



Research Governance Policy

The Department of Health is undertaking a review of research governance within the WA health system which is likely to lead to major amendments being made to the Research Governance Policy and Procedures.

The current policy and procedures are provided to Health Service Providers to reflect current policy requirements.

1. Purpose

The purpose of this Policy is to implement effective and efficient research governance to support and facilitate the responsible conduct of human research within the WA health system.

This Policy outlines the principles that WA health system entities must uphold under the National Health and Medical Research Council (NHMRC) *Australian Code for the Responsible Conduct of Research* and the NHMRC *National Statement on Ethical Conduct in Human Research* (National Statement), to ensure research is conducted with the highest ethical and scientific standards and is appropriate to be undertaken at a specific site. It is recognised that high quality, accountable and responsible research underpins the delivery of contemporary health policy and practice.

The relevant legislation for this Policy is listed in the *Research Governance Procedures*.

This Policy is a mandatory requirement under the *Research Policy Framework* pursuant to section 26(2)(a) of the *Health Services Act 2016*.

This Policy is also a mandatory requirement for the Department of Health pursuant to section 29 of the *Public Sector Management Act 1994*.

This Policy supersedes OD0411/12 *WA Health Research Governance Policy and Procedures* and OD446/13 *WA Health Research Governance and Single Ethical Review Standard Operating Procedures*.

2. Applicability

This Policy is applicable to all WA health system entities, as defined in this Policy.

3. Policy requirements

WA health system entities must ensure that all human research is reviewed, approved and monitored in accordance with the *Research Governance Procedure*.

All processes described in these policy requirements must be performed through the [Research Governance Service](#) where applicable, as described in the Research Governance Procedure.

3.1 Review and approval of human research

3.1.1 Ethical and scientific review

All human research must be ethically and scientifically reviewed through an appropriate pathway by a Human Research Ethics Committee (HREC), or other ethical review body, as detailed in the *Research Governance Procedure* to ensure the research is:

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

3.1.2 Site review by the Research Governance Office

Before research can commence at a nominated site, the WA health system entity's Research Governance Office must conduct a site review and provide site authorisation.

A site review must be a comprehensive risk assessment, including verification of ethical approval/s, as detailed in the *Research Governance Procedure*, to ensure that research is:

- feasible
- adequately resourced
- conducted by authorised and appropriately qualified personnel on authorised and suitably equipped sites
- able to be conducted in a safe and responsible manner in compliance with regulatory and professional standards, legislation and codes of conduct at the State and national level
- authorised by the Chief Executive of the Health Service Provider (or delegate) or Assistant Director General of the Department of Health (or delegate).

3.2 Monitoring of human research

3.2.1 Project monitoring by the ethical review body

HRECs and other ethical review bodies must monitor research to ensure that projects they approve are conducted ethically, and in accordance with the approved protocol including reviewing proposed protocol amendments. The processes for project monitoring are detailed in the *Research Governance Procedure*.

3.2.2 Site-specific monitoring by the Research Governance Office

Research Governance Offices have a responsibility for site-specific monitoring of the conduct of research projects, to ensure that projects that they authorise are conducted with integrity and in compliance with relevant requirements as detailed in the *Research Governance Procedure*.

4. Compliance monitoring

WA health system entities are responsible for ensuring compliance with this Policy for all research projects conducted at their sites.

The Department of Health will provide reports to the Assistant Director General, Clinical Excellence, when requested. These reports will be based on:

- data extracted from the Research Governance Service
- targeted review of research projects which will be undertaken in consultation with the applicable WA health system entities
- a statement of compliance from applicable WA health system entities.

5. Related documents

The following document is mandatory pursuant to this Policy:

- [Research Governance Procedure](#)

6. Supporting information

The following information is not mandatory but informs and/or supports the implementation of this Policy:

- [Research Governance Service Help Wiki](#)

7. Definitions

The following definition(s) are relevant to this Policy.

| Term | Definition |
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| Health Service Provider (HSP) | As defined in the Health Services Act 2016 . |
| 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. |
| National Health and Medical Research Council (NHMRC) | The national organisation in Australia responsible for providing a strategy for health and medical research, including a strong integrity framework for research and guideline development, underpinning rigorous and ethical research and relevant and accurate guidelines, and promoting community trust. |
| National Statement | The NHMRC National Statement on Ethical Conduct in Human Research . |
| Research | As per the Australian Code for the Responsible Conduct for Research , the concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative. |

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| Research Governance | A process used by an organisation for the oversight, assessment, authorisation and monitoring of research conducted at one or more of its sites or under its auspices. A research governance framework includes good research culture and practice, organisational strategy, role definition and accountabilities, risk, resource and financial assessment and management, compliance with legal, regulatory and contractual requirements, competencies and training of personnel, site assessment, scientific review, ethical review and approval, site authorisation, monitoring of research, and management of conflicts of interest, complaints and allegations of research misconduct (Independent Hospital Pricing Authority, 2014). |
| Research Governance Service (RGS) | A centralised information technology system used to process and manage all human research ethics and site authorisation applications involving WA health system entities. |
| Site | A facility, location or service within the WA health system: <ul style="list-style-type: none"> • where the research is being conducted • that resources, conducts and/or manages the research. |
| Site authorisation | The authorisation granted by the Chief Executive of the health entity (or delegate) or Assistant Director General of the Department of Health (or delegate) for the commencement of a research project at the site. |
| WA health system entities | <ul style="list-style-type: none"> • All Health Service Providers as established by an order made under section 32(1)(b) of the <i>Health Services Act 2016</i> • The Department of Health as an administrative division of the State of Western Australia pursuant to section 35 of the <i>Public Sector Management Act 1994</i>. <p>Note: Contracted health entities are not considered WA health system entities.</p> |

8. Policy contact

Enquiries relating to this Policy may be directed to:

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9. Document control

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10. Approval

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| Approval by | Nicole O’Keefe, Assistant Director General, Strategy and Governance, Department of Health |
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