

Monash University Policy

Policy Title	Ethical Research and Approvals Policy
Date Effective	25-November-2009
Review Date	25-November-2012
Policy Owner	Manager, Research Ethics and Compliance
Category	Academic Quality and Standards
Version Number	1.1
Content Enquiries	Manager Research Ethics
Scope	This policy applies to all Monash University staff and students, full time, part time, casual or adjunct, from any Monash University campuses, national and international, who host, conduct, participate in or disseminate the results of research involving human or animal subjects. Visitors to the University who participate in research are also covered by this policy.
Purpose	<p>The aim of this policy is to ensure that research conducted at Monash University is of the highest ethical standard by incorporating ethical review of all research activities involving human or animal subjects conducted by staff and students. By subjecting research to appropriate review Monash will ensure maximum compliance with current ethical guidelines and legislative frameworks as they apply to research.</p> <p>All research-related policies and procedures at Monash University are being reviewed to ensure compliance with the <i>Australian Code for the Responsible Conduct of Research (2007)</i> and to comply with the new Monash University Policy Bank format.</p>
POLICY STATEMENT	

As an educational and research institution, Monash recognises its responsibility to the community to ensure all research activities are conducted in accordance with the highest ethical standards and to ensure that staff and students are seen as positive role models amongst their peers and in the wider community. It is committed to protecting the rights, dignity, health, safety and privacy of the community, including research subjects, and to the welfare of animals and the integrity of the environment. While acknowledging all mandated requirements for secure data retention, protection of privacy and confidentiality, the University is also committed to promoting access to the benefits of research through collecting, storing and making research data accessible in such a way that it can be used in future by members of the research community and other interested parties. By achieving the above, the University also aims to protect the health, safety, rights and academic freedom of researchers and the reputation of the University for excellence in research.

Some subsets of research conducted at Monash will come under the purview of either an animal ethics committee or the human research ethics committee while others will not. It is to be understood by all researchers that an approval by the appropriate ethics committee is a necessary but not sufficient assurance that the research complies with ethical standards. At all times all research will still require self reflection and review: while acknowledging that there are conflicting and contested interests, a researcher must choose where the greatest good or least harm may be done.

In conducting research of the highest ethical standard the University is committed to complying with all relevant Australian, Malaysian, South African and other relevant countries' applicable laws, codes of practice and guidelines as they apply to research including, but not limited to, all those listed in relevant sections of this policy. Responsibility for ethical review of all research involving animals is invested in departmental/school-

based Animal Ethics Committees (AECs) and the Monash University Animal Welfare Committee (MUAWC) as described in accompanying procedures. All research involving human participants requires approval from the Monash University Human Research Ethics Committee (MUHREC), as described in accompanying procedures.

The University aims to achieve maximum compliance through continually improving the level of consideration for ethical issues associated with conducting research involving human and animal subjects. This will be achieved by:

- continual education of its human research and animal ethics committee members on the content of the relevant legislation and other developing ethical issues relating to research;
- continual education of the Monash research community about ethical issues as they relate to research and the ethical clearance framework described in the procedures supporting this policy;

the monitoring of research activities to ensure researchers are aware of their obligations under the relevant legislation and Monash policy and procedures and are maintaining compliance.

Supporting Procedures	Ethical Research and Approvals: Human Research Ethics Committee Procedures Ethical Research and Approvals: Research Involving Human Participants Procedures Ethical Research and Approvals: Scientific Activities involving Animals Procedures
Responsibility for implementation	Deputy Vice Chancellor (Research) Campus Research Committee (Sunway) Deputy Pro Vice-Chancellor Research (South Africa) Monash Research Committee (MRC) Monash University Human Research Ethics Committee (MUHREC) Monash University Animal Welfare Committee (MUAWC) Departmental/School Animal Ethics Committees Monash Research Office Heads of academic/administrative units and controlled entities Research supervisors and managers Research staff All Students
Status	New
Approval Body	Name: Academic Board Meeting: 06/2009 Date: 25-November-2009 Agenda item: 17.1.1
Endorsement Body	Name: Monash Research Committee Meeting: 04/2009 Date: 07-July-2009 Agenda item: 9.1
Definitions	

Legislation Mandating Compliance	<p>Australia</p> <p>Prevention of Cruelty to Animals Act, 1986 and Regulations</p> <p>Research Involving Human Embryos Act 2008</p> <p>Prohibition of Human Cloning Act, 2002</p> <p>South Africa</p> <p>South African Constitution Act, 1996</p> <p>South Africa: National Health Act, 2003</p>
Related Policies	<p>Use of Animals in Coursework Programs Policy</p> <p>Use of Animals in Coursework Programs Procedures</p> <p>Conduct and Compliance Policy</p> <p>Conduct and Compliance Procedures - Conflict of Interest (including Conflict of Interest in Research)</p> <p>Conduct and Compliance Procedures - Privacy</p> <p>Recordkeeping Policy</p> <p>Monash University Procedures for Dealing with Allegations of Research Misconduct</p>
Related Documents	<p>All campuses</p> <p>International Ethical Guidelines for Biomedical Research Involving Human Subjects</p> <p>World Health Organisation, Operational Guidelines for Ethics Committees that Review Biomedical Research</p> <p>ICH Guideline for Good Clinical Practice</p> <p>Australia</p> <p>Australian Code for the Responsible Conduct of Research 2007</p> <p>Australian Code of Practice for the Care and Use of Animals for Scientific Purposes</p> <p>National Statement on Ethical Conduct in Human Research</p> <p>Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practices and Research</p> <p>South Africa</p> <p>South African, Ethics in Health Research: Principles, Structures and Processes</p> <p>Sunway</p> <p>Malaysia Guidelines for Good Clinical Practice, Ministry of Health Malaysia, 2nd Edition 2004</p> <p>National Institutes of Health Guidelines for Conducting Research in Ministry of Health Institutions and Facilities: KKM/NIHSEC/03/0301-01 Circular Ref. 9/2007</p>