational structure is documented.</p> <p>Standard Operating Procedures are established for those involved in the management of research activities.</p> <p>Terms of Reference are established for the HREC.</p>



Position	Responsibilities	Accountability Criteria
<p>Research Director and/or Manager responsible for Research Ethics and Governance</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • providing support and advice to the relevant WA Health Executive/delegate, HREC, ethics/governance and research personnel, and sponsors in accordance with the WA Health Research Governance Policy and Procedures; • facilitating a culture of safe and high quality research through the promotion and awareness of the National Statement and The Code; • ensuring administrative systems are in place to review, monitor and evaluate research being conducted in WA Health; • facilitating and coordinating the preparation of the annual research report; • monitoring research activity within the relevant service of WA Health in line with conditions of approval; and • participating in the development of systems to improve the conduct and governance of research. 	<p>Prepare annual report of research activity and research revenue.</p> <p>Prepare annual (or more frequently as required) report on the approval time frames for ethics and governance approvals.</p> <p>Prepare annual report of research complaints, including research misconduct and fraud.</p> <p>Prepare annual report on training attended by WA Health HREC members, ethics/governance and research personnel.</p>
<p>Heads of Department, Division and Supporting Departments</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • discussing the research project with the PI and assessing whether the project meets the appropriate governance requirements; • ensuring additional support and services can be provided for each research project; and • ensuring authorisation is documented. 	<p>Authorisation is documented on the SSA form.</p>
<p>Business Manager</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • assisting the CPI (single-centre)/PI (multi-centre) in preparing a budget for the conduct of the project; • ensuring funding sources and costs of the research project have been identified on the SSA form; • ensuring research costs can be met by the sponsor or the Health Service; and • ensuring cost centres are created (as required) to manage research funds. 	<p>Authorisation is documented and cost centres are identified on the SSA form.</p>
<p>Clinical Research Coordinator</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • liaising between the CPI/PI, the WA Health HREC and RGO; • facilitating arrangements for the research team to access the Health Service’s resources and support, as agreed in the research contract and identified on the SSA form; and • liaising with the CPI/PI and research sponsor regarding the management, monitoring and financial reporting of the research project. 	<p>All documentation and records associated with research projects are maintained and auditable.</p>



Position	Responsibilities	Accountability Criteria
<p>Coordinating Principal Investigator (This role is applicable in single-centre and multi-centre research)</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • submitting the ethics application(s) (with input from the PI in multi-centre projects) for ethical and scientific approval of the research project; • ensuring that if required, the research project satisfies any specific review requirements; • relaying information between the HREC and the PI in multi-centre projects; • communicating the outcome of the ethical review to the PI in multi-centre projects; • preparing a budget for the conduct of the project in association with the Business Manager; • submitting the SSA for institutional approval (submitted by PI in multi-centre research); • submitting an Access Request Form for research that requires support from a Health Service in the form of access to participants, tissue or data but does not involve the conduct of research at that Health Service; • registering all clinical trials on a publicly accessible clinical trial registry, prior to the commencement of the clinical trial; • conducting clinical intervention projects in accordance with credentialing privileges and experience; • conducting research in accordance with national guidelines and the WA Health Research Governance Policy and Procedures; • ensuring that the research is carried out in accordance with the conditions of ethics approval; • ensuring research practices reflect current professional (ethical and legal) standards for research, including reporting conflicts of interest; • ensuring compliance with legislative and policy requirements for patient contact, consent and confidentiality of patient information; • maintaining good research records and making records available for review; • responding promptly to reporting and monitoring standards, including adverse events, complaints and clinical incidents; • submitting annual and final reports to the HREC and institution (submitted by PI in multi-centre projects) in a timely fashion; and • submitting notification of early project termination. 	<p>Submit the relevant ethics application form available from the Research Governance Portal for uploading into RGS IT system.</p> <p>Submit additional specialist HREC applications as required e.g. WAAHEC.</p> <p>In single-centre research (submitted by PI in multi-centre), submit the relevant SSA/Access Request Form available from the Research Governance Portal for uploading into the RGS IT system.</p> <p>Ensure Health Service/site authorisation is obtained prior to commencement of research.</p> <p>Register all clinical trials on an authorised clinical trial registry.</p> <p>Only conduct research that is consistent with professional privileges and training.</p> <p>Provide scheduled progress and final reports to the Ethics and Governance Officer (submitted by PI in multi-centre projects) and other monitoring requirements as per research authorisation.</p>



Position	Responsibilities	Accountability Criteria
<p>Principal Investigator (This role is applicable in multi-centre research)</p>	<p>In multi-centre projects this position is responsible for:</p> <ul style="list-style-type: none"> • the responsibilities related to the conduct of the research project which are synonymous with the CPI; except for the application for ethical and scientific approval, direct submission of reports to the HREC and registration of clinical trials; • providing the CPI with local information relevant to the ethics application; • preparing & providing information for participants at a local level that relates specifically to the institution; • submitting the SSA form for site approval; • notifying the CPI of research commencement; • complying with institutional reporting requirements; • advising the institution of any HREC outcomes/changes; and • providing information to the CPI to report to the HREC. 	<p>Only conduct research that is consistent with professional privileges and training.</p> <p>Ensure a relevant SSA is completed by the PI and authorisation obtained prior to commencement of research.</p> <p>Provide scheduled progress and final reports to the HREC (through the CPI) and RGO and other monitoring requirements as per research authorisation.</p>
<p>Ethics Executive Officer</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • providing expert advice to investigators seeking to undertake research within WA Health in accordance with policies; • providing secretariat support for a HREC (and sub-committees if applicable); • document HREC decisions and maintain a current record on the RGS IT system; • assisting in the preparation on the annual reporting of HREC activity to the NHMRC; • managing approved research amendments; • managing annual progress/final reports; and • managing appeals and notification of complaints, misconduct and conflicts of interest. 	<p>Accurate data entry into RGS IT system and maintenance of records.</p> <p>Timeliness of ethics reviews (i.e. within a 60 calendar day timeframe, which allows for a ‘stop clock’ capability).</p> <p>Prepare minutes and correspondence for all relevant committees.</p> <p>Annual HREC report to the NHMRC.</p>
<p>Human Research Ethics Committee (HREC) and Scientific sub-committee</p>	<p>These committees are responsible for:</p> <ul style="list-style-type: none"> • conducting ethical and scientific review of research proposals in line with the NHMRC National Guidelines and WA Health Research Governance Policy and Procedures; • determining the compliance of a human research project with the National Statement and approving applications that satisfy the NHMRC National Guidelines and any other relevant policy; • monitoring the ethical and scientific aspects of research; and • providing advice on strategies to promote awareness of the ethical conduct of research. 	<p>Research protocols are reviewed in accordance with the NHMRC standards and guidelines.</p>



Position	Responsibilities	Accountability Criteria
<p>Research Governance Officer</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • providing expert advice to investigators seeking to undertake research within WA Health in accordance with national, State and local policies; • providing expert advice to the Chief Executive or delegate on all research governance matters; • reviewing the SSA form or Access Request Form and recommending authorisation of research to the Chief Executive or delegate; • Reviewing agreements, indemnity and insurance documents and consulting with RiskCover and the LLS as required; • documenting all research governance decisions and maintaining a current record on the RGS IT system; • reviewing and managing amendment documentation related to authorised research projects; • having an oversight of authorised research projects through review of safety, annual progress and final reports submitted by the CPI/PI; • managing complaints, misconduct or conflicts of interest related to the conduct of authorised research projects; and • conducting or coordinating audits of research projects, where required. 	<p>Accurate data entry into RGS IT system and maintenance of records.</p> <p>Timeliness of research governance reviews (i.e. within a 60 calendar day timeframe, which allows for a ‘stop clock’ capability).</p>
<p>Research Supervisor</p>	<p>This position is responsible for:</p> <ul style="list-style-type: none"> • ensuring university students applications are of a high standard. It is recommended that students submit their research projects to university HRECs for approval prior to submission to the WA Health HREC; • fulfilling a supervisory role, taking responsibility for the student and acting as a primary source of guidance to the student; • advising each student of applicable government and institutional guidelines for the conduct of research, IP rights and obligations; and • overseeing the implementation and conduct of the research at the site. 	<p>Student applications for review by WA Health HRECs are of a high standard and do not require resubmission.</p> <p>All students will have an on-site WA Health research supervisor.</p>





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