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

Research Governance Procedures

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Contents

1. Introduction

1.1. Scope of research governance procedures

Research governance ensures that the principles, requirements and standards of research are upheld. It addresses the protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management, and monitoring arrangements. Effective research governance promotes a positive research culture and sustainable practices that facilitate the conduct of high-quality clinical research.

Research governance consists of:

- ethical and scientific review by a Human Research Ethics Committee (HREC) or appropriate other ethical review body
- site authorisation by each participating site, following review by the Research Governance Office (RGO)
- monitoring by HRECs and sites throughout the project life cycle.

These Procedures describe the mandatory requirements that apply to WA health system entities for implementing research governance for their site/s. These mandatory requirements apply to human research activities only. They do not apply to research involving animals or non-research activities.

These Procedures are mandatory pursuant to the *Research Governance Policy* and are applicable to all WA health system entities.

The *Research Governance Policy* and these *Research Governance Procedures* supersede OD0411/12 *Research Governance Procedures* and OD0446/13 *WA Health Research Governance and Single Ethical Review Standard Operating Procedures*.

1.2. Classification of research and non-research activities

It is recognised that RGOs may be asked to advise investigators on whether their proposed activity is classified as research, and consequently subject to the mandatory requirements of the *Research Governance Policy* and *Research Governance Procedures*. Health system entities should have site-specific policies and processes in place for the classification of projects as research or non-research activities. RGOs may also consult their site Safety and Quality Unit and/or the HREC (or HREC Chair) for advice.

While the requirements described within these Procedures are not mandatory for non-research activities, HRECs and RGOs may find it useful to consider these Procedures when reviewing and advising on activities including quality assurance/improvement, evaluation or case studies.

1.3. Terminology

This document refers to the roles of the Ethics Office (EO) and the Research Governance Office (RGO). The EO is the first point of contact to the HREC and encompasses any ethics administrative staff. The RGO is responsible for reviewing application forms and supporting documents related to research governance, to provide recommendation for site authorisation to the Chief Executive (CE)/delegate. The RGO encompasses Research Governance officers and/or any other staff that a WA health system entity see fit, such as Site Specific Assessment Officers. Staff within the EO and RGO are also responsible for providing guidance to investigators seeking to undertake research within the WA health system. Office names and roles may differ between WA health system entities.

The site authorisation process is sometimes colloquially referred to as “governance review”; however, it is important to note that research governance is a framework that encompasses both ethical approval and site authorisation.

In line with WA health system policy, the use of the term ‘Aboriginal’ within this document refers to Australians of both Aboriginal and Torres Strait Islander peoples, in recognition that Aboriginal people are the original inhabitants of Western Australia. No disrespect is intended to our Torres Strait Islander colleagues and community.

Further information on terminology is detailed within the Definitions section of this document.

2. Research Governance Service

The Research Governance Service (RGS) is a centralised Information Technology (IT) system which supports the *Research Governance Policy* and *Research Governance Procedures* for all research conducted within the WA health system.

The RGS must be used for all stages of the research governance process, including reviewing, processing, monitoring and closure of research projects, unless otherwise specified in these Procedures. All research project members that are accessing identifiable information within the WA health system must be project members in the RGS. Formal communications between relevant parties regarding research governance must occur via the RGS.

The RGS Help Wiki provides details on the specific processes that enable compliance with these Procedures.

3. Delegation of authority

The WA Minister for Health (in their 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 WA health system entities. The responsibility for research governance and the authority for signing agreements on behalf of the State are delegated from the Director General to the WA health system entity's Chief Executive. For the Department of Health, this delegation is to the Assistant Director General. Only 'Chief Executive' is referred to from this point on, but it should be noted that all WA health system entity Chief Executive roles and responsibilities also apply to the Department of Health Assistant Director General.

The Chief Executive must decide whether to sign contractual agreements and authorise the commencement of research projects for sites that they are responsible for. If further delegation is required, the Chief Executive must determine the appropriate delegation for authorisation. This delegation must be documented in the Authorisations and Delegations Schedule. The Chief Executive remains responsible and accountable for providing site authorisation and signing contracts on behalf of the site, even if these responsibilities are delegated.

The Director General is the delegated owner of all data and information collected, stored, used and disclosed within the WA health system. 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. The Data Steward's responsibility of authorising the access, use and disclosure of data from a data collection may also sometimes be delegated to a Data Custodian.

4. Ethical Review

Research projects within the WA health system must be ethically and scientifically reviewed utilising the:

- WA Health Single Ethical Review process
  or
- National Mutual Acceptance Scheme.

For the purpose of these *Research Governance Policy* and *Research Governance Procedures*, ethical review includes scientific review.

All research must be ethically reviewed and approved by a Lead HREC, and/or a relevant Specialist HREC (if applicable), before it can be recommended for authorisation by the RGO(s) and authorised by the CE/delegate, and before the commencement of any active part of a research project, including recruitment and data collection.

The Lead HREC is the HREC that provides approval for the research project. In the case of low and negligible risk (LNR) research, an alternative LNR review pathway may be utilised instead of Lead HREC review, at the discretion of the site (section 4.4).

HREC review of research that does not occur via the WA Health Single Ethical Review process (section 4.1) or the National Mutual Acceptance Scheme (section 4.2) cannot be accepted by WA health system entities.

4.1. WA Health Single Ethical Review

For research involving a single WA health system entity's site or involving multiple sites only within the WA health system, HREC approval must be sought from a WA Health System HREC in line with the WA Health Single Ethical Review Process.

The WA Health Single Ethical Review process was implemented in 2013 for intra-jurisdictional (within WA) multi-site research. Under this process, all single and multi-site research projects conducted at WA health system entities must be ethically and scientifically reviewed only once, by a WA health system Lead HREC or an LNR review pathway if appropriate and available. An exception applies to projects that require additional Specialist HREC review (section 4.3).

Under the WA Health Single Ethical Review process, the Lead HREC must be a WA health system HREC and is usually the HREC for one of the sites participating in the research project. However, a non-participating WA health system HREC may act as the Lead HREC if it agrees to undertake the ethical review and ongoing monitoring responsibilities for the project.

WA Health Single Ethical Review can occur using either:

1. the WA Health Ethics Application Form (WAHEAF)
2. the Human Research Ethics Application (HREA) and WA-Specific Module (WASM).

4.2. National Mutual Acceptance

For research involving sites across multiple Australian jurisdictions and including at least one WA health system site, the National Mutual Acceptance (NMA) scheme must be used to enable efficient review.

The NMA scheme is a national system for the mutual acceptance of scientific and ethical review of multi-site human research projects conducted in publicly funded health services across Australian jurisdictions.

An NMA Memorandum of Understanding (MoU) is in place between all participating state and territory jurisdictions and sets out the arrangements between the parties to achieve single ethical and scientific review of multi-site research projects under the NMA scheme. The Director General signs the NMA MoU on behalf of all WA health system entities. EOs and RGOs must ensure that the review and acceptance of research projects under the NMA scheme is in line with the NMA Standard Principles for Operation, in addition to these *Research Governance Policy* and *Research Governance Procedures*.

Research under the NMA scheme undergoes scientific and ethical review only once by a Lead HREC. An exception applies to projects that require additional Specialist HREC review (section 4.3). The Lead HREC must be a Certified Reviewing HREC under the NMA scheme.

There are three HRECs in the WA health system that can provide Lead HREC approval for inter-jurisdictional research under the NMA scheme:

1. Child and Adolescent Health Service HREC
2. Sir Charles Gairdner and Osborne Park Health Care Group HREC
3. South Metropolitan Health Service HREC

Each of the above HRECs is also certified under the NMA scheme to undertake NMA review of research for specific certification categories, as detailed in *Table 1.* below.

Table 1. NMA certification categories for WA health system HRECs

HREC	**Certification period**	**Certification categories**
Child and Adolescent Health Service HREC	Continuous from 1 July 2020	• Clinical trials phase I, II, III, IV • Clinical trials drugs and devices • Clinical interventional research other than clinical trials • Population health and/or public health • Qualitative research • Mental health • Paediatric research • Other health and medical research ○ observational / non-clinical intervention
Sir Charles Gairdner and Osborne Park Health Care Group HREC	Continuous from 1 July 2020	• Clinical trials phase I, II, III, IV • Clinical trials drugs and devices • Clinical interventional research other than clinical trials • Population health and/or public health • Qualitative research
South Metropolitan Health Service HREC	Continuous from 1 July 2020	• Clinical trials phase I, II, III, IV • Clinical trials drugs and devices • Clinical interventional research other than clinical trials • Population health and/or public health • Qualitative research • Mental health • Other health and medical research ○ Observational non-clinical research

The HREA must be used for ethics review under the NMA scheme. For projects conducted in Western Australia, submission of the WASM and completion of relevant (if any) specialist review is also required.

The RGO must confirm the HREA and WASM have been reviewed and approved by the Lead HREC and that any additional specialist HREC approvals are obtained before recommending the project for site authorisation. The RGO must also check that the reviewing Lead HREC is certified in the appropriate category for the research project. The NHMRC website should be consulted for a list of NMA certified categories for HRECs participating in the NMA scheme.

4.3. Specialist Human Research Ethics Committees

Specialist HREC ethical approval may be required in addition to or instead of general Lead HREC ethical approval. Where only specialist HREC review is required, as in the case of projects only using data from the Department of Health Data Collections, the specialist HREC becomes the Lead HREC. Within this section, "specialist HRECs" refer to HRECs that must approve certain types of research projects before the research can commence within the WA health system.

The three specialist HRECs in WA are:

1. The **Department of Health HREC,** who must review all research projects that require the use and disclosure of personal health information from the Department of Health Data Collections, including data linkage research (section 16).
2. The **WA Aboriginal Health Ethics Committee (WAAHEC),** who must review all research projects that involve research in, or in relation to, Western Australia, and where the following applies:
   - the research is related to Aboriginal health and well-being; and
   - the experience of Aboriginal and/or Torres Strait Islander people is an explicit focus of all or part of the research; or
   - data collection is explicitly directed at Aboriginal people; or
   - research outcomes explicitly related to Aboriginal people; or
   - it is proposed to conduct sub-group analyses and separately analyse Aboriginal people in the results; or
   - the information, potential over-representation in the dataset, or geographic location has an impact on one or more Aboriginal communities; or
   - Government Aboriginal health funds are a source of funding.
3. The **Coronial Ethics Committee WA**, who must review all research that requires access to coronial samples, data or information.

Research that falls into the categories of one or more of the above HRECs must be reviewed by the relevant specialist HREC, regardless of whether they have been reviewed by a Lead HREC.

The RGO must ensure that any required specialist HREC approval has been obtained before recommending the project for site authorisation.

4.4. Low and negligible risk review pathways

The NHMRC *National Statement on Ethical Conduct in Human Research* (National Statement) provides guidance regarding when research may be classified as low and negligible risk in relation to research participants for ethical purposes.

If a research project carries only low or negligible risk and does not fall under any of the research categories requiring HREC review (section 4.6), the WA health system entity may allow the project to be reviewed via an alternative LNR review pathway.

There is no standardised alternative pathway for the review of low risk research in the WA health system. The structure of the LNR review pathway is to be determined by each WA health system entity and detailed in the site procedures. Those reviewing research at a non-HREC level must refer any research that they identify as involving more than low risk to HREC review.

LNR ethical review may be reciprocated between sites without duplication under the WA single ethical review process. Research that has been ethically reviewed via an LNR review pathway must still undergo a standard site authorisation process.

4.5. Exemption from ethical review

A WA health system entity may choose to exempt negligible risk projects from ethical review, according to National Statement guidelines. The decision of whether a project may be exempted from ethical review may be made by the HREC or through an alternate process, as detailed in the WA health system entity's Procedures.

If approved for ethical exemption, the WA health system entity must provide an exemption letter to the Coordinating Principal Investigator (CPI) that declares that the project meets the requirements of the National Statement and is ethically acceptable.

The process for ethical exemptions described in this section can occur outside of the RGS. WA health system entities must ensure that adequate records are maintained in line with the Department of Health Information Management Framework.

4.5.1. Data project exemptions

Data projects may be exempted from HREC review by a WA health system entity, provided that the data is non-personal, there is written agreement that the data provided will not be used in conjunction with other data to make it re-identifiable, and it is not against any legislative requirements that the information was collected under.

To provide data project ethical review exemptions, the WA health system entity must have a policy for this exemption process that requires the following details to be provided at a minimum:

- the legislation that the data was collected under
- restrictions to the secondary use of the data
- who will be analysing the data
- where the dataset will reside
- what the timeframe for access will be
- a data destruction plan.

4.6. Research requiring Human Research Ethics Committee review

Certain types of human research must be ethically and scientifically reviewed by an HREC and cannot be reviewed through an alternative low risk pathway or be exempted from ethical review.

The National Statement must be consulted for guidance on whether a research project must undergo HREC review. Research requiring review by an HREC includes:

- Any research that involves more than low risk to research participants.
- Projects involving personal information and utilising a waiver of consent.
- Use of an opt-out approach to recruitment where NHMRC *Guidelines under Section 95 of the Privacy Act 1988* or *Guidelines approved under Section 95A of the Privacy Act 1988* apply.
- Research that uses identifiable personal health information from the Department of Health Data Collections.
- Research that:
  - involves active concealment or planned deception
  - aims to expose illegal activity.
- Research involving the derivation of embryonic stem cell lines or other products from a human embryo.
- Prospective collection of human biospecimens for research.
- In general, research including genomics unless no information that can identify an individual is used and no linkage of data is planned.
- Xenotransplantation research.
- Any other research specified by the National Statement as requiring HREC review.

5. Administrative procedures for Human Research Ethics Committee meetings

5.1. Publicly available information

All HRECs must establish Procedures and Terms of Reference (ToR). HREC ToR must be made publicly available and must include details of the HREC's and any alternate ethical review body's review pathways.

HRECs must determine and publish their schedule for HREC meetings and application dates for the following calendar year by 31 October on their website and in the RGS.

5.2. Pre-meeting

All HREC members must be given access to the RGS and provided with adequate support and training to utilise the RGS to carry out their HREC duties effectively. All administrative records for HREC meetings must be maintained in the RGS.

HRECs may cap the number of new projects they are able to accept at a meeting. In the case of refusal, the EO must instruct the CPI that they may submit the application at the next meeting or to another eligible HREC.

Once received, the EO must assign the latest versions of ethics applications, amendments, complaints and reports to an ethics meeting agenda.

The EO must invite HREC members to upcoming meetings via the RGS and provide members with the agenda (including relevant attachments) and the previous meeting's minutes. Members must be given at least one calendar week to review all relevant documentation before the meeting date. The RGS may be used by committee members to share comments, ask questions of other members, and make notes related to the submissions for discussion at the meeting.

5.3. Post-meeting

Following each HREC meeting, the EO must create meeting minutes based on the agenda items. Minutes must include decisions on each research project including:

- the main scientific and ethical issues
- whether additional information is required and the process by which that new submission will be reviewed
- whether any additional ethical approval is required from a specialist HREC
- the outcome of the review (section 6.3)
- the details of all standard and special conditions that apply to the ethical approval (if granted).

Minutes must be reviewed and approved by the HREC Chair, then endorsed by the HREC at the next meeting.

5.4. Out of session review

HRECs must detail in their ToR what items may be reviewed out session and by delegation.

Any matter settled out of session must be tabled for members' information at the next HREC meeting.

6. Scientific and ethical review by a Human Research Ethics Committee

6.1. Review process

When an ethics application is received, the EO must perform a validation assessment of the submission. Validation involves determining if the form and attached documents are appropriate, complete and accurate, including appropriate signatories.

If validated, the application is assigned to the next HREC meeting. If more information is required, the item is marked as AIR and a request for the additional information is issued to the CPI. If the application is invalid, the EO must comment why it is not valid to allow the CPI to submit an alternative form or withdraw the project.

During an HREC meeting, the HREC must apply the National Statement's guidance to its scientific and ethical review of research, considering the four principles of merit and integrity, justice, respect and beneficence. The operational process used by an HREC to conduct its ethical and scientific review is a matter for it to dictate in their Procedures (including the use of a scientific subcommittee), provided that it operates in accordance with the National Statement, any other relevant guidelines set by the NHMRC and these *Research Governance Procedures*. If desired, HRECs may seek and accept advice from private organisations (e.g. if expertise is required to be sourced from an external organisation).

HRECs within the WA health system must be directly accountable to the WA health system entities that they are constituted under and must operate in accordance with their Terms of Reference and Procedures.

The Lead HREC must be responsible for all aspects of ethical and scientific review. This includes post-approval reviews of amendments and reports. The on-site HREC, if not the Lead HREC, must have no role in these review and approval activities.

6.2. Duration of ethical approval

Duration of ethical approval must be appropriate for the proposed duration of the project in accordance with the following information.

6.2.1. WA Health Single Ethical Review

Under WA Health Single Ethical Review, it is recommended that the duration of ethical approval is a maximum of 5 years, but this is at the discretion of the Lead HREC. Extensions must be requested via an ethics amendment request in the RGS, and the extension period must be limited to three years per extension. While the first extension to this initial approval period may be approved out of session, subsequent extensions must be reviewed at an HREC committee meeting.

6.2.2. National Mutual Acceptance

The NMA Standard Principles for Operation allow for approval for up to 5 years or rolling approval on receipt of an annual/progress report. Accordingly, some non-WA health system HRECs may choose to provide rolling approval for NMA projects. However, WA health system HRECs cannot provide rolling approval because an end-date must be provided. Therefore, under NMA, the duration of ethical approval may be longer than 5 years. Extension of the ethical approval period may be requested by the CPI. The request must be submitted to the Lead HREC through an amendment process prior to expiry of the current approval period. The process to be followed depends on the relevant jurisdiction of the Lead HREC. For WA health system HRECs, this process should reflect the WA Health Single Ethical Review approach to

extensions of ethical approval. Following the HREC meeting, the EO must provide a formal letter of notification via the RGS to the CPI with the outcome of the HREC review.

6.3. Notification of outcome

6.3.1. Application approved

If the ethics application is approved, this must be reflected in the RGS and letter of notification. This letter of notification must include the sites and documents approved, and the duration of approval.

The HREC may apply project specific conditions to its approval (e.g. a waiver of consent). These conditions must be clearly communicated to the CPI via the RGS and letter of notification. The HREC must review compliance with conditions of approval via ongoing monitoring.

6.3.2. Additional information required

Where an HREC requires additional information and/or amendments to the research project before a decision is made, the EO must request that the CPI submit their response (with attachments as required) in the RGS. The EO must receive a response within 4 months of notification, or the application may be withdrawn at the discretion of the HREC. Once the additional information is received from the CPI, the application must be reviewed as per the HREC's determination, their Terms of Reference and their Procedures.

6.3.3. Application not approved

If an application is not approved, the HREC must provide the CPI with clear reasons for this decision, in relation to the National Statement or relevant legislation. The EO must withdraw the application in the RGS and ensure that the CPI/PI notifies the relevant RGO(s) to cease the site-specific assessment of the project.

7. Site authorisation types

Applications for site authorisation must be submitted to the RGO using the appropriate site application form.

The two site application forms are:

1. Site Specific Assessment (SSA) form.
2. Access Request (AR) form.

Upon request, the RGO must assist investigators with determining which form is appropriate for their research project. Investigators must be encouraged to consult the RGO before submission.

7.1. Site Specific Assessment form

If research activities are occurring at a site, an SSA form must be used to apply for site authorisation. Examples of research activities requiring the use of an SSA include:

- participant enrolment and consent
- conducting research procedures with or on participants at the site
- managing and analysing data, biospecimens and/or responses from surveys and questionnaires for research at the site
- administration of surveys and questionnaires to site participants or staff that requires oversight by investigators or site personnel.

7.2. Access Request form

If the research activity has minimal impact on the resources of the site(s), and only access to the site's patients and/or staff, their biospecimens or data is being requested, then an AR form may be used, at the discretion of the RGO. Examples of research activities where the use of an AR may be appropriate include:

- participant recruitment through posters, leaflets, handouts or letters of invitation
- administration of surveys and questionnaires to site patients and/or staff that do not require oversight by investigators or site personnel (such as e-surveys)
- access to data or biospecimens held at the site (but not processing or analysis at that site).

Where significant resources, as determined by the RGO, are involved in the retrieval, preparation and/or transport of data or biospecimens, the RGO may require the use of an SSA form rather than an AR form, such that costs associated with these activities may be considered in the budget form.

8. Site review

The appropriate site application form must be submitted by the Principal Investigator (PI) or delegate via the RGS. The RGO must conduct a site review and provide a recommendation to the CE/delegate. The CE/delegate must authorise or not authorise the project occurring at the site, with consideration of the RGO recommendation. Authorisation via the RGS by the CE/delegate and receipt of an authorisation letter by the researcher is required before research commences at or involving that site.

The RGO must review all application documents to ensure that information between the SSA/AR, research protocol, application for data (if applicable), and any other agreements is consistent and remains consistent when amendments are made.

8.1. Review timeline

The RGO review of a valid site application must be completed within 60 calendar days of the submission date of the SSA/AR (i.e. a 60-day clock commences from the submission date). Time spent waiting for the PI to provide extra information is excluded from the 60-day clock.

During the review process, the RGO may mark a submission as 'Additional Information Required (AIR)' to request clarification or additional information from the PI. If the PI does not supply the requested information within 4 months of the request, the RGO may withdraw the application.

8.2. Validation

The first step of a site review by the RGO is to complete a validation assessment of the submission. Validation involves determining if the form and documents are appropriate, complete and accurate, including appropriate signatories.

If validated, the site authorisation review continues. If the form or a document is marked as 'AIR', a request for the additional information is issued. If the form is marked as not valid, the RGO must comment why it is not valid to allow the PI to submit an alternative form or withdraw the project from the site.

8.3. Review of site application forms and documents

The RGO must review the site application and attached documents to ensure that information between the SSA/AR, research protocol, application for data (if applicable) and any other agreements is consistent and remains consistent when amendments are made.

8.3.1. Site Specific Application/Access Request

The RGO must review the SSA/AR and all associated forms and documents. Before determining if the application can be recommended, not recommended or escalated for CE/delegate decision, the RGO must ensure that:

- No information in project details is missing.
- Investigators have adequate credentials and training.
- The budget form is appropriately completed with funding and costings (section 8.3.2).
- Adequate insurance and indemnity are provided (sections 13 and 14).
- Appropriate research agreements are in place (sections 12 and 20).
- IP arrangements have been considered (section 15).
- Relevant approvals from regulatory bodies are provided (e.g. Radiological Council, Reproductive Technology Council) (section 8.4).
- Declarations of confidentiality and conflicts of interest are provided where relevant (sections 10 and 11).

- Sign offs from the relevant hospital administrators (e.g. business manager, divisional director and/or regional manager) are provided.
- Risks to the site or participants are identified, acceptable and have been properly mitigated.

To inform their review, the RGO may request advice from external parties such as:

- the lead or specialist HREC
- legal services (e.g. Department of Health Legal and Legislative Services)
- the insurer (e.g. Insurance Commission of WA)
  or
- the funding entity.

The time taken to obtain this advice is considered part of the site review 60-day clock. If an AIR request is generated during this time, the time spent waiting for additional information from the PI is excluded from the 60-day clock.

8.3.2. Budget

The RGO must ensure that the site's budget form contains:

- costs of all items to be utilised in each department at the site
- funding amounts and sources, including in-kind funding
- approvals from all relevant Heads of Department and/or ED or CE
- details and contacts for the Research Department, Supporting Department(s) and relevant Third Party Agencies.

The CTRA/CIRA and budget may contain different information due to the different purposes these two documents serve.

The budget must be included when the SSA is submitted to the site Business Manager and Divisional Director before the forms are submitted for site authorisation.

The RGO must recommend that that investigators consider item costs with regard to the Independent Hospital Pricing Authority (IHPA) *Determination of standard costs associated with conducting clinical trials in Australia*.

The overhead charges applicable to a site must be in accordance with the Department of Health *Standard Model for Managing Clinical Research Funds*. Determination of overhead charges for each WA health system entity remains at the discretion of the WA health system entity.

8.3.3. Participant Information and Consent Form

The RGO must ensure that the PICF contains appropriate contact details for complaints submission (section 23).

A site-specific PICF may be produced for each site based on the master PICF approved by the HREC. The RGO must ensure that the site-specific PICF only contains minor amendments from the master PICF, for example, site specific information, branding and contact details, and does not impact the ethical acceptability of the project. More extensive amendments to the master PICF must be re-submitted to the HREC for approval, as appropriate (section 24.2).

8.4. Research types requiring special consideration

Certain types of research projects require registration with a regulatory body, close consideration of the relevant legislation and thorough risk assessment and mitigation (Table 2).

Risk mitigation mechanisms must be detailed in the site application and the RGO must review compliance with the relevant legislation and regulatory body requirements through initial review and ongoing monitoring.

Table 2. Legislative and regulatory considerations for research types requiring special consideration.

Research Type	Legislation	Guidelines	Regulatory Body	Additional Considerations
Ionising Radiation	*Radiation Safety Act 1975*, *Australian Radiation Protection and Nuclear Safety Act 1998*	Australian Radiation Protection and Nuclear Safety Agency Regulations, Radiological Council	Radiological Council	Appointment of a Radiation Safety Officer and consultation with the Site Imaging Service Head of Department is required.
Human Embryos or Gametes	*Research Involving Human Embryos Act 2002*, *Human Reproductive Technology Act 1991*, *Human Tissue and Transplant Act 1982*	NHMRC Ethical Guidelines for Assisted Reproductive Technology	Reproductive Technology Council Embryo Research Licensing Committee	HREC approval is required before consideration by the Reproductive Technology Council.
Biospecimens	*Human Tissue and Transplant Act 1982*	NA	NA	Infectious or genetically modified biospecimens may require review from an Institutional Biosafety Committee (IBC).
Coronial and Non-Coronial Post-Mortem Material	*Coroners Act 1996*	*Non-Coronial Post-Mortem Examinations Code of Practice 2007*	WA Government Coroner's Court of WA: Coronial Ethics Committee	Additional ethical approval by the Coronial Ethics Committee is required.
Genetic Information	*Gene Technology Act 2000* (Cwth), *Gene Technology Act 2006* (WA), *Gene Technology Regulations 2001*	NHMRC Genomics resources for clinicians and researchers	Gene Technology Regulator or an IBC	NA

9. Human Research Ethics Committee and Research Governance Office review fees

WA health system entities must make HREC and RGO fees publicly available.

Fees must be charged in full for all commercially sponsored research projects, except for teletrials where sites may choose to cover all or part of the costs in-kind to encourage participation during the beginning phase of a teletrial. Where commercial sponsor charges apply, the payment must be invoiced directly to the sponsor to cover the review costs incurred by the site, irrespective of whether the research project commences.

For all non-commercial/investigator-initiated research projects, the site may choose to cover all or part of the costs in-kind.

Refer to the Research Governance Service for information on HREC review fees and RGO review fees.

9.1 Human Research Ethics Committee review fees

WA health system entities must follow the HREC fee structure detailed in Table 3.

Table 2. HREC fee structure

Service	Fee (incl. GST)
New applications that require HREC review (including submissions under NMA)	$3,850
HREC Review on behalf of each additional site	$660
Review of an Amendment (including those requesting an extension of approval)	$660
Further review of an amendment/requirement for resubmission of amendment (each occasion)	$320
Applications submitted for review by the Low and Negligible Risk (LNR) ethics review pathway	$275
Applications that require an excessive level of administrative support	$50 per query to a maximum of $500

9.2 Research Governance Office review fees

WA health system entities must follow the RGO review fee structure detailed in Table 4.

Table 2. Site authorisation fee structure

Service	Fee (incl. GST)
Review and Authorisation of new project	$3,850
Addition of a site-specific assessment form	$1100
Addition of sub-studies or extensions to approved projects	$1,925
Review of substantial amendments to approved projects	$660

10. Conflicts of interest

All conflicts of interest must be managed in line with the MP 0138/20 *Managing Conflicts of Interest Policy*.

WA health system entity staff should be aware that the above policy includes a requirement for Department of Health employees and Health Service Provider staff to record all declared conflicts of interest using the System Manager Conflicts of Interest Declaration Registry (COIR). The EO and RGO must advise staff (e.g. HREC members, investigators) about this policy requirement, where relevant. See *MP 0138/20 Managing Conflicts of Interest Policy for* further information.

10.1. Human Research Ethics Committee member conflicts of interest

The EO must produce a meeting agenda including declarations of conflicts of interest by the HREC members. These conflicts of interest must be identified and addressed according to the MP 0138/20 *Managing Conflicts of Interest Policy* and recorded in the HREC meeting minutes.

10.2. Hospital Administrator conflicts of interest

If a Hospital Administrator is both the Head of the Department in which the research project will be conducted, and an investigator, the department budget for the project must be authorised by an alternative Administrator (such as the Head of Department's line manager/Service Director).

10.3. Investigator conflicts of interest

The RGO must ensure, to the best of their knowledge, that investigators declare any actual, perceived and potential conflicts of interest using a WA Health Research Conflict of Interest Form. The RGO must review conflict of interest declarations and allegations in accordance with the MP 0138/20 *Managing Conflicts of Interest Policy* and NHMRC Identifying and managing conflicts of interest.

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. intellectual property interests, business partnerships, travel and gifts)
  or
- 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).

If the RGO identifies that a potential conflict of interest is an issue, the investigator must be alerted that they are required to either provide further information or take a course of action to manage the potential conflict. Management strategies may include:

- reporting the conflict of interest on a Conflict of Interest Register
- disclosing the conflict of interest in reports
- disclosing the conflict of interest to participants
- restricting or removing the investigators involvement in a project
- ensuring a third party who does not have a conflict of interest be involved in overseeing decisions
- the investigator relinquishing their private interest that prompted concerns about a conflict of interest
- another investigator taking on the responsibility of conducting the research

or

- in some cases, the research may not be conducted.

If requested by the investigator, the RGO must assist with identifying and addressing potential conflicts of interest, to the best of their ability and knowledge.

The research must not be authorised until the conflict of interest is addressed to the satisfaction of the CE/delegate.

11. Confidentiality

11.1. WA health system employees

All WA health system employees, including HREC members, RGO and EO staff, and WA health system investigators, are subject to the *Public Sector Management Act 1994* to keep information confidential.

11.2. Non-WA health system employees

Research project members external to the WA health system that are accessing identifiable information within the WA health system must be added as project members in the RGS and must sign a project specific Declaration of Confidentiality. This declaration is signed either when creating a new project workspace as a CPI or accepting an invitation to a research project in the RGS. All research project members must comply with the provisions of the *Privacy Act 1988*.

Additionally, the Student Research and Confidentiality Declaration must be completed by all research personnel undertaking research as part of their studies (irrespective of whether they are WA health system employees). In the RGS, the Student Research and Confidentiality Declaration must be attached as a supporting document to the site application or an amendment form if the project is in the monitoring phase. The declaration template can be found on the RGS.

11.3. Confidentiality disclosure agreements

Confidentiality Disclosure Agreements (CDAs) are legal agreements that bind one or more parties to non-disclosure of confidential information.

Where appropriate, a CDA must be signed between WA health system entities and external entities, such as a sponsor or Contract Research Organisation (CRO). The RGO must negotiate the CDA with the external entity prior to signing by the CE/delegate. The RGO may seek appropriate legal advice (e.g. from LLS) to inform these negotiations if required. Standard CDAs ensure expedited execution and are strongly encouraged. Negotiation and signing occurs outside of RGS before the WA health system entity is confirmed as a research site by the external entity. Templates can be found on the RGS.

Investigators may receive requests from external entities to personally sign a CDA relating to a proposed research project. RGOs must advise investigators that the State Solicitor's Office (SSO) recommends that WA health system employees do not sign CDAs. CDAs are legally binding agreements that can give rise to legal liability and must only be signed by the WA health system entity authorised signatory, not the individual.

12. Research agreements

Research involving WA health system employees, participants, data or biospecimens and that is undertaken in collaboration with an external entity must be the subject of a written agreement. The type of the agreement required will be dependent on the nature of the research project.

Research agreements are legally binding agreements between two or more parties that establish the respective responsibilities and obligations of the parties conducting a research project.

The type of research activity and entities party to the project will determine the type of research agreement required. Standard research agreement templates are publicly available for download on the RGS documents templates page. The RGO must assist the PI to identify the appropriate agreement to use and facilitate negotiations with the external entity regarding the research agreement. See section 20 for more information on types of research agreements for clinical trials.

The research agreement must be submitted to the RGO via the RGS at any time prior to or during submission of the site application.

The RGO must review the research agreement along with the ethically approved research protocol. Review may include direct negotiation with the external entity and referral of the research agreement to LLS. All amended versions of the research agreement must be uploaded to the RGS.

It is recommended that amendments to the standard research agreements are set out in a Special Conditions Schedule to the agreement and not in the body of the agreement. Bespoke research agreement templates, incorporating an external entity's amendments for use across the WA health system, may be established for external entities seeking to conduct research with more than one WA health system entity. This avoids the need for each WA health system entity to individually review the same external entity's amendments to the standard template. Establishment and maintenance of entity-specific research agreement templates for use across the WA health system must occur through the Research Contracts Review Working Group (RCRWG). The RCRWG is chaired by the Department of Health and includes representation from each WA health system entity.

Once the RGO has reviewed and the external entity has signed the agreement, the CE/delegate must authorise and sign the research agreement.

The RGO must ensure that all relevant research agreements are properly executed (i.e. have been signed by all parties) and current, as part of the research governance process.

13. Indemnity

Indemnity refers to an agreement by one party to another that it will cover losses incurred by the other party due to the acts of the indemnitee or any other party. The CE/delegate must ensure that WA health system entities do not assume liabilities attached to external entities. Indemnity must be mutual and specifically tailored to the risks and liabilities associated with the project.

For commercially sponsored research projects, the RGO, as part of site review, must ensure that the WA health system entity and WA health system HREC (if applicable) are indemnified by the sponsor. The details of the indemnity may be included in the research contract with the sponsor, and the indemnity form must be signed and uploaded to the RGS as a site application supporting document.

For non-commercially sponsored projects, HRECs must be indemnified by their associated WA health system entity for their decisions in reviewing research projects. Under the NMA scheme, each participating jurisdiction is required to ensure that the NMA certified HRECs within its jurisdiction are indemnified with respect to the HREC's decisions in reviewing each non-commercially sponsored project.

14. Insurance

Insurance refers to a policy taken out by the institution to cover its own risks or liabilities. The party providing indemnity must have and maintain appropriate insurance. For commercially sponsored projects, the party responsible for this is the sponsor. For non-commercially sponsored projects, the responsible party is the WA health system entity. For commercially sponsored projects, the details of the insurance must be in schedule 4 of the research agreement.

The Insurance Commission of Western Australia (ICWA) manages the WA Government's self-insurance arrangements, which incorporate the WA health system, including research activities. ICWA also provides a support service for scrutiny and advice regarding external parties' insurances. RGOs must operate under ICWA's guidelines and should seek advice from ICWA as required.

Where insurance is provided by the sponsor, an insurance certificate of currency must be submitted in the RGS as part of the site application and be reviewed by the RGO. The RGO must review the insurance certificate of currency, in consultation with ICWA if required, to ensure the insurance will meet any liabilities and does not contain relevant exclusions.

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. The RGO must also ensure that insurance policies do not prevent legal action from being heard in Australian courts. For the period of the required research liability cover, updated insurance policies must be reviewed and approved by the RGO following submission in the RGS as an amendment.

15. Intellectual Property

As part of site review, RGOs must ensure that research conducted in the WA health system complies with the Western Australian Government Intellectual Property Policy 2015 and *MP 0156/21 Intellectual Property Policy.*

Additional guidance on the ownership of Intellectual Property (IP) internal to WA health system entities and the Department of Health can be found in the Intellectual Property Procedures and the Intellectual Property Guidelines.

RGOs must ensure that research agreements 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. Collaborative research projects and those procuring services from external sources may require extra consideration.

IP questions and issues should be referred to the RGO in the first instance, then to the Department of Health IP Coordinator if required.

For further information and/or assistance from the Department of Health IP Coordinator, refer to the Department of Health Intellectual Property Management website.

16. Data and privacy

16.1. Principles

Protecting participants and the responsible handling of their information is extremely important in human research. Confidentiality and privacy processes must be implemented for all research projects conducted within the WA health system.

Every state-wide health data collection containing health information from WA health system patients must be overseen by a Data Steward and governed by a Data Custodian. Approval to access data from these collections, including linked and unlinked data, must be obtained from the relevant Data Steward. This approval is required in addition to obtaining ethical approval and site authorisation. The Data Steward may delegate the responsibility for approving access to data to a Data Custodian.

RGOs must consult the *WA health system* *Information Register* for information on the data collections held within the WA health system, including details for Data Stewards and Data Custodians.

RGOs and/or Data Stewards must ensure that the project's proposed process of collection, storage/retention, access, disclosure, use and disposal of data in research projects complies with:

- MP 0152/21 *Information Management Governance Policy*
- MP 0144/20 *Information Retention and Disposal Policy*
- MP 0015/16 *Information Access, Use and Disclosure Policy*
- MP 0145/20 *Information Storage Policy*
- MP 0146/20 *Information Classification Policy*
- MP0067/17 *Information Security Policy*
- MP 0135/20 *Information Breach Policy*
- MP 0001/16 *Information and Communications Technology (ICT) Governance Policy*
- MP 0066/17 *Acceptable Use of Information and Communications Technology Policy*
- MP 0124/19 *Code of Conduct Policy*
- *Guidelines for Human Biobanks, Genetic Research Databases and Associated Data*
- Department of Health *Data Access and Release Policy*
- State Records Office of Western Australia Recordkeeping Guidelines
- NHMRC *Management of Data and Information in Research*
- TGA *Guideline for Good Clinical Practice*
- Information technology - Code of practice for information security management
- Information technology - Security techniques - Code of practice for information security management
- Information technology - Security techniques - Information security risk management

Data Stewards must only approve access and disclosure of data in line with the above policies, and when:

- consent has been provided by the participant for their data to be used for research purposes;
- the empowering legislation governing the relevant data collection(s) allows for participant information to be released for a specific research project in absence of participant consent; or
- if the information being requested is non-personal health information and the disclosure of information in absence of consent is not prohibited by legislation.

16.2. Types of information

Information that is accessed, used or disclosed for the purposes of research is defined according to MP0015/16 *Information Access, Use and Disclosure Policy*. The different types of information described in the policy are:

- non-personal information
- personal information (noting this has the same meaning given in the *Freedom of Information Act 1992*)
- reasonably identifiable information
- sensitive information.

Sensitivity of information must be determined in line with MP0146/20 *Information Classification Policy*, which provides a consistent approach across the WA health system for the classification of information assets by outlining the minimum requirements and responsibilities of WA health system entities.

The level of risk associated with the proposed type of information to be collected, analysed, and stored, and the security measures in place to mitigate this risk, must be assessed by the HREC as part of the ethical review.

The RGO must consider relevant legislative and policy requirements when conducting site review of research involving the disclosure of information. This includes, but is not limited to, requirements under the *Health Services Act 2016*, *Health Services (Information) Regulations 2017* and MP0015/16 *Information Access, Use and Disclosure Policy 2019*. It is particularly important to consider if an individual's consent is required to disclose the information, as this is dependent on the type of information that is being disclosed (section 17). The Data Stewards of the relevant datasets are responsible for determining the type of information being disclosed.

16.3. Department of Health Data Collections and Data Linkage

Data Steward approval for access to data held within the Department of Health's Data Collections, including linked data, must be coordinated through the Department of Health Research Data Services (DoH RDS) team. The WA health system Information Register (intranet link) should be consulted to determine if a data collection is held by the Department of Health. Requests to EOs or RGOs from researchers for information relating to the Data Steward approval process must be directed to the DoH RDS team and/or the Data Linkage WA website.

Research projects that propose the use of health information from one or more of the Department of Health's Data Collections must:

- receive a feasibility letter from the Research Data Services team or relevant Data Steward/s
- be reviewed and approved by the Department of Health HREC
  - review and approval cannot occur until a feasibility letter is supplied
- receive approval from the relevant Data Steward/s
  - Data Steward approval cannot occur until a Department of Health HREC approval letter is supplied.
- undergo site specific assessment through the Department of Health RGO
- be granted site authorisation by the DG (or delegate)
- be monitored by the Department of Health HREC and RGO throughout the life of the project through Amendments, Progress Reports, Safety Reports and the Final Report (section 22).

The WA Health HREC and RGO(s) must be notified of the following details when the destruction of information from the Department of Health Data collections is complete:

- RGS Project Reference Number
- the title of the project/information
- when the information was destroyed
- how the information was destroyed
- who destroyed information
- who approved the destruction.

16.4. Information security, retention and disposal

For all research projects, the RGO must ensure through initial review and subsequent monitoring that investigators take reasonable steps to ensure information is:

- protected against theft, loss and unauthorised access, use and disclosure
- protected against unauthorised copying and modification
- retained, transferred and disposed of in a secure manner as per MP 0145/20 *Information Storage Policy*
- managed in line with MP 0067/17 *Information Security Policy*.

For all projects involving WA health system information, the RGO must ensure as part of site review, that there is an adequate plan to manage and dispose of the data, including a data security plan addressing the protection of identity, physical and technological security, and transport.

RGOs must confirm, through site review and subsequent monitoring, that investigators are ensuring that information is retained and managed in accordance with MP 0145/20 *Information Storage Policy* and MP 0144/20 *Information Retention and Disposal Policy*.

For research projects involving information from a Department of Health Data Collection, the Data Steward must ensure an adequate retention and disposal plan is detailed in the Application for Data and the research protocol.

16.5. Information breaches

Breaches and suspected breaches of the approved use of information must be reported by the person who identified the breach and/or the Data Custodian (if applicable) using an Information Breach Notification Form to notify the line manager or other appropriate contact, as per the relevant WA health system entity procedures, and the Data Steward/s if appropriate. The breach must then be managed according to MP 0135/20 *Information Breach Policy* and any other relevant reporting requirements as per the WA health system entity's Procedures.

If the information breach is also identified as an adverse event, the breach must also be handled as per section 24.1.1 with the generation of a safety report and notification of the HREC and RGO.

17. Consent

17.1. Informed consent

Informed consent must be obtained from research participants, or their legal guardian/decision maker as appropriate, for their participation in research including the use of their data or biospecimens. Under certain circumstances, alternatives to informed consent (i.e. a waiver of consent or the opt-out approach) may be justified if all ethical, policy and legislative requirements are met.

HRECs and RGOs must check that the secondary use of biospecimens or data for research purposes is covered by the original informed consent provided by participants, or that it fulfils the requirements for alternatives to informed consent. If informed consent is required but has not been obtained under the original consent form, HRECs and RGOs must ensure there is an approved process for new consent to be obtained from participants.

HRECs must ensure that the ethical requirements for consent are met for all research projects, as per the National Statement. This includes reviewing all materials used in recruiting potential research participants (such as the master PICF) and ensuring that all requirements for alternatives to informed consent are met (if applicable).

RGOs must ensure that site-specific requirements for consent are met, including reviewing the master PICF against site-specific PICFs (section 8.3.3). RGOs are also responsible for ensuring that relevant policies and legislation are adhered to.

HRECs and RGOs must be aware of the specific legal requirements for consent under the *Health Services Act 2016* that apply to the disclosure of personal information for research purposes. If no personal information is involved, then no legal requirement for consent applies (refer to section 16.2 regarding types of information).

RGOs and HRECs must familiarise themselves with special considerations and/or additional requirements for consent that apply to certain types of research projects. This includes any additional requirements set out in the National Statement, site-specific policies and relevant legislation. Refer to sections 16 and 19 for special considerations relating to research projects involving biobanks and the use of participant/patient data. If a waiver of consent or the use of the opt-out approach is granted by an HREC, the RGO must also ensure that the research satisfies all legislative requirements for consent that may apply to the information being used for research. Some of the specific legislative requirements relating to waiver of consent/opt-out approach are described below (section 17.2).

It should be noted that the National Statement provides ethical guidance on obtaining consent for research, whereas relevant legislation (such as the *Health Services Act 2016*) sets out legal obligations relating to confidentiality and the circumstances under which information can be disclosed. HRECs and RGOs must consider that research that satisfies the ethical considerations of the National Statement may not always satisfy legal obligations. This is particularly important for RGOs when reviewing research that has been approved by a non-WA HREC via the NMA scheme (section 4.2), as state-specific legislative requirements differ.

17.2. Waiver of consent

The National Statement provides that an HREC may grant a waiver of consent for research if, along with other conditions, it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records).

The *Health Services Act 2016* allows the disclosure of information for the purpose of research in according with the *Health Services (Information) Regulations 2017*. Regulation 3(2) of the

Information Regulations states, among other things, that consent must be obtained for the disclosure of personal information for research purposes, unless it is impracticable to obtain the consent of the individual to whom the information relates.

The threshold for being “impracticable” to obtain consent is relatively high, Notably, the term “impracticable” is not synonymous with “difficult” or “undesirable”. It means that something more than expenditure of reasonable resources or effort must be demonstrated. For example, if the contact details of the potential research participants are known, then the cost and difficulty of obtaining consent may not satisfy the “impracticable” threshold. Whether the legislation permits the disclosure of personal information without consent must be determined on a case-by-case basis. Depending on the complexity of the research project in relation to the legislation, RGOs may obtain legal advice specific to the research project as part of site-specific authorisation review.

HRECs must consider these above requirements when ethically reviewing research projects involving waivers of consent and must record the waiver of consent as a special condition of approval on the HREC approval letter.

17.3. Opt-out approach

As per the National Statement, the opt-out approach is a method used in the recruitment of participants into research where information is provided to the potential participant regarding the research and their involvement, and where their participation is presumed unless they take action to decline participation.

While an opt-out approach makes it possible for people to make an informed choice about their participation, this choice can only be made if participants receive and read the information provided, and they understand that they are able to act on this information to decline to participate.

The National Statement provides that an opt-out approach to participant recruitment may be ethically appropriate when it is feasible to contact the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible. However, the use of an opt-out approach carries with it a significant risk, because there cannot be certainty of why a participant has not objected to the proposed disclosure of their personal information.

The use of an opt-out approach does not satisfy the legal requirements set out by the *Health Services Act 2016* for consent to the disclosure of personal information. Therefore, HRECs and RGOs must ensure that the legal requirements for a waiver of consent (section 17.2) are also applied to research utilising an opt-out approach.

If an opt-out approach is approved by the HREC, this must be recorded as a special condition of approval on the HREC approval letter.

18. Participant groups requiring additional consideration during ethical and site review

Special consideration must be given in terms of research project design, consent process and risk mitigation as per the National Statement for participant groups including:

- women who are pregnant and the human fetus
- children and young people
- people in dependent or unequal relationships
- people highly dependent on medical care who may be unable to give consent
- people with a cognitive impairment, an intellectual disability, or a mental illness
- people who may be involved in illegal activities
- aboriginal peoples
- people in other countries.

HRECs must ensure, as part of ethical review, that the appropriate risk mitigation mechanisms and special considerations are detailed in the ethics application for projects involving the participant groups mentioned above.

RGOs must ensure that the relevant legislation and guidance has been considered by the HREC and that the project complies with state-specific legislation and guidance.

18.1. Children and young people

Regarding research projects involving children and/or young people, the HREC must ensure that all aspects of the recruitment and participation by children and/or young people is consistent with the National Statement Chapter 4 and fully documented in the protocol.

The RGO must ensure that:

- all investigators with direct contact with participants under 18 years of age (*Age of Majority Act 1972*) have or obtain a WA Government "Working with Children Check" (*Working with Children (Criminal Record Checking) Act 2004*)
- the process of recruitment and consent of minors detailed in the protocol is consistent with MP 0175/22 *Consent to Treatment Policy*, the National Statement chapter 4.2 and the *Children and Community Services Act 2004*
- the protocol accounts for how the consent of a young person is to be re-established to continue/resume their participation in the research once the young person has reached the age of 18 years (if applicable).

The composition of the Lead HREC, or the scientific advisory panel to the Lead 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, several paediatricians may be required, representing the major subspecialties.

18.2. Adults who lack the capacity to give consent

Part E – Medical Research of the *Guardianship and Administration Act 1990* prescribes how the recruitment of adults who lack the capacity to give consent into research may occur.

HRECs must ensure that all health and medical research involving the participation of adults who lack the capacity to provide consent is compliant with the Department of Health Involving

Incapacitated Adults in Health and Medical Research Guidance Document. RGOs must ensure that proposed processes to enrol patients who lack capacity to provide consent at the site are in line with both the Guardianship and Administration Act (Part 9E) and any specific conditions applied by the HREC.

18.3. Aboriginal Peoples

Research involving Aboriginal Peoples must be informed by and abide by the National Statement, the NHMRC *Ethical conduct in research with Aboriginal people and communities: Guidelines for researchers and stakeholders* and the NHMRC *Keeping Research on Track II*.

In addition to Lead HREC approval, approval from the WAAHEC is required when research projects involve research in, or in relation to, Western Australia and the following applies:

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

The WAAHEC undertakes review of research applications that are related to the health and well-being of Aboriginal and Torres Strait Islander people. The definition of health for this purpose is as defined by the National Aboriginal Community Controlled Health Organisation:

“Aboriginal health” means not just the physical well-being of an individual but refers to the social, emotional and cultural well-being of the whole Community in which each individual is able to achieve their full potential as a human being thereby bringing about the total well-being of their Community. It is a whole of life view and includes the cyclical concept of life-death-life.

More information on WAAHEC may be found on the Aboriginal Health Council of Western Australia (AHCWA) website.

19. Biobanks

HRECs and RGOs must ensure that all research projects involving biospecimens and/or data from biobanks follow the National Statement, the NHMRC *Biobanks Information Paper* and the Guidelines for human biobanks, genetic research databases and associated data (Biobank Guidelines). The Biobank Guidelines are currently under review to produce updated guidelines. In the interim, in the absence of updated guidelines, the Biobank Guidelines must be consulted.

When reviewing research that involves the establishment of a biobank, or the donation of biospecimens or data to a biobank, HRECs and RGOs must ensure that:

- the biobank has a clearly articulated current and future purpose(s), focus and proposal for operation
- approval to access biospecimens or data from the biobank is governed by a Biobank Custodian, and that any relevant approvals have been obtained
- an appropriate governance structure is in place for the biobank prior to its establishment, including the nomination of the Biobank Custodian
- requirements for informed consent have been met for the collection, storage, access and use of biospecimens and/or data for research purposes (section 16).
- any ownership rights (legal or ethical) that apply to the biospecimens or data in the biobank are considered during HREC and/or RGO review
- there is an established plan for closing the biobank if it no longer meets a need or encounters an unforeseen demise (e.g. end of funding), including a disposal plan for biospecimens and data (section 16.4).

20. Clinical trial specific requirements

The Australian Clinical Trials website defines clinical trials as research investigations in which people volunteer to test new treatments, interventions or tests as a means to prevent, detect, treat or manage various diseases or medical conditions. The conduct of clinical trials within the WA health system requires specific approvals and the use of specific research agreements.

20.1. Clinical Trial/Investigation Research Agreements

Externally sponsored clinical trials must be subject to either a Clinical Trial Research Agreement (CTRA) or Clinical Investigation Research Agreement (CIRA). Templates for these research agreements may be found on the RGS.

CTRAs must be used for clinical trials involving the use of medicine products, biotherapeutic products and vaccines. CIRAs must be used for clinical trials involving the use of non-pharmaceutical medical technologies.

Standard templates for CTRAs and CIRAs are based on templates from Medicines Australia (CTRA) and the Medical Technology Association of Australia (CIRA); the use of other templates may incur significant delays and additional costs. These standard templates must be used when conducting clinical trials within the WA health system.

See section 12 for more information on research agreements.

20.2. Therapeutic Goods Administration Approval/Notification

The Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods in Australia. Products for which therapeutic claims are made must be entered into the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia.

Clinical trials involving the use of any medicine, biological or device not entered in the ARTG, or the use of a marketed medicine, biological or device beyond the conditions of its marketing approval, must comply with the guidance in the TGA's *Australian Clinical Trial Handbook*. Clinical trials using unapproved therapeutic goods must occur under the Clinical Trial Approval (CTA) scheme (previously Clinical Trial Exemption scheme) or Clinical Trial Notification (CTN) scheme.

The choice of which scheme to use (CTN or CTA) lies firstly with the trial sponsor and then with the Lead HREC (except for certain Class 4 biologicals, which must be approved under the CTA scheme). For more information on which scheme a project may come under, see the *Australian Clinical Trial Handbook* or contact the TGA.

The RGO must ensure a CTN/CTA is in place by confirming that a CTN/CTA reference number has been provided for the research project. If this not available at the time of initial site review, the RGO must ensure that a CTN/CTA is in place by the time of the first progress report and update the project details in the RGS accordingly.

The trial sponsor is responsible for correspondence with the TGA, as per the Australian Clinical Trial Handbook. Where the WA health system entity is the sponsor, these responsibilities may be delegated back to the investigators.

20.3. Registration of clinical trials

The International Committee of Medical Journal Editors (ICMJE) member journals require registration in a public trials registry, such as the Australian New Zealand Clinical Trials Registry or ClinicalTrials.gov, as a condition of consideration for publication. This is required prior to

recruitment commencing. For more information on criteria for registration, see the ICMJE website.

21. Withdrawal prior to ethical approval or site authorization

The HREC must allow the CPI to withdraw an ethics application that has already been submitted at any time prior to approval.

The RGO must allow the PI to withdraw a site application that has already been submitted at any time prior to site authorisation.

The HREC/RGO must be notified via email or a letter in the RGS that withdrawal is intended or that the application has been withdrawn, with the reason for the withdrawal detailed. The HREC/RGO must then mark the application as withdrawn on the RGS.

If the review cost has already been invoiced, this cost is not refunded if the project is withdrawn.

22. Addition of site to approved research project

When a new site is added to an approved project, the HREC(s) must receive an amendment including the details of the PI of the new site from the CPI. The HREC(s) must review this information and other relevant details to ensure compliance with the National Statement.

If approved, the HREC(s) must issue an approval for the research project listing the new site to the CPI.

If the new site is within the WA health system, the RGO of the new site must receive the appropriate site authorisation form and other relevant documents from the site PI via the RGS. The RGO must validate and review the site application as per section 8. The project may only commence at the new site once site authorisation has been obtained from the site CE/delegate and an authorisation letter has been received.

22.1. Single-site to multi-site project

If a single-site research project has been approved by an HREC through either WA Health Single Ethical Review or National Mutual Acceptance (section 4), then additional sites can be added to the existing ethical approval with agreement of the Lead HREC considering:

- If the project was originally approved by a WA health system HREC, then additional WA health system sites can be added to the existing approval in accordance with the WA Health Single Ethical Review process and the WA health system HREC's expertise.
- If the project was originally approved by an HREC certified under the NMA scheme, then additional sites can be added to the existing approval in accordance with the National Mutual Acceptance scheme.

The EO must help to determine if the addition of the site(s) is feasible based on factors including the HREC's NMA certification status (e.g. to ensure that the HREC has the authority to review research for interstate sites) and expertise.

22.2. Addition of a site to a multi-site project

Additional sites may be added to an existing HREC approval for multi-site projects via an amendment in the RGS.

Sites that gain ethical approval from an HREC must be required to comply with the special conditions of approval, and the ongoing monitoring and reporting requirements of the HREC.

23. Complaint management

These procedures relate to complaints concerning the following processes:

- the conduct of a research project
- the HREC review process
- the RGO review process.

All other complaints must be handled internally as per each WA health system entity's procedures.

Complaints relevant to these processes must be submitted and handled through the RGS using the Complaint Form and managed in line with the NHMRC's National Statement, in addition to any other appropriate action as per the WA health system entity's internal procedures. Complaints from external parties, notably research participants, must be accepted by the HREC, site contact person or other entity by whatever means are suitable for the complainant (e.g. phone, email).

Complaints from research participants must be handled as per MP 0130/20 *Complaints Management Policy*. Complaints from WA health system entity employees must be handled as per the MP 0116/19 *Grievance Resolution Policy*. All WA health system entities must have comprehensive complaint management procedures in place.

Complaints involving allegations of misconduct by WA health system employees must be managed in accordance with MP 0125/19 *Notifiable and Reportable Conduct Policy* and MP 0127/20 *Discipline Policy*.

Table 5. Complaint management procedure for complaints about the conduct of the project, HREC review process and RGO review process.

Type of Complaint	Submission of the Complaint	Acknowledgement to Complainant	Resolution of the Complaint	Notification of Resolution	Potential for Escalation
Complaints About the Conduct of the Project	The complaint must be submitted, directly or via the EO or RGO, through the RGS to the site contact person for site specific or HREC for ethical issues	The HREC/site contact person must acknowledge the complaint and notify the CPI/PI	The HREC and/or site contact person must investigate and resolve the complaint according to the WA health system entity policy	The HREC and/or site contact person must notify the complainant and the CPI/PI of the resolution of the complaint	If the complainant is not satisfied with the outcome, the matter may be referred to the CE/delegate for further investigation
Complaints About the HREC's Review Process	The complaint must be submitted to the CPI, who must submit the complaint via the RGS to the HREC Chair	The EO must acknowledge the complaint	The HREC Chair must investigate and recommend a resolution to the HREC, who must enact the resolution	The EO must notify the CPI of the resolution of the complaint	If the CPI is not satisfied with the outcome, the matter may be referred to the CE/delegate for further investigation

Complaints About the RGO's Review Process	The complaint must be submitted to the PI, who must submit the complaint via the RGS to the site contact person	The site contact person must acknowledge the complaint	The site contact person must notify the CE/delegate of the complaint. The CE/delegate must delegate investigation of the complaint	The site contact person must notify the PI of the resolution of the compliant	If the PI is not satisfied with the outcome, the matter may be referred to the CE/delegate for further investigation

Investigations must be managed within the timeframe set out in the MP 0130/20 *Complaints Management Policy*. Additional information may be requested from the complainant if required.

The outcome of the investigation must be recorded by the HREC and/or site contact person as appropriate, in a de-identified manner in the RGS. If the complainant is not satisfied with the outcome of the investigation, the complaint may be referred to the WA health system entity's CE/delegate to determine whether there is to be a further investigation. The WA health system entity complaints policy must clearly define a transparent escalation process and responsible officers, as well as a process for seeking independent review if required.

If a PICF is used in the project, the HREC and RGO must ensure, as part of ethical review and site review, that it contains contact details for submitting complaints concerning matters relating to the site (site contact person) and matters relating to an aspect of the research or the conduct of the research project (HREC).

24. Project monitoring

All approved and authorised research projects must be monitored by the Lead HREC, Specialist HREC (if applicable) and RGO(s) throughout the lifetime of the project, in line with the National Statement and the *Australian Code for the Responsible Conduct of Research*. Monitoring ensures that research complies with the approved/authorised protocol and the special conditions of approval/authorisation, and that changes to project protocol only occur with prior approval of the HREC and authorisation by the site. Monitoring must occur via the receipt of safety reports, amendments and progress reports from the CPI and PI via the RGS. On-site monitoring and audits may also be used by the site, HREC or sponsor to further monitor the project.

The HREC and RGO(s) must ensure that research projects involving therapeutic goods, including implantable medical devices, are aware of the monitoring standards set out by the TGA and the NHMRC *Safety monitoring and reporting in clinical trials involving therapeutic goods*.

WA health system entities may implement mechanisms to enforce consequences for investigators who do not comply with the reporting requirements, such as suspending active projects or withholding site authorisation for future projects until notification/reporting obligations are met. WA health system entities must provide investigators with clear guidance on project monitoring requirements and inform them of the potential consequences of non-compliance.

More information on the submission of final reports can be found in section 25.

24.1. Safety reports

A safety report must be received by the RGO(s) and EO of the Lead and Specialist (if applicable) HREC via the RGS when a Serious Adverse Event (SAE) occurs, as per the NHMRC *Safety monitoring and reporting in clinical trials involving therapeutic goods*. If the project involves an intervention, an annual safety report must be submitted, independent of whether any SAE has occurred.

24.1.1. Serious adverse events

The management and documentation of Adverse Events (AEs) is the responsibility of the sponsor, as per the NHMRC *Safety monitoring and reporting in clinical trials involving therapeutic goods*. The HREC and the site must receive a safety report from the sponsor, via the CPI and PI respectively, when a SAE occurs.

When a safety report is received:

- If urgent, the EO must forward the report to the HREC chair or delegated HREC safety reviewers and any other relevant HREC members
- the EO must assign the report to be tabled at the next HREC meeting
- the HREC must review or note the report
- the EO must notify the CPI of the outcome of the HREC review, if relevant
- the relevant RGO(s) must review the report and recommend a course of action to the CE
- the CE/delegate must decide on the appropriate course of action
- the RGO(s) must notify the PI of the course of action to be taken.

The order of these items depends on the origin of the safety report and the location of the HREC.

Review of a safety report may include the following actions by the HREC Chair/delegate and/or the RGO:

- acknowledging receipt of report
- noting of the event
- referral to an HREC subcommittee for advice
- immediate request for additional information
- immediate suspension of ethical approval and/or site authorisation
- immediate discontinuation of ethical approval and/or site authorisation or
- other action as recommended by the HREC or CE/delegate.

If additional information is required, the CPI/PI is required to amend and resubmit the report.

Where the HREC or RGO considers that the project requires immediate suspension or discontinuation of the ethical approval and/or site authorisation, the HREC/RGO must immediately notify the CPI/PI and sponsor, followed by notification via the RGS.

24.1.2. Annual safety report

For all research projects involving more than low risk and involving the use of a protocol mandated intervention, the following must be provided at least annually to the HREC and RGO(s):

- Annual safety report including sponsor comments detailing any planned actions based on the reports.
- Current approved product information (e.g. Investigator's Brochure), if appropriate.
- Executive summary from the Data Safety Monitoring Board (DSMB) or equivalent if appropriate.
- Any other reports consistent with TGA Good Clinical Practice Guidelines.

Review of annual safety reports must follow the process in SOP 24.1.1.

24.1.3. Data Safety Monitoring Boards

As part of ethical review, HRECs must ensure that research projects involving an intervention have a Data Safety Monitoring Board (DSMB) or equivalent, as per the National Statement and NHRMC *Data Safety Monitoring Boards (DSMBs)*. The DSMB/equivalent's function and responsibilities must be described in the project protocol.

A DSMB/equivalent executive summary must be submitted to the HREC as part of the annual safety report.

24.2. Amendments

Changes to a project's protocol must be approved by the HREC and authorised by the site via an amendment form in the RGS, prior to being implemented. Exceptions to this are changes that only involve administrative aspects of the project and changes that are required to eliminate hazards to participants.

Amendments to the conduct of the project that have potential ethical or scientific implications must be submitted as an Amendment Form which is first submitted to the HREC, and when approved, submitted to the RGO(s).

Amendments to the conduct/administration of the project that have potential site implications, including budgetary changes, but no ethical or scientific implications, must be submitted using a Governance Only Amendment Form to the RGO(s) for review.

Amendments that are submitted to the HREC and/or RGO(s) must be reviewed and the investigator(s) must be notified of the outcome after the HREC meeting or site review. The RGO must review then recommend the amendment for authorisation by the CE/delegate.

The outcome of the review may be approved/authorised or additional information required. The outcome of the review must be sent to the CPI/PI via the RGS. Approved/authorised amendments may be implemented. If additional information is required, a revised Amendment Form must be submitted.

24.3. Progress reports

Progress reports must be submitted to the HREC and RGO(s) via the RGS at least annually or more frequently, as per the site-specific authorisation and ethical approval conditions. Continuation of ethical approval and site authorisation must be contingent upon the receipt of progress reports.

Progress reports must be reviewed by the HREC and RGO(s), and either approved, marked as additional information required or not approved. Site approval must be provided by the CE/delegate after review by the RGO. The outcome of the review must be sent to the CPI/PI via the RGS. If additional information is required, an amended progress report must be resubmitted by the CPI/PI for review by the HREC and/or RGO(s). If the progress report is not approved, the reason why and the actions required must be communicated to the CPI/PI.

24.4. Audit

Auditing may be used as a form of monitoring by sites, HRECs, sponsors and regulatory bodies. Sites and HRECs may develop audit programs that are tailored to specific needs and that operate within the constraints of available resources.

For projects using data from the Department of Health Data Collections, the Department of Health may request an audit or inspection of the security arrangements outlined in the security plan of the data agreement.

If a project is selected for auditing, the person conducting the audit must provide sufficient notice to the PI and ensure the audit conducted with transparency and with the ability to provide additional information. If the report identifies serious breaches of the protocol or Good Clinical Practice, the report must be supplied to the approving HREC and site by the CPI.

24.5. Suspension of a project

Research projects may be suspended by the sponsor, CPI, HREC or site CE/delegate for any reason, including issues that are identified as part of the monitoring processes described in section 24.

If the HREC or site CE/delegate suspends the project, this decision and reasons for this decision must be communicated to investigators and other relevant parties, along with any recommended actions or conditions required to reactivate the project.

If the CPI suspends the project, this decision must be communicated to the HREC and RGO(s) via an amendment or safety report, depending on the circumstances of suspension.

After the period of suspension, the project may either be reactivated or closed (section 25).

25. Closure of the project

25.1. Early termination of an authorised project

The HREC(s) and RGO(s) must be notified when a research project is:

- prematurely terminated - commenced at the site but terminated on ethical, safety, financial or other grounds
- suspended - commenced at the site but temporarily stopped for any reason
  or
- completed ahead of schedule.

Notification and reason of termination must be submitted as a final report to the HREC(s) by the CPI and the RGO by the PI at each site. Wherever possible, the PI must notify research participants if the research project is to be discontinued before the expected date of completion and discuss their ongoing management or care, if applicable. Unless terminated for an urgent safety reason, any written information provided to the participants regarding the early termination of the trial must have HREC approval.

Any project that is terminated early must submit the site final report to both the HREC and the RGO. Submission of the site final report must only occur after the ongoing management of the participants has been approved by the HREC and RGO, if applicable.

25.2. Completion of a project

Before a research project site may be closed, the PI must notify the RGO via a Site Final Report in the RGS. The HREC must also be notified of the closure of a site but is only required to acknowledge the report rather than review it.

When a research project is closed at all sites under the HREC's approval, the CPI must notify the HREC via a Project Final Report in the RGS.

The RGO/EO must validate, review and authorise/approve the Site/Project Final Report before the project is marked as closed in the RGS. Site authorisation is given by the CE/delegate after review by the RGO.

The CPI should be encouraged to log publications and other outputs, including a description of how the project findings have translated into routine practice, into the Publications section of the RGS project workspace.

Definitions

Term	Definition
Aboriginal	The use of the term “Aboriginal” within this document refers to both Aboriginal and Torres Strait Islander people.
Access Request (AR)	A shorter type of site application for accessing participants, data or biospecimens from a site when research activities are not occurring on-site.
Additional Information Required (AIR)	Forms or documents may be marked as AIR at either the validation or review stage indicating that more information is required from the investigator to complete the review.
Adverse Event (AE)	Any untoward medical occurrence in a participant administered a medicinal product that does not necessarily have a causal relationship with the treatment.
Australian Code for the Responsible Conduct of Research (The Code)	A principles-based document that articulates the broad principles and responsibilities that underpin the conduct of Australian research.
Australian Register of Therapeutic Goods (ARTG)	A register maintained by the Therapeutic Goods Administration listing what therapeutic goods can be lawfully supplied in Australia.
Business Manager	A person responsible for providing financial information and advice on financial management information systems, implications and risks of current and projected services, and future financial management strategy, for a Department, Division, Site or Region within a WA health system entity.
Chief Executive (CE)	As defined in the *Health Services Act 2016*. A Chief Executive of a health service provider is the chief employee of the health service provider for the purposes of the *Public Sector Management Act 1994.* The CE is responsible for providing authorisation for a research project to commence at their site. For the *Research Governance Policy* and *Research Governance Procedures*, the roles and responsibilities of the Chief Executive at a health service provider apply to the Assistant Director General at the Department of Health.
Clinical Investigation Research Agreement (CIRA)	A written agreement between two or more parties, which sets out the responsibilities of each party. The WA health system uses a standard CIRA based on the Medical Technology Association of Australia version that contains common, standard provisions to reduce the need for institutions to obtain extensive legal advice in negotiating a CIRA.
Clinical Trial	As defined by Australian Clinical Trials. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
Clinical Trial Approval (CTA) Form	A form used to submit an application to the TGA under the Clinical Trial Approval scheme.
Clinical Trial Notification (CTN) Form	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 therapeutic goods that are not registered in the ARTG.

Clinical Trial Research Agreement (CTRA)	A written agreement between two or more parties, which sets out the responsibilities of each party. The WA health system uses a set of standard CTRAs based on the Medicines Australia versions that contain common, standard provisions to reduce the need for institutions to obtain extensive legal advice in negotiating a CTRA.
Commercial Research Project	A research project that is funded and sponsored by a commercial company, where the company designs the protocol and owns the results and intellectual property rights arising from the project.
Confidentiality Disclosure Agreement (CDA)	A written agreement between two or more parties that 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. The WA health system uses a standard CDA to be used by institutions.
Contract Research Organisation (CRO)	A person or an organisation (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's research-related duties and 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.
Data Custodian	The person responsible for the ongoing development, data collection, maintenance and review of data collection/s. They are responsible for the quality of the data, its security, timeliness and adherence to standards. Data Custodians may often be delegated responsibilities of the Data Steward regarding the access, use and disclosure of data from a data collection.
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 the WA health system's strategic goals. They authorise the access, use and disclosure of data from the data collection for purposes that comply with the WA health system's statutory obligations.
Department of Health	The system manager for the WA health system established under the *Health Services Act 2016* for providing stewardship, guidance and support to health services using a collection of binding Policy Frameworks.
Department of Health Research Data Services (DoH RDS)	The team responsible for managing the data delivery pipeline from the DoH Data Collections, from assisting with project design, through to data delivery.
Ethics	As defined in the National Statement (Section 1).
Ethics Office (EO)	The ethics office's role is to provide administrative support to the HREC and answer queries about scientific and ethical review. The EO encompasses any ethics administrative staff.

Head of Research Department (HoD)	The head employee within an organisation where the research project will be conducted i.e. the department which is spearheading the project at a site. The HoD is responsible for reviewing the project's feasibility to be conducted within their department based on the resources, services, costs and funding outlined in the budget. The HoD is not responsible for any administrative support for the project.
Head of Supporting Department (HoSD)	A person that is the Head of a Supporting Department within an organisation where the project will be conducted i.e. the department which is providing resources or services to support the project. The HoSD is responsible for providing information and estimated costs in the budget, for their department to provide resources and/or services required for the conduct of the project.
Human Research Ethics Application (HREA)	A standardised ethics application for submitting to HRECs through the NMA scheme, completed on the HREA website.
Human Research Ethics Committee (HREC)	A committee constituted under the guidance of the National Statement and registered with the NHMRC to conduct the ethical and scientific review of a human research project.
Independent Hospital Pricing Authority (IHPA)	An independent agency established under Commonwealth legislation as part of the National Health Reform Act 2011 that provides advice in relation to funding for public hospitals.
Institutional Biosafety Committee (IBC)	A committee that oversees the proper acquisition, production, transport, handling, use, storage, disposal, record-keeping and reporting requirements needed to undertake research involving genetically modified organisms, or biohazardous organisms or substances at the WA health system entity.
Intervention	As per the National Statement: an intentional change in the circumstances of research participants. The aim of interventional research is to evaluate the impact of that change on one or more outcome measures. The intervention can be a health-related procedure or process or a behavioural, educational or social modification. It can involve a policy change, a therapeutic strategy, a change in service provision or an approach to provision of information that is introduced and manipulated, controlled or directed by the researcher.
Insurance Commission of WA (ICWA)	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.
Intellectual Property (IP)	The tangible representation of intellect and creativity that has value and is protectable by law.
International Committee of Medical Journal Editors (ICMJE)	A small group of general medical journal editors and representatives of selected related organizations that works together to improve the quality of medical science and its reporting.
Lead HREC	The Lead HREC is the HREC primarily responsible for the ethical and scientific review of a research project, and its subsequent monitoring.
Legal & Legislative Services (LLS)	A Directorate within the Department of Health, responsible for providing legal services to WA health system entities.
Low and Negligible Risk (LNR) research	As defined in the National Statement (section 2).
Medical Technology Association of Australia	The national association representing companies in the medical technology industry.
Medicines Australia	The national association that represents companies in the pharmaceutical industry.

Multi-Centre Research	Research that is conducted at more than one site within the authority of the Lead HREC.
National Health and Medical Research Council (NHMRC)	A statutory authority and the primary agency of the Australian Government responsible for medical and public health research.
National Mutual Acceptance (NMA)	The National Mutual Acceptance scheme allows the mutual acceptance of scientific and ethical review of multi-centre human research projects across participating jurisdictions.
National Statement on Ethical Conduct in Human Research (National Statement)	The National Statement on Ethical Conduct in Human Research is the major guidance document in ethical review developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. Compliance with the National Statement is a prerequisite for receiving NHMRC funding.
NHMRC Certified HREC	An 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.
Non-Commercial Research Project	A research project where a non-commercial (not for profit) organisation retains control of the protocol and is the sponsor. Non-commercial projects are usually publicly funded (e.g. by government/charities) but may also be partially funded/supported by a commercial company.
Participant Information and Consent Form (PICF)	A document providing information and the ability to provide consent for participants involved with a research project.
Personal Information	As per the Privacy Act 1988: Information or an opinion about an identified individual, or an individual who is reasonably identifiable: a) whether the information or opinion is true or not; and b) whether the information or opinion is recorded in a material form or not.
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 Assurance (QA)	A project designed to measure compliance against established standards to ensure these aims are being met.
Quality Improvement (QI)	A project designed to define optimum service delivery 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*.
Research Agreement	A legally binding agreement between two or more parties that establish the respective responsibilities and obligations of the parties conducting a research project.
Research Contracts Review Working Group (RCRWG)	A group formed to develop and implement a consistent approach to the legal review of research contracts, to allow for an effective and timely review process for external sponsors pursuing research in the WA health system.
Research Governance	The framework through which the WA health system 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 Office (RGO)	The research governance office is responsible for the site specific review of research projects. The RGO encompasses Research Governance officers and/or any other staff that a WA health system entity see fit, such as Site Specific Assessment Officers
Research Governance Service (RGS)	A centralised IT system for investigators, project members, sponsors, site administrators, Human Research Ethics Committees and Research Governance Offices. It enables the completion, submission, administration, tracking and reporting of research projects through their life cycle, including ethics approval, site authorisation, monitoring and publication.
Serious Adverse Event (SAE)/Serious Adverse Reaction (SAR)	Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
Serious Breach	A breach of the protocol or Good Clinical Practice (GCP) that is likely to affect to a significant degree: • the safety or rights of a participant or • the reliability and robustness of the data generated in the project.
Significant Safety Issue (SSI)	A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the trial. Often SSIs do not fall within the definition of a Suspected Unexpected Serious Adverse Reaction (SUSAR), thus are not reported as SUSARs but require other action such as the reporting of an urgent safety measure (USM), an amendment, a temporary halt or early termination of a trial.
Single-Centre Research	Research that is conducted at only a single site within the WA health system or at two or more sites under the authority of a single WA healthy system entity HREC.
Site	A facility, location or service within the WA health system: • where the research is being conducted • that resources, conducts and manages the research.
Site Authorisation	The authorisation granted by the Chief Executive or delegate of the health system entity for the commencement of a research project at the site.
Site review	The review process of the site application and associated documents undertaken by the RGO prior to recommendation for site authorisation by the CE.
Site-Specific Assessment (SSA)	A mechanism used by the WA health system 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.
Specialist HREC	Specialist HRECs have expertise in certain fields that general HRECs do not have expertise in and cannot review for. Specialist HREC ethical approval may be required in addition to or instead of the Lead HREC ethical approval. Where only specialist HREC review is required, as in the case of projects only using data from the

	Department of Health Data Collections, the specialist HREC is the Lead HREC. The three specialist HRECs in WA are: • The **Department of Health HREC** • The **WA Aboriginal Health Ethics Committee (WAAHEC),** • The **Coronial Ethics Committee WA**
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).
Suspected Unexpected Serious Adverse Reaction (SUSAR)	An adverse reaction that is both serious and unexpected.
Unanticipated Serious Adverse Device Effect (USADE)	A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.
WA Aboriginal Health Ethics Committee (WAAHEC)	The WAAHEC is a specialist HREC that undertakes review of research applications that are related to the health and well-being of Aboriginal and Torres Strait Islander people. The definition of health for this purpose is as defined by the National Aboriginal Community Controlled Health Organisation: "Aboriginal health" means not just the physical well-being of an individual but refers to the social, emotional and cultural well-being of the whole Community in which each individual is able to achieve their full potential as a human being thereby bringing about the total well-being of their Community. It is a whole of life view and includes the cyclical concept of life-death-life.
WA Health Ethics Application Form (WAHEAF)	A form used in the WA health single ethical review process that is submitted via the RGS to the WA health HREC. This form may not be used for projects being reviewed via the NMA scheme.
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 System Entity	• All Health Service Providers as established by an order made under section 32(1)(b) of the *Health Services Act 2016*; • The Department of Health as an administrative division of the State of Western Australia pursuant to section 35 of the *Public Sector Management Act 1994*. • Note: Contracted health entities are not considered WA health system entities.
WA-Specific Module (WASM)	A form in the RGS that must be submitted to the HREC in addition to the HREA. It addresses additional ethical issues specific to WA that are not addressed in the HREA and must be considered when conducting human research in WA.

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