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Supporting Process: Research Processes

Research Ethics and Biorisk Management Policy (MPF1341)

1. Objective

The objectives of this policy are to ensure:

(a) the University meets its obligations to conduct research that at least meets relevant ethics requirements;

(b) work with regulated biological material (RBM) is properly regulated and meets compliance requirements; and

(c) the University complies with export controls and sanctions obligations.

2. Scope

2.1. This policy applies to research and work conducted at the University and by University employees and researchers, wherever located, where this:

(a) is conducted with or about people, their data or tissue;

(b) uses animals or is a teaching activity that uses animals;

(c) uses RBM; and/or

(d) involves dual-use goods or technologies.

3. Authority

This policy is made under the *University of Melbourne Act 2009* (Vic) and the Vice-Chancellor's Regulation and supports compliance with the:

(a) Australian Code for the Care and Use of Animals for Scientific Purposes ;

(b) Australian Code for the Responsible Conduct of Research ;

(c) *Autonomous Sanctions Act 2011* (Cth);

(d) *Biosecurity Act 2015* (Cth);

(e) *Charter of the United Nations Act 1945* (Cth);

(f) *Customs Act 1901* (Cth);

(g) *Customs (Prohibited Exports) Regulations 1958* (Cth);

(h) *Defence Trade Controls Act 2012* (Cth);

(i) *Gene Technology Act 2000* (Cth);

(j) *National Health Security Act 2007* (Cth);

(k) National Statement on Ethical Conduct in Human Research and associated guidelines;

(l) *Occupational Health and Safety Act 2004* (Vic);

(m) *Prevention of Cruelty to Animals Act 1986* (Vic);

(n) *Prevention of Cruelty to Animals Regulations 2008* (Vic);

(o) *Privacy and Data Protection Act 2014* (Vic);

(p) *Public Records Act 1973* (Vic) *;*

(q) *Weapons of Mass Destructions (Prevention and Proliferation) 1995* (Cth); and

(r) other legislation as applicable.

4. Policy

Principles of human research ethics

4.1. The University and its researchers are committed to the ethical conduct of human research.

4.2. Ethical human research must meet the following principles:

(a) respect for the rights, interests and welfare of the participants in human research;

(b) beneficence through minimising risk of harm or burden to research participants and enhancing potential benefits of research;

(c) justice in the distribution of benefits and burdens of research; and

(d) research merit and integrity.

Principles of animal ethics and welfare

4.3. Animals are only used in research and teaching activities if there is need for their use, and the activity has merit, integrity and justifiable benefit.

4.4. The impact on animals used in research and teaching is minimised.

4.5. In research and teaching, the University and its researchers:

(a) replace the use of animals with alternatives wherever possible;

(b) reduce the number of animals used without jeopardising the statistical validity of research results or teaching objectives and without placing an excessive cumulative burden on individual animals; and

(c) refine research and teaching practice, and facilities to minimise adverse impacts on animals.

4.6. The University continuously improves the standards it sets for the welfare and use of animals in research and teaching activities.

4.7. The University educates researchers and teachers on advancements in animal welfare, care and use standards.

Principles of working safely with regulated biological material

4.8. The University, its employees and researchers will protect the health and safety of people, animals and the environment by identifying and managing risks posed by work with RBM.

Principles of export controls and sanctions obligations

4.9 The University is committed to compliance with applicable export control legislation and regulations.

5. Procedural principles

Human research ethics

5.1. Researchers must:

(a) obtain the approval of a properly constituted Human Research Ethics Committee (HREC) for more than low-risk research, or Human Ethics Advisory Group (HEAG) for low-risk research before human research may be undertaken;

(b) carry out human research only as approved;

(c) obtain approval for any amendments to the approved human research activity before implementing any amendment or change;

(d) act on and promptly report adverse events in accordance with the relevant process; and

(e) report annually on the progress of the approved human research.

5.2. The University:

(a) maintains and resources the system required for the ethics review of human research to ensure that regulatory requirements and ethical principles are met;

(b) provides training and education in the theory and practice of the ethical conduct of human research; and

(c) promulgates clear statements of policy and process for the ethical conduct of human research.

5.3. Complaints about HEAG and HREC processes or decisions, or human research at the University, are handled in accordance with the relevant process.

Animal ethics and welfare

5.4. Researchers and teachers must:

(a) obtain the approval of a properly constituted Animal Ethics Committee (AEC) of the University before undertaking any research and teaching activities using animals;

(b) carry out their activities only as approved by the AEC and according to any conditions of approval;

(c) obtain AEC approval for any amendments to the approved research and teaching activities before implementing any amendment;

(d) act on and promptly report unexpected adverse events in accordance with supporting processes;

(e) report annually on the progress of the approved activity; and

(f) stay informed of and practise improved methods in the care and use of animals.

5.5. The University:

(a) maintains and resources the system required for reviewing research and teaching activities using animals to ensure that regulatory requirements and ethical principles are met;

(b) provides relevant education and training in the theory and practice of the ethical conduct of research and teaching activities using animals; and

(c) promulgates clear statements of policy, processes and guidelines for the ethical conduct of research and teaching activities using animals.

Biorisk management

5.6. Employees and researchers who work with RBM must:

(a) exercise caution when working with RBM;

(b) obtain the approval of a properly constituted Institutional Biosafety Committee (IBC) before undertaking any work or research activities involving the use of gene technology or viable genetically modified organisms;

(c) meet the conditions of any licence or approval issued by the Office of the Gene Technology Regulator;

(d) meet the conditions of any permit or approval issued by the Department of Agriculture and Water Resources;

(e) obtain approval before undertaking any work or research activities with RBM that is not approved as part of another regulatory scheme in accordance with the supporting process;

(f) conduct work or research activities only when the relevant approvals are in place according to any conditions of approval; and

(g) conduct work or research activities only in facilities and with equipment that meet the appropriate biosafety requirements and in accordance with the supporting process.

5.7. The University:

(a) develops effective processes and standards, and advises and directs its employees and researchers in the proper use and management of RBM;

(b) maintains and resources the system required for reviewing research, teaching activities and work using RBM to ensure that regulatory requirements are met;

(c) provides relevant education and training in the regulatory requirements of conducting research, teaching activities and work using RBM; and

(d) maintains a register of RBMs in use by University employees and researchers in accordance with the supporting process to:

- manage compliance; and
- direct advice to relevant personnel.

Export Controls

5.8. The University:

(a) conveys compliance expectations and requirements for University staff, students and affiliates;

(b) facilitates a framework for review and authorisation of work under the *Defence Trade Controls Act 2012* (Cth);

(c) provides training and assistance with preparation of application[s] to Export Controlled Goods and Technology;

(d) ensures all conditions specified on permits/approvals are followed;

(e) ensures records relating to export/supply transactions are appropriately maintained; and

(f) prepares an annual report to the institution outlining all University activities related to export control from the previous year. The report will be provided to the Deputy Vice-Chancellor (Research), as the Vice-Chancellor's delegate.

Autonomous Sanctions

5.9. The University:

(a) supports staff to assess and respond to identified situations to facilitate compliance with Sanctions Laws

(b) provides relevant education in the application of the Autonomous Sanctions Act 2012; and

(c) conveys updates on changes to the Sanctions Laws for University staff, students and affiliates.

6. Roles and responsibilities

Role/Decision/Action	*Responsibility*	*Conditions and limitations*
Approve proposals	Relevant committee by delegation from the Deputy Vice-Chancellor (Research) (DVCR)	...

Suspend human research	Chair, Central Human Research Ethics Committee with notification to DVCR	Only where the continuation of the project presents significant and ongoing risk to participants, researchers or the University.
Suspend animal research or teaching	Chair, Animal Ethics Committee (AEC) that approved the work, or Animal Welfare Officer (AWO) with notification to DVCR	Only where, in the view of the Chair of the AEC or the AWO, the continuation of the project presents significant and ongoing animal welfare concerns.
Suspend work with RBMs	Gene Technology and Biosafety Officer or Biosafety and Biosecurity Officer	Only where the continued use of a containment facility, or continuation of work with RBMs, or both, presents a significant risk to the health and safety of people or the environment or to compliance with regulations.
Intervene to ensure animal care and welfare	Animal Welfare Officer (AWO)	Where the impact on animals has been or may be greater than expected by the AEC approval, the AWO may intervene. This intervention may include providing treatment, directing others to provide treatment or humanely killing the animal(s).
Authorise Facility Manager	DVCR through the Biosafety and Biosecurity or Responsible Officer	In accordance with this policy, legislation referred to in sections 3d and 3j, and the relevant process.
Authorise processes and standards for the proper use and management of RBM	IBC by delegation from the DVCR	In accordance with this policy and the legislation and codes of conduct referred to in section 3 of this policy.
Maintain a register of RBMs	Director, REI	
Oversee the system for management of SSBAs	Responsible Officer by delegation from the DVCR	In accordance with this policy and the legislation referred to in section 3 of this policy.
Enter into external compliance arrangements	DVCR through Director, REI or delegate	In accordance with this policy, legislation referred to in section 3d, 3i and 3j of this policy and the relevant process.
Ensure compliance with export controls and sanctions obligations, where relevant	Export Controls Officer, by delegation from the DVCR	In accordance with this policy and the legislation referred to in section 3 of this policy.

7. Definitions

Animal means any live non-human vertebrate, that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife, and also cephalopods such as octopus and squid.

Export controls and sanctions obligations means obligations arising from the *Customs Act 1902* (Cth), *Customs (Prohibited Exports) Regulations 1958* (Cth), *Weapons of Mass Destruction (Prevention and Proliferation) Act 1995* (Cth), *Defence Trade Controls Act 2012* (Cth), *Charter of the United Nations Act 1945* (Cth) and the *Autonomous Sanctions Act 2012* (Cth).

Facility Manager means a University employee with the responsibility for an external compliance arrangement for biorisk management with a department of the Commonwealth Government.

Infectious agent means a bacterium, fungus, virus or other agent that is able to invade and replicate in a host organism (e.g. human, animal, plant) and which may or may not cause a disease.

Regulated biological material (RBM) means biological material that is governed by a regulatory scheme or recognised set of guidelines or standards, and includes:

(a) infectious agents (as above);

(b) hazardous infectious agents, that is infectious agents able to cause disease in an otherwise healthy host (e.g. human, animal or plant);

(c) biological material such as blood, tissues, cell lines or body fluids sourced from a living organism that might reasonably be expected to contain hazardous infectious agents;

(d) genetically modified organisms, including viable organisms that have been modified by gene technology, or that have inherited particular traits from an initial organism that occurred because of gene technology;

(e) imported material under biosecurity control due to biosecurity risk (based on the probability of a disease or pest being introduced to Australia that may cause harm); and

(f) Security Sensitive Biological Agents (SSBAs).

Research means diligent and systematic enquiry or investigation into a subject to discover facts or principles.

Researcher means student, employee, honorary appointee, independent contractor, or visitor engaged in research at the University.

Unexpected adverse event (in animals) means an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity. An unexpected adverse event may result from different causes, including:

(a) death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure, treatment or other intervention);

(b) adverse effects following a procedure or treatment that were not expected;

(c) adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study;

(d) a greater level of pain or distress than was predicted during the planning of the project or activity;

(e) power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

Work means handling, storage, transportation and disposal.

POLICY APPROVER

Deputy Vice-Chancellor (Research)

POLICY STEWARD

Director, Research Ethics and Integrity

REVIEW

This policy is to be reviewed by 31 March 2019.

VERSION HISTORY

Version	Approved By	Approval Date	Effective Date	Sections Modified
1	DVCR	16 July 2018	19 July 2018	New policy arising from the Policy Consolidation Project. Consolidating relevant content from the former: • Containment Facility Internal Certification Policy (MPF1195), • Containment Facility Internal Certification Procedure (MPF1151), • Infectious Agent Project Approval Policy (MPF1246), • Infectious Agent Project Approval Procedure (MPF1153), • Infectious Agent Reporting Policy (MPF1250) and • Infectious Agent Reporting Procedure (MPF1161).