POLICY

Human Research

TABLE OF CONTENTS

POLICY STATEMENT 2

EVALUATION, MONITORING AND REPORTING OF COMPLIANCE TO THIS POLICY 2

KEYWORDS 2

KEY LEGISLATION AND STANDARDS 2

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POLICY STATEMENT

Monash Health is committed to clinical and health services research being conducted to the highest ethical standards, protecting the welfare of individual participants and respecting their rights, safety and dignity whilst also protecting and supporting researchers in accordance with the applicable national guidelines and regulatory requirements.

EVALUATION, MONITORING AND REPORTING OF COMPLIANCE TO THIS POLICY

Compliance to this policy will be monitored, evaluated and reported through the Monash Health Research Council, Human Research Ethics Committee, auditing of research projects and annual research reports.

KEYWORDS

Ethics, research governance, participants, researchers, legislative compliance.

KEY LEGISLATION AND STANDARDS

The following legislation, regulations, standards and other instruments are applicable to this policy:

- Health Records Act 2001
- Health Services Act 1988
- Human Tissue Act 1982
- Human Tissue Regulations (Vic) 2025
- Industry Research and Development Act 1986 (Cth)
- Information Privacy Act 2000
- Medical Treatment Planning and Decisions Act 2016
- Privacy and Data Protection Act 2014
- Research Involving Human Embryos Act 2002 (Cth)
- Research Involving Human Embryos Act 2008 (Vic)
- Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Act 1989 (Cth)

- Therapeutic Goods Regulations 1990 (Cth)
- National Statement on Ethical Conduct in Human Research(2025)
- Australian Code for the Responsible Conduct of Research(2018)
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods(2016)
- ICH GCP E6(R3) Guideline for Good Clinical Practice

Document governance	
Approving body	Monash Health Executive Policy and Strategy Committee
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Responsible Program, Service, Unit, Department or Committee	Research Support Services
Primary Contact	Research Governance Manager



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