

## Purpose:

To ensure that research conducted at the Royal Victorian Eye and Ear Hospital (RVEEH) is done so appropriately and acknowledged.

## Scope:

This policy applies to all persons employed by RVEEH and to any person undertaking research involving patients, staff and/or other resources of RVEEH; this includes access to test results, samples and medical records.

## Policy:

RVEEH is committed to research being conducted to the highest ethical standards, protecting the welfare of participants and respecting their rights, safety, confidentiality and dignity.

Research at RVEEH will be undertaken in a manner:

- that meets all legislative requirements, standards, regulation, codes and other guidelines
- within the constraints of funding arrangements
- in accordance with RVEEH's Human Research Ethics Committee (HREC) guidelines
- in accordance with RVEEH's Animal Research Ethics Committee (AREC) guidelines
- in accordance with National Health and Medical Research Council (NHMRC) National Statement of Ethical Conduct in Human Research (2007)
- in accordance with Australian Code for Responsible Conduct of Research (2007)
- in accordance with the NHMRC's Australian code of practice for the care and use of animals for scientific purposes

All research conducted on the RVEEH campus must be approved by the HREC or AREC prior to commencement.

A priority should be to ensure that the outcomes of clinical research are translated into practice.

## Outcome:

A systematic process of reviewing and evaluating research programs at RVEEH.

## Definitions:

**Research:** Involves the systematic investigation to establish facts, principles and knowledge.

**NHMRC:** National Health and Medical Research Council.

**HREC:** Human Research Ethics Committee.

**AREC:** Animal Research Ethics Committee.

**Campus Partners:** Royal Victorian Eye and Ear Hospital (RVEEH), Centre for Eye Research Australia (CERA), University of Melbourne, Bionic Ear Institute of Australia, HEARing CRC.

## Standard:

- Australian Research Council Act 2001 (Cth)
- Epidemiology Studies (Confidentiality) Act 1981 (Cth)
- Freedom of Information Act 1982 (Vic)
- Gene Technology Act 2001 (Cth)
- Gene Technology Act 2001 (Vic)
- Guardianship and Administration Act 1986 (Vic)

- Health Records Act 2001 (Vic)
- Health Services Act 1988 (Vic)
- Health Services (Conciliation and Review) Act 1997 (Vic)
- Human Tissue Act 1982 (Vic)
- Information Privacy Act 2000 (Vic)
- Mental Health Act 1986 (Vic)
- Narcotic Drugs Act 1967 (Cth)
- NHMRC Act 1992 (Cth)
- Prevention of Cruelty to Animals Act 1986 (Vic)
- Privacy Act 1988 (Cth)
- Prohibition of Human Cloning Act 2002 (Cth)
- Public Health & Wellbeing Act 2008 (Vic)
- Public Records Act 1973 (Vic)
- Quarantine Act 1908 (Cth)
- Radiation Act 2005 (Vic)
- Therapeutic Goods Act 1989 (Cth)

## References:

- Australian Code of Conduct for the responsible conduct of research
- NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007)
- ICH Harmonised Tripartite Guideline - Guideline for Good Clinical Practice E6 (R1) (1996)
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - annotated with TGA comments.
- Access to Unapproved Therapeutic Goods - Clinical Trials in Australia 2004 (TGA)
- Human Research Ethics Committees and the Therapeutic Goods Legislation 2001 (TGA)
- When does quality assurance in health care require independent ethical review? (February 2003, NHMRC)
- Code of Practice - Exposure of Humans to Ionising Radiation for Research 2005 (Cth)
- Statement on Consumer and Community Participation in Health and Medical Research 2001 (NHMRC)
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 7th edition, 2004 (NHMRC)
- Prevention of Cruelty to Animals Regulations 1997 (principal regulations) (Vic)
- Guidelines for Genetic Registers and Associated Genetic Material 1999 (NHMRC)
- Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies 1999 (NHMRC)
- Ethical Aspects of Human Genetic Testing: an Information Paper 2000 (NHMRC)
- Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2004 (NHMRC)
- Code of Conduct for the Victorian Public Sector 2007 (Vic)
- Statement of Ethical Principles for Biotechnology in Victoria 2006 (Vic)

## EQUIP Focus Area(s):

2.5.1 – Support Function, Research Program

## Linked Policy & Procedure:

Health Information Policy

Legislative Compliance Policy

Risk Management Policy

Governance Policy

Intellectual Property Policy

## Reporting Lines:

Responsible Executive: ED Medical Services

Operational Reporting Committee: Animal Research Ethics Committee + Human Research Ethics Committee.

Board Reporting Committee: Board Committee

## Evaluation:

This policy will be evaluated through internal analysis of research applications and annual review of the organisations Research Policy and associated procedures.

All employees must abide by this RVEEH Policy and its associated Procedures at all times. Breaches may result in disciplinary action.

## Author / Contributors:

Name	Position	Service / Program
Kerryn Baker	Project Manager	Research & Medical
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## Policy Details:

Details		
Policy Number:	P18.0	
Manual:	Policy Manual	
Section:	Support	
Criteria:	2.5.1 – Research Programs	
Legislation Section:	Section B – Provision of Health Care Services	
Approval Date:	01/08/2010	
Review Date(s):	08/09/2011	
Next Review Due:	01/08/2013	