Research Policy

Purpose:

To ensure that research at The Royal Victorian Eye and Ear Hospital (Eye and Ear) is conducted to the highest ethical standard and respecting human research participants, animals and the environment and meets best practice research governance.

This policy describes the mechanisms that will assist the Eye and Ear in meeting the requirements of:

- National Safety and Quality Health Service Standards
- National Statement on Ethical Conduct in Human Research (National Statement) (National Health and Medical Research Council; NHMRC; 2007 and as amended)
- Australian Code for the Responsible Conduct of Research (2008 and as amended) (The Code) (NHMRC; 2008 and as amended)
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013)

Scope:

This policy applies to all persons employed by the Eye and Ear, honorary Eye and Ear researchers and to any person undertaking research involving patients, staff, health information, animals, genetically modified organisms (GMOs) and/or other resources of the Eye and Ear.

Policy:

1. The Eye and Ear is committed to research being conducted to the highest ethical standards, protecting the welfare of participants and respecting their rights, safety, confidentiality and dignity. The Eye and Ear is equally committed to the translation of outcomes of basic and clinical research into practice.

2. The research culture at the Eye and Ear is consistent with the principles of The Code and promotes:
    - honesty and integrity
    - respect for human research participants, animals and the environment
    - good stewardship of public resources used to conduct research
    - appropriate acknowledgment of the role of others in research
    - responsible communication of research results
3. All research involving humans conducted at the Eye and Ear or by Eye and Ear staff must be approved by an NHMRC registered HREC and hold institutional Research Governance Authorisation prior to commencement of the research.
4. All research involving animals conducted at the Eye and Ear or by Eye and Ear staff must be approved by an NHMRC registered AREC.
5. All research involving genetically modified organisms conducted at the Eye and Ear or by Eye and Ear staff must be approved by a registered Institutional Biosafety Committee and in an accredited organisation.
6. More specifically, research conducted in the Eye and Ear environment will be undertaken in a manner that is consistent with best practice research governance including:
    - legislative requirements, standards, regulation, codes and other guidelines
    - funding and contractual arrangements
    - Human Research Ethics Committee (HREC) approval and conditions
    - Animal Research Ethics Committee (AREC) approval and conditions
    - the National Statement on Ethical Conduct in Human Research (2007 and as amended)

- Australian Code for the Responsible Conduct of Research (2007 and as amended)
- Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (8th Edition, 2013)
- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2)

7. All persons conducting research must be appropriately qualified and experienced for their role and scope of practice.
8. All Principal Investigators of clinical trials must have current training in Good Clinical Practice evidenced by a certificate from a Transcelerate approved course provider.

Outcome:

A systematic process of reviewing and evaluating research conducted at the Eye and Ear.

Definitions and acronyms:

AREC: Animal Research Ethics Committee.

HREC: Human Research Ethics Committee

A committee established in accordance with the *National Statement* and whose primary purpose is to review and approve projects involving human participants to ensure the welfare and rights of research participants is protected and to promote ethically sound research.

GMO: Genetically Modified Organism

IBC: Institutional Biosafety Committee

NHMRC: National Health and Medical Research Council.

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

Standards:
National Clinical Trials Governance Framework (Australian Commission on Safety and Quality) *when implemented*

Legislation:
Commonwealth
Biosecurity Act 2015 (Cth)
Epidemiology Studies (Confidentiality) Act 1981 (Cth)
Gene Technology Act 2001 (Cth)
Narcotic Drugs Act 1967 (Cth)
National Health and Medical Research Council Act 1992 (Cth)
Privacy Act 1988 (Cth)
Guidelines under Section 95 of the Privacy Act 1988 (Cth)
Guidelines approved under Section 95A of the Privacy Act 1988 (Cth)
Prohibition of Human Cloning Act 2002 (Cth)
Therapeutic Goods Act 1989 (Cth)
Therapeutic Goods Regulations 1990
Therapeutic Goods (Medical Devices) Regulations 2002

Victorian
Gene Technology Act 2001 (Vic)
Gene Technology Regulations 2001 (Cth) –Office of the Gene Technology Regulator and Associated Legislation and Regulations

Guardianship and Administration Act 1986 (Vic)
Health Records Act 2001 (Vic)
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)
Human Tissue Act 1982 (Vic)
Medical Treatment Planning and Decisions Act 2016 (Vic)
Mental Health Act 2014 (Vic)
Privacy and Data Protection Act 2014 (Vic)
Prevention of Cruelty to Animals Act 1986 (Vic)
Public Records Act 1973 (Vic)
Radiation Act 2005 (Vic)
Radiation Regulations 2007 (Vic)

Guidelines, Codes and Regulations

The Australian Clinical Trial Handbook October 2018
Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th edition, 2013 (NHMRC)
Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes 2005 (Cth)
Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2)
Statement on Consumer and Community Participation in Health and Medical Research 2016 (NHMRC)
NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC; November 2016)
NHMRC Guidance Risk-based management and monitoring of Clinical Trials involving Therapeutic Goods (NHMRC; 2018)
NHMRC Guidance Reporting of Serious Breaches of Good Clinical Practice (GDP) or the Protocol for Trials Involving Therapeutic Goods (NHMRC; 2018)
NHMRC Guidance Data Safety Monitoring Boards (DSMBs) (NHMRC; 2018)
VMIA Clinical Trials Risk and Insurance Guide

References:

National Health and Medical Research Council (NHMRC) National Statement of Ethical Conduct in Human Research (2007 and as amended) (National Statement)

NHMRC Australian Code for the Responsible Conduct of Research (2007 and as amended) (The Code).

NHMRC Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition 2013)

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - annotated with TGA comments

Linked Policy & Procedure:

Eye and Ear

Health Information Policy

Legislative Compliance Policy

Risk Management Policy

Governance Policy

Intellectual Property Policy

Code of Conduct

Research Office

Handling Research Related Complaints (RS1.1)

Safety Monitoring and Reporting for research projects (RS1.4)

Determining Authorship (RS1.7)

Good Clinical Practice (GCP) Series of SOPs (RS1.11)

Credentialing of Eye and Ear Hospital Researchers (RS1.18)

When a Principal Investigator Leaves the Eye and Ear Precinct (RS1.19)

Research Data Storage, Retention and Disposal (RS1.20)

Human Research Ethics Committee

Human Research Ethics Committee Terms of Reference

Administration of Ethical Review (RS1.8)

Authorised Prescriber Approval Procedure (RS1.2)

Handling Conflicts of Interest in Ethical Review of Research (RS1.0)

Independent Expert Advice for High Risk Research Projects (RS1.16)

Retrospective Review (RS1.15)

Suspension or Withdrawal of Approval for Conduct of Research Projects (RS1.5)

Use of Human Biospecimens in Research (RS1.21)

Reporting Lines:

Responsible Executive: Executive Director Medical Services/Chief Medical Officer

Annual report to Board by Human Research Ethics Committee

Evaluation:

This policy will be evaluated through review of research applications, monitoring the conduct of research, and regular review of the organisation's Research Policy and associated procedures.

All employees and honorary researchers must abide by this policy, its associated procedures and work within ethics approvals at all times. Breaches may result in disciplinary action.

Policy Review:

This policy will be reviewed at least every three years.

Key Words for Search:

Research; Human Ethics; Research Governance

Author / Contributors:

Name	Position	Service / Program
Dr Jason Goh	Acting Executive Director Medical Services/Chief Medical Officer	Medical Services
Dr Andrea Johannessen	Research Manager	Research Office

Policy Details:

Details		
Policy Number:	P18.0	
Manual:	Policy Manual	
National Standards	Clinical Governance	
Legislation Section:	Section H - Research	
Approval Date:	01/08/2010	
Review Date(s):	08/09/11, 15/08/13, 12/6/14, 14/07/2016, 11/07/2019	
Next Review Due:	11/07/2022	