Research Ethics and Governance

This document is relevant to all Western Health sites, including Bacchus Marsh, Melton and Caroline Springs

Policy code: P-GC7	Effective date: February 2022
Last review date: July 2018	Next review date: February 2025
Section: Growing & Improving Care	Section name: Research & Quality Systems

1. Intent

Western Health (WH) recognises the importance of research to the provision of high quality health care. It is committed to ensuring that research activities, including clinical trials, are conducted according to best practice guidelines and legislative responsibilities, and that the welfare and rights of all research participants are respected and protected. This also applies to the researchers and the institution.

Obtaining research ethics approval helps to ensure that the research is carried out professionally and takes into account relevant legal, ethical, organisational, and cultural standards. Governance authorisation 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.

2. Outcomes

2.1. Policy Statement

Western Health will:

- Maintain robust systems for the governance and management of research including:
  - Approval of research projects by a properly constituted research and ethics committee (LREP or HREC);
  - Approval of quality assurance activities by appropriate mechanisms;
  - Disclosure of conflicts of interest;
  - Reporting and investigation of adverse events and study breaches;
  - Monitoring and audit of appropriate records to ensure compliance with legislative requirements;
  - Systems to manage data and protect privacy and confidentiality;
  - Ensure adequate resourcing & financial management;
  - Use of Human Bio-specimens in Research;
  - Ensure Legal and insurance compliance;
  - Record Qualification & Credentials of all researchers;
  - Manage External Researchers & Study Monitors
  - Handling of Complaints
  - Monitor the outcomes of research including completion of projects, publications, and communications
  - Ensure compliance to relevant regulatory and legislative requirements
- Facilitate and promote appropriate research within Western Health.
- Support the advancement of knowledge and understanding of research through education and training.
- Provide guidance and expert advice for research grant applications.

2.2. Policy Coverage

Procedural aspects of this policy are detailed in OP-GC7 Research Ethics and Governance Procedure

3. Applicability

This policy applies to all Western Health employees, agents of Western Health (including persons with honorary appointments, university partners, visitors, and students), and any entity conducting research on its behalf or on Western Health patients, their data, and/or samples, staff and/or other resources. All collaborative research projects in which Western Health is involved must also comply with this policy.

4. Accountability

Individuals or groups undertaking research within Western Health are accountable to the Western Health Board, under the Western Health Governance structure. The Western Health Board is accountable to the Minister of Health, who is the community's elected representative.

The Western Health Board is accountable for maintaining, via the Western Health Executive Team, an Office for Research that provides direction and leadership in relation to research matters, undertakes monitoring and auditing activities, liaises with relevant Research and Ethics and Governance committees, encourages learning about and participation in research activities among all staff and reports the outcomes of research at the Health Service level.

The Executive Team, Divisional Directors and Clinical Services Directors are responsible for working with the Office for Research to ensure that, where appropriate, systems are in place to promote and monitor research activities within Divisions.

All Managers are responsible for ensuring that relevant staff receives education, training, or experience necessary to implement the requirements of this policy.

All Directors of Departments in receipt of any NHMRC grant funding supporting health and medical research are responsible for ensuring that the funds awarded, and any interest accrued from these funds, are used and managed as per the corresponding approved Deed of Agreement.

Western Health Office for Research (Directors, Managers, Research Governance Officers, Research Ethics and Governance Administration Officers) are responsible for the ethical/governance review of research projects being undertaken across Western Health, and ongoing monitoring of approved projects and are also responsible for ensuring the overall efficient and effective coordination of research governance applications, procedures, and processes.

It is the responsibility of staff in supervisory positions to ensure that staff, trainees, and students involved in research projects at Western Health have the appropriate education, training, experience, mentoring, and support to conduct quality research, safely and responsibly.

Researchers (all Western Health staff and affiliates, including students, who are involved in research associated with the Western Health) are responsible for undertaking research across Western Health in a safe and ethical manner, in compliance with all relevant policies, guidelines and procedures.

5. Associated Procedures/Instructions

In support of this policy, the following Manuals, Procedures, Instructions, Guidelines, and/or Forms apply:

Code	Name
	NHMRC Australian Code for the Responsible Conduct of Research (2018)
	National Statement on Ethical Conduct in Human Research (2007 and updates)
	Western Health Research Code of Conduct 2018
OP-GC7	Research Ethics and Governance Procedure
OG-GC7	Data Management in Research Guideline
OP-EP1	Honorary Appointments
P-GC7	Intellectual Property and Moral Rights
OP-RS2	Conflict of Interest Procedure
P-CP2.1	Western Health Information Privacy Policy
P-CM5	Western Health Record Keeping Policy
	Western Health Office for Research – Information on procedures and processes for ethical and governance review of research, Research Agreements, Honorary Researcher Appointments
	Western Health Standard Operating Procedures – Good Clinical Practice (GCP)

6. Definitions and Abbreviations

Include here all definitions of terms or abbreviations used in the policy. It is preferable that pre-existing definitions are used.

6.1. Definitions

For purposes of this policy, unless otherwise stated, the following definitions shall apply:

Human Research Ethics Committee (HREC)	A committee established in accordance with the National Statement on Ethical Conduct in Human Research 2007 and updates, whose purpose is to review and approve projects involving human participants. The primary role of an HREC is to protect the welfare and rights of participants in research and to promote ethically good human research. Each member of a HREC is responsible for deciding whether, in his or her judgement, a proposal submitted to the HREC meets the requirements of the NHMRC National Statement and is ethically acceptable.
Low Risk Ethics Panel (LREP)	A body which reviews low & negligible risk research proposals involving human participants and their data to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. The National Statement (2007 and updates) requires that all research proposals involving human participants be reviewed and approved by an ethics committee.
National Statement	National Statement on Ethical Conduct in Human Research 2007. This has been jointly developed by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellor's Committee. The purpose of the National Statement is to promote ethically good human research. Fulfilment of this purpose requires that participants be accorded the respect and protection that is due to them. It also involves the fostering of research that is of benefit to the community. The National Statement clarifies the responsibilities of: (i) institutions and researchers for the ethical design, conduct and dissemination of results of human research; and (ii) review bodies in the ethical review of research.
Participants	People who take part in research whether directly or indirectly (e.g. through the use of their information or stored tissue samples).

Researcher	Anyone undertaking research activities as defined above.

6.2. **Abbreviations**

For purposes of this policy, unless otherwise stated, the following abbreviations shall apply:

Abbre'n	Expanded abbreviation, including reference if there is a separate authoritative source of the definition
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
LREP	Low Risk Ethics Panel
NHMRC	National Health and Medical Research Council
VMIA	Victorian Managed Insurance Authority

7. References

7.1. **Legislation**

- Australian Research Council Act 2001 (Cth)
- Epidemiology Studies (Confidentiality) Act 1981 (Cth)
- Freedom of Information Act 1982 (Vic)
- Gene Technology Act 2001 (Cth)
- Gene Technology Act 2001 (Vic)
- Guardianship and Administration Act 1986 (Vic)
- Public Health and Wellbeing Act 2008 (Vic)
- Health Records Act 2001 (Vic)
- Health Complaints Act 2006 (Vic)
- Human Tissue Act 1982 (Vic)
- Infertility Treatment Act 1995 (Vic)
- Privacy and Data Protection Act 2014 (Vic)
- Mental Health Act 2014 (Vic)
- Narcotic Drugs Act 1967 (Cth)
- National Health and Medical Research Council Act 1992 (Cth)
- Prevention of Cruelty to Animals Act 1986 (Vic)
- Privacy Act 1988 (Cth)
- Payment of participants in research: information for researchers, HRECs and other ethics review bodies 2019 (NHMRC) (Cth)
- Prohibition of Human Cloning Act 2002 (Cth)
- Public Records Act 1973 (Vic)
- Biosecurity Act 2015 (Cth)
- Radiation Act 2005 (Vic)
- Therapeutic Goods Act 1989 (Cth)
- Charter of Human Rights and Responsibilities Act 2006 (Vic)

7.2. **Guidelines, Codes and Regulations**

- Australian Charter of Healthcare Rights 2008 (Cth)
- ICH Guidelines
- ICH Efficacy Guideline for Good Clinical Practice E6 2016
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - annotated with TGA comments
- Therapeutic Goods Regulations 1990
- Therapeutic Goods (Medical Devices) Regulations 2002
- The Australian Clinical Trial Handbook March 2006
- Access to Unapproved Therapeutic Goods- Clinical Trials in Australia October 2004
- Human Research Ethics Committees and the Therapeutic Goods Legislation June 2001
- Review of Quality Assurance Projects at Western Health
- Health Records Act 2001 (Vic) - Statutory Guidelines on Research issued for the purposes of Health Privacy Principles 1.1 (e) (iii) & 2.2 (g) (iii) - Office of the Health Services Commissioner (Victoria) February 2002 (Vic)
- Guidelines under Section 95 of the Privacy Act 1988 (Cth)
- Guidelines approved under Section 95A of the Privacy Act 1988 (Cth)
- Radiation Regulations 2007 (Vic)
- Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes 2005 (Cth)
- Statement on Consumer and Community Participation in Health and Medical Research 2016 (NHMRC)
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th edition, 2013 (NHMRC)

- Gene Technology Regulations 2001 (Cth) – Office of the Gene Technology Regulator and Associated Legislation and Regulations
- DNA Genetic Testing in the Australian Context: A Statement (NHMRC)
- Medical Genetic Testing - Information for Health Professionals (NHMRC) 2010
- Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical practice and research (NHMRC) 2017
- VMIA Clinical Trials Insurance and Risk Management Guidelines 2012 (Vic)
- National Statement on Ethical Conduct in Human Research (2007)- updated 2018
- Australian Code for the Responsible Conduct of Research (2018)

8. Document History

Number of previous revisions: 4

Previous issue dates: September 2006, September 2011, May 2015, July 2018

9. Sponsor

Chief Medical Officer

10. Authorisation Authority

Western Health Board of Directors