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| Document : Research Policy | |
| Category : Research | iPolicy No. : MH18 |
| Subcategory : Research | Version No. : 3.0 |
| Department : Melbourne Health | Expiry Date : 31 Jul 2020 |

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| RESPONSIBLE EXECUTIVE | Executive Director of Research |
| PRIMARY AUTHOR | Director of Research Governance and Ethics |
| IMPLEMENTATION STRATEGY | Email update to all employees and uploaded to iPolicy |
| EVALUATION STRATEGY | Updated policy to be evaluated by Melbourne Health Research Advisory Council and the Executive Management Team. |
| EQUIP NATIONAL STANDARDS | Standard 15 Corporate Systems and Safety; Criteria 4 The organisation’s research program develops the body of knowledge, protects staff and consumers/patients and has processes to appropriately manage the organisational risk. |
| VERSION SUMMARY | This policy has been updated to include essential requirements for (i) GCP training for all investigators undertaking clinical trials, (ii) written agreements for all collaborative research and (iii) site specific research governance approval as essential pre-requisites to any research project commencing at Melbourne Health, (iv) use of the Clinical Trials Centre (v) real-time completion of the “Research Participation” tab on iPM at patient participant enrolment and (vi) post approval audits of research projects. |

| EXECUTIVE SUMMARY | |
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| 1. | All research and quality assurance projects undertaken at Melbourne Health or involving Melbourne Health staff, patients or resources must be submitted to the Office for Research for review and approval prior to commencement. |
| 2. | All research at Melbourne Health must comply with all relevant legislation, regulations, codes and guidelines and Melbourne Health policy and procedures. |
| 3. | All persons at Melbourne Health undertaking research must be appropriately qualified and experienced for their role and must participate in ongoing training and education appropriate to their role. |
| 4. | Clinical trials – It is expected that all clinical trials involving ambulatory patients will be conducted as appropriate in the Melbourne Health Clinical Trials Centre. |
| 5. | All collaborative research in which Melbourne Health is involved requires a written agreement. |
| 6. | The “Research Participation” tab on iPM must be completed for all research projects that recruit patient participants at Melbourne Health. |
| 7. | All research projects undertaken at Melbourne Health are subject to monitoring by the Office for Research. |

1. PURPOSE AND SCOPE

This research policy has been developed to clearly set out the framework within which all research at Melbourne Health must be undertaken. This policy applies to all persons employed by Melbourne Health, all staff with honorary appointments to Melbourne Health and to any person undertaking research involving Melbourne Health patients, staff and/or other resources. All collaborative research projects in which Melbourne Health is involved must also comply with this policy.

2. DEFINITIONS

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| Human Research Ethics Committee (HREC) | A committee established in accordance with the <i>National Statement on Ethical Conduct in Human Research 2007</i> , 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. |
| Institutional Biosafety Committee (IBC) | A Committee constituted in accordance with the <i>Gene Technology Act 2000</i> and the <i>Gene Technology Regulations 2001</i> . The aim of an IBC is to protect the health and safety of people, and the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with |

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| | genetically modified organisms (GMOs). An IBC also aims to ensure that researchers are aware of and comply with institutional Occupational Health and Safety policies and all relevant research safety requirements. |
| National Statement | <i>National Statement on Ethical Conduct in Human Research</i> 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. |
| NHMRC | National Health and Medical Research Council of Australia. |
| Participants | People who take part in research whether directly or indirectly (e.g. through the use of their information or stored tissue samples). |
| Quality Assurance | An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation). |
| Research | Research includes scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research. Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through: taking part in surveys, interviews or focus groups; undergoing psychological, physiological or medical testing or treatment; being observed by researchers; researchers having access to their personal documents or other materials; the collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, and head, bones, tumour and other biopsy specimens) or their exhaled breath; access to their identifiable information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database. |
| Therapeutic Goods Administration (TGA) | The TGA is a division of the Commonwealth Department of Health and Ageing . The objective of the Therapeutic Goods Act 1989 which came into effect on 15 February 1991, is to provide a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices. The TGA is responsible for administering the provisions of the legislation. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. At the same time the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances. |

3. RESPONSIBILITIES

The Office for Research is responsible to the Chief Executive Officer and Board of Melbourne Health, through the Executive Director of Research, for ensuring that all research activities in which Melbourne Health is involved are conducted in full compliance with all applicable legislation, ethical standards, guidelines, regulations, codes of practice and policies. The Office for Research is responsible for the management of all Melbourne Health research and ethics committees, research governance, management of research funds and employment of research staff.

4. POLICY

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- 4.1. All research and quality assurance projects undertaken at Melbourne Health or involving Melbourne Health staff, patients or other resources must be submitted to the Office for Research for review and approval prior to commencement. The Office for Research will undertake a site specific assessment / governance review of each project which will include ensuring that all projects involving human research have been reviewed and approved by an NHMRC accredited HREC and that any projects involving Genetically Modified Organisms have been reviewed and approved by an accredited IBC. Research projects may not commence until after written approval of the site specific research governance application has been issued by the Office for Research. Encourage staff to undertake research in collaboration with campus and precinct research partners e.g. University of Melbourne, WEHI, and VCCC.
- 4.2. The budget for all research projects undertaken by staff of Melbourne Health or involving Melbourne Health resources must be reviewed and approved by the Management Accountant Research. This approval should be in one of two forms – (i) a final agreed budget, prepared on the Melbourne Health template for research projects and signed by both the Principal Researcher and the Management Accountant Research; or (ii) an email from the Management Accountant Research approving the financial arrangements for a particular project. Such written approval must be included with new research project applications as part of the site specific research governance application to the Office for Research. All amendments to research projects with possible financial implications also require review and written approval of the Management Accountant Research before approval of the amendment can be issued.
- 4.3. All applications for research grants to be administered by Melbourne Health must be submitted to the relevant funding body through the Office for Research. The Executive Director of Research will submit the application to the funding body on behalf of Melbourne Health. Researchers are not permitted to directly submit applications to funding bodies.
- 4.4. All persons undertaking research must be appropriately qualified and experienced for their role and must participate in ongoing training and education, including Good Clinical Practice (GCP), regulatory practices, consent, ethics and any other training appropriate to their role. All investigators and coordinators on clinical trials must hold current, formal GCP certification. Melbourne Health has recognised the certification process that TransCelerate Biopharma Inc. has implemented to recognise GCP training courses that contain material meeting the minimum criteria agreed to by its member organisations: http://www.transceleratebiopharmainc.com/wp-content/uploads/2013/10/TransCelerate-GCP-Training-Minimum-Criteria-in-Operating-Principles_0.pdf; See also: <http://www.transceleratebiopharmainc.com/gcp-training-attestation/#headline4>. Clinical trial research applications cannot be approved to commence at the RMH without the investigators having completed such GCP training.
- 4.5. Clinical trials – It is expected that all clinical trials involving ambulatory patients will be conducted as appropriate in the Melbourne Health Clinical Trials Centre.
- 4.6. All collaborative research in which Melbourne Health is involved requires execution of an appropriate research collaboration agreement before research can commence.
- 4.7. The “Research Participation” tab on iPM must be completed for all research projects that recruit patient participants at Melbourne Health This initiative aims to
 - a (i) improve patient safety by ensuring details of patients participation in a research project is made available to the clinical and ward staff at RMH via alerts - especially for staff in the Emergency Department; and
 - b (ii) report to staff and the community about how many of our patients are involved in research and assess our performance against proposed recruitment targets.
- 4.8. Monitoring of research projects is an important means by which MH ensures that research conducted under its auspices is conducted in accordance with good clinical practice and approved ethical guidelines as well as MH requirements. Monitoring of research projects is also an educational activity aimed at improving and streamlining procedures. All research projects undertaken at Melbourne Health are subject to monitoring by the Office for Research. Monitoring includes review of reports (annual, final, amendments, adverse events etc.) and audit of research projects.
- 4.9. All research at Melbourne Health must comply with:

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- a [National Statement on Ethical Conduct in Human Research \(2007\)](#)
- b [Australian Code for the Responsible Conduct of Research \(2007\)](#)
- c [Research Guidelines](#)
 - i Guidelines for Research Practice 2015
 - ii Guidelines for Data Management in Research 2015
 - iii Guidelines for the Use of Human Tissue Samples in Research 2015
 - iv Guidelines for Research Publications and Authorship 2015
 - v Guidelines for Handling Complaints in Research 2016
 - vi Guidelines for Handling Conflicts of Interest in Research 2015
 - vii Guidelines for Monitoring and Reporting of Safety for Clinical Trials involving Therapeutic Products and Other Clinical Research 2015
 - viii Research Project Costing Financial Process and Related Matters 2015
 - ix Research Project Payments Financial Process 2015
- 4.10. All research at Melbourne Health must comply with all relevant legislation, regulations, codes and guidelines as applicable and other regulations from time to time.
- 4.11. All research at Melbourne Health must comply with Melbourne Health policies and procedures, as applicable, including for example:
 - a [MH05 Documentation and Records Management Policy](#)
 - b [MH 05.01 Clinical Documentation](#)
 - c [MH02.02.01 Consent](#)
 - d [MH12 Intellectual Property Policy](#)
 - e [MH03.08 Privacy and Confidentiality of Patient Information](#)
 - f [MH09.05.05 Protected Disclosure](#)
 - g [MH09.04.01 Grievance Procedure](#)
 - h [MH17 Radiation Safety Policy](#)
 - i [MH03.02 Consumer Feedback Management](#)
 - j [Melbourne Health Code of Conduct](#)
 - k [Melbourne Health By-laws](#)

5. ASSOCIATED PROCEDURES

- 5.1. [Melbourne Health Office for Research - information on procedures and processes for ethical review of research](#)
- 5.2. [Melbourne Health Office for Research - information on procedures and processes for governance review of research governance](#)

6. REFERENCES

- 6.1. Legislation
 - a [Australian Research Council Act 2001 \(Cth\)](#)
 - b [Epidemiology Studies \(Confidentiality\) Act 1981 \(Cth\)](#)
 - c [Freedom of Information Act 1982 \(Vic\)](#)
 - d [Gene Technology Act 2001 \(Cth\)](#)
 - e [Gene Technology Act 2001 \(Vic\)](#)
 - f [Guardianship and Administration Act 1986 \(Vic\)](#)
 - g [Public Health and Wellbeing Act 2008 \(Vic\)](#)

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- h [Health Records Act 2001 \(Vic\)](#)
- i [Health Complaints Act 2006 \(Vic\)](#)
- j [Human Tissue Act 1982 \(Vic\)](#)
- k [Infertility Treatment Act 1995 \(Vic\)](#)
- l [Privacy and Data Protection Act 2014 \(Vic\)](#)
- m [Mental Health Act 2014 \(Vic\)](#)
- n [Narcotic Drugs Act 1967 \(Cth\)](#)
- o National Health and Medical Research Council [Act 1992 \(Cth\)](#)
- p [Prevention of Cruelty to Animals Act 1986 \(Vic\)](#)
- q [Privacy Act 1988 \(Cth\)](#)
- r [Prohibition of Human Cloning Act 2002 \(Cth\)](#)
- s [Public Records Act 1973 \(Vic\)](#)
- t [Biosecurity Act 2015 \(Cth\)](#)
- u [Radiation Act 2005 \(Vic\)](#)
- v [Therapeutic Goods Act 1989 \(Cth\)](#)
- w [Charter of Human Rights and Responsibilities Act 2006 \(Vic\)](#)

6.2. Guidelines, Codes and Regulations

- a [Australian Charter of Healthcare Rights 2008 \(Cth\)](#)
- b [ICH Guidelines](#)
- c [ICH Efficacy Guideline for Good Clinical Practice E6 2016](#)
- d [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) - annotated with TGA comments](#)
- e [Therapeutic Goods Regulations 1990](#)
- f [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)
- g [The Australian Clinical Trial Handbook March 2006](#)
- h [Access to Unapproved Therapeutic Goods- Clinical Trials in Australia October 2004](#)
- i [Human Research Ethics Committees and the Therapeutic Goods Legislation June 2001](#)
- j [Review of Quality Assurance Projects at Melbourne Health](#)
- k [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 \(Vic\)](#)
- l [Guidelines under Section 95 of the Privacy Act 1988 \(Cth\)](#)
- m [Guidelines approved under Section 95A of the Privacy Act 1988 \(Cth\)](#)
- n [Radiation Regulations 2007 \(Vic\)](#)
- o [Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes 2005 \(Cth\)](#)
- p [Statement on Consumer and Community Participation in Health and Medical Research 2001 \(NHMRC\)](#)
- q [Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 7th edition, 2004 \(NHMRC\)](#)
- r [Gene Technology Regulations 2001 \(Cth\) –Office of the Gene Technology Regulator and Associated Legislation and Regulations](#)
- s [Guidelines for Genetic Registers and Associated Genetic Material 1999 \(NHMRC\)](#)
- t [Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies 1999 \(NHMRC\)](#)

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- u [DNA Genetic Testing in the Australian Context: A Statement \(NHMRC\) DNA Genetic Testing in the Australian Context: A Statement 2012](#)
- v [Medical Genetic Testing - Information for Health Professionals \(NHMRC\) 2010](#)
- w [Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research \(NHMRC\) 2007](#)
- x [VMIA Clinical Trials Risk and Insurance Guide](#)

6.3. [National Statement on Ethical Conduct in Human Research \(2007\)](#)

6.4. [Australian Code for the Responsible Conduct of Research \(2007\)](#)

7. FURTHER INFORMATION

7.1. For further information please contact the Office for Research.

7.2. Telephone: 03 9342 7550; Fax: 03 93428548; Email: angela.watt@mh.org.au

8. DOCUMENTATION

8.1. Research Ethics And Governance Applications

9. REVISION AND APPROVAL HISTORY

| Date | Version | Author and approval |
|---------------|---------|--|
| November 2007 | 0 | Dr Angela Watt, Manager Office for Research; Ingrid Winship, Executive Director Research. Approved by Delegations, Procedures and Organisational Policy Committee. Authorised by the Chief Executive |
| February 2010 | 1 | Dr Angela Watt, Manager Office for Research; Rob Merriel Director, Business Development; Ingrid Winship, Executive Director Research; Nic Thomas, Legal Council. Approved by the Corporate Policy Committee and EMT and authorised by the Chief Executive. |
| May 2013 | 2 | Dr Angela Watt, Director of Research Governance and Ethics; Professor Ingrid Winship, Executive Director of Research. Approved by the Research Advisory Council. Approved and authorised by the Corporate Policy Committee. |
| July 2017 | 3 | Director of Research Governance and Ethics; Executive Director of Research. Approved by the Research Advisory Council. Approved by Non-Clinical Policy Committee |