

# Research Ethics and Governance – Research Governance and Site Authorisation

## Procedure

### TARGET AUDIENCE and SETTING

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Principal Investigator and all staff conducting research.

Monash Health as a whole and in particular members of the Human Research Ethics Committees (HRECs) operating at Monash Health.

### PURPOSE

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Research Governance is the process by which the Research Governance Office (RGO) assesses the suitability of a research study to commence at an institution in accordance with its policies and procedures and capabilities in being able to undertake the research. Site Specific Authorisation must be obtained in order to commence a project at any particular site. The purpose of this document is to outline requirement for research governance compliance at Monash Health.

### DEFINITIONS

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#### Research Governance

Processes used by institutions to ensure that they are accountable for the research conducted under their auspices. To be properly governed, research must be conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy.

### PRECAUTIONS/CONTRAINDICATIONS

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All researchers at Monash Health must conduct research in the manner indicated in the Human Research Policy and the Research Governance Procedure.

### STANDARD REQUIREMENTS

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All investigators must abide by relevant legislation, the Australian code for the responsible conduct of research (NHMRC, 2018), the National Statement on Ethical Conduct in Human Research (NHMRC 2023), the Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016) and the International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

### PROCEDURE

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#### A. Responsibilities of the Research Support Services:

##### 1. Research Support Services will promote the responsible conduct of research:

Research Support Services will:

- Promote awareness of all guidelines and legislation relating to the conduct of research.
- Provide documents setting out clearly the policies and procedures based on the Australian Code for the Responsible Conduct of Research.

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- Actively encourage mutual cooperation with open exchange of ideas between peers, and respect for freedom of expression and inquiry.
- Maintain a climate in which responsible and ethical behaviour in research is expected.

#### 2. Research Support Services will establish good governance and management practices:

Research Support Services will:

- Provide an appropriate research governance framework through which research is assessed for quality, safety, privacy, risk management, financial management and ethical acceptability. The framework specifies the roles, responsibilities and accountabilities of all those who play a part in research.
- Ensure that the research governance framework does demand compliance with laws, regulations, guidelines and codes of practice governing the conduct of research in Australia. Common law obligations also arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.
- Ensure the availability of the documents that help guide good research governance, conduct and management.
- Provide a clear policy on collaborative research projects with other organisations, which requires arrangements to be agreed before a project begins, documented by a research agreement. As a minimum, these arrangements will cover financial management, intellectual property, authorship and publication, consultancies, secondments, ethics approval, and ownership of equipment and data.
- Establish a well-defined process for receiving and managing allegations of research misconduct.
- Be responsible for a process for regular monitoring of Monash Health’s research performance and provide reports to the Monash Health Research Council, Monash Health Executive Committee and the Board.

#### 3. Research Support Services will assist in the training of staff:

Research Support Services will:

- Assist in providing induction, formal training and continuing education for all research staff, including research trainees. Training will cover research methods, ethics, confidentiality, data storage and records retention, as well as regulation and governance. Training should also cover the institution’s policies regarding responsible research conduct, all aspects of the Code, and other sources of guidance that are available. Institutions may make arrangements for joint induction and training with other institutions.

#### 4. Research Support Services will assist in the promotion of mentoring:

Research Support Services will:

- Assist in promoting effective mentoring and supervision of researchers and research trainees. This includes advising on research ethics, research design and methods, and the responsible conduct of research.

#### 5. Research Support Services will assist in ensuring a safe research environment

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Research Support Services will:

- Work with researchers to ensure a safe working environment in which to conduct each research project

### B. Researcher Responsibilities in the conduct of Research:

#### 1. Maintain high standards of responsible research

Researchers must foster and maintain a research environment of intellectual honesty and integrity, and scholarly and scientific rigour. Researchers must:

- respect the truth and the rights of those affected by their research;
- manage conflicts of interest so that ambition and personal advantage do not compromise ethical or scholarly considerations;
- adopt methods appropriate for achieving the aims of each research proposal;
- follow proper practices for safety and security;
- cite awards, degrees conferred and research publications accurately, including the status of any publication, such as under review or in press;
- promote adoption of this Code and avoid departures from the responsible conduct of research;
- conform to the policies adopted by their institutions and bodies funding the research.

#### 2. Report research responsibly

- Researchers should ensure that research findings are disseminated responsibly.

#### 3. Respect research participants

Researchers must comply with:

- Ethical principles of integrity, respect for persons, justice and beneficence. All research projects must be submitted to Research Support Services for review and approval by the Human Research Ethics Committee, prior to commencement. The National Statement on Ethical Conduct in Human Research sets out principles for protecting human participants in research.

#### 4. Respect animals used in research

Researchers must respect the animals they use in research, in accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.

#### 5. Respect the environment

Researchers should conduct their research so as to minimise adverse effects on the wider community and the environment.

#### 6. Report research misconduct

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A researcher who considers that research misconduct may have occurred must act in a timely manner, having regard to the “Handling of Research Misconduct and Resolving Allegations” procedure.

#### KEY STANDARDS, GUIDELINES OR LEGISLATION

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Australian code for the responsible conduct of research (NHMRC, 2018),

National Statement on Ethical Conduct in Human Research (NHMRC 2023)

Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016)

International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

#### KEYWORDS

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Research governance, human research, Principal Investigator;

<b>Document Governance</b>	
<b>Supporting Policy</b>	<a href="#">Human Research</a>
<b>Executive Sponsor</b>	Chief Medical Officer
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