ST VINCENT'S HEALTH AUSTRALIA

Serving, Seeing, Striving for something greater

St Vincent's Health Australia Group Policy

All SVHA policies must comply with the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, the Ethical Framework for Mary Aikenhead Ministries and the SVHA Ethics Policy.

SVHA Research

1. Purpose:

Policy Statement

This policy provides guidance on research practices across St Vincent's Health Australia (SVHA) and affiliated institutes. The policy provides a framework for health and medical research governance across SVHA facilities and affiliated institutions that collaborate with SVHA.

Objectives

To provide an overall policy statement of health and medical research including but not limited to the following:

- Research involving people, human biospecimens or human-derived data
- Research involving animals
- Research involving genetically modified organisms

Scope

All campuses of St Vincent's Health Australia and the individual research institutes and groups for whom St Vincent's Health Australia provides research governance and services.

2. Definitions and Key Concepts:

Definitions

The National Health and Medical Research Council Research defines research[1] as *'original investigation undertaken to gain knowledge, understanding and insight'.* It does not include routine testing and routine analysis of materials, components and processes as distinct from the development of new analytical techniques.

Research should be considered separately from quality assurance (also called peer review, quality improvement, quality activities, quality studies, program evaluation and audit such as medical, clinical, surgical or record audit). The National Health and Medical Research Council defines quality

[1] Australian Code for the Responsible Conduct of Research (2018) NHMRC

assurance[2] as *'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)'.*

Acronyms

AEC: Animal Ethics Committee
CHA: Catholic Health Australia
HREC: Human Research Ethics Committee
IBC: Institutional Biosafety Committee
NHMRC: National Health and Medical Research Council
OGTR: Office of the Gene Technology Regulator
RGU: Research Governance Unit
TGA: Therapeutic Goods Administration

3. Policy

3.1 Code of Conduct

All research must comply with the Australian Code for the Responsible Conduct of Research (2007, updated 2018) NHMRC, the National Statement on Ethical Conduct in Human Research (2018), the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2013), any other statutory requirements of State and Federal Legislation, and any other relevant guidelines.

In addition, as a Catholic organisation, all research must also comply with the Code of Ethical Standards (2001) CHA.

3.2 Responsibilities

3.2.1 **Human Research Ethics Committees** (HRECs) – the SVHA affiliated HRECs operate under the auspices of individual SVHA healthcare facilities. The main purpose of each HREC is to ensure that human research projects it reviews conform with the ethical standards demanded by:

- the community at large
- the statutory requirements of State and Federal legislation and
- the relevant guidelines of the National Health and Medical Research Council (2007) (NHMRC) plus updates.

and, in the case of research being performed in SVHA facilities, that it also conforms with the Code of Ethical Standards for Catholic Health and Aged Care Services (2001) and with the Policies of SVHA.

3.2.2 **Animal Ethics Committees** (AEC) - the SVHA affiliated AECs operate under the auspices of individual SVHA healthcare facilities. The main purpose is to ensure that animal research conducted at St. Vincent's Health Australia facilities and related institutions conforms to the ethical standards demanded by:

- the community at large

[2] When does quality assurance in health care require independent ethical review? (2004) NHMRC

- St Vincent's Health Australia
- the statutory requirements of relevant State and Federal legislation and
- the relevant guidelines of the NHMRC.

3.2.3 **Institutional Biosafety Committee** (IBC) - the SVHA affiliated IBCs operate under the auspices of individual SVHA healthcare facilities. The main purpose of the IBCs is to review and oversee critical biological safety and related policy and procedures, and to ensure compliance with statutory requirements of relevant State and Federal legislation, Australian Standards, AQIS and the relevant guidelines of the Office of the Gene Technology Regulator.

3.2.4 **Group Chief Research Officer** – The Group Chief Research Officer oversees the group health and medical research governance framework, research strategy, and research facilitation across the SVHA facilities and promotes collaborative relationships with affiliated and external institutions, including universities, government, advocacy bodies and industry.

3.2.5 **Directors of Research** – where appointed, the Director of Research at an SVHA facility is responsible for overseeing the health and medical research activities on site, the local research governance offices, and the development of research policy for their local St Vincent's Hospital facility.

3.2.6 **Research Governance Offices** - the main responsibility of each site research governance office is to ensure SVHA meets its research governance obligations and to provide executive support to St Vincent's research-related committees and their sub-committees. The research governance office must maintain databases of all research activities submitted to the committees and undertake mandated monitoring of research occurring on site at SVHA facilities.

3.2.7 **Departments Heads/Heads of Units** are responsible for authorising research projects in their area for submission to the relevant committee/s, and for overseeing research in their department/unit.

3.2.8 **Individual Researchers** are responsible for ensuring their project/s have been approved by the relevant committee/s and are conducted according to that approval.

3.3 Indemnity

3.3.1 **Research Participants** – in the event of injury, research participants are covered for compensation and treatment either under each Hospital's malpractice insurance or in the case of commercially funded research by the indemnity and insurance provided by the commercial sponsor, or in the event of research conducted on private patients by the researcher's own medical defence insurance.

3.3.2 **Committee Members** – All members of research ethics committees that operate under the auspices of individual SVHA healthcare facilities must be covered by the facility insurance that provides legal protection in respect of liabilities that may arise in the course of the conduct of the committee members' duties.

3.4 Financial Management

3.4.1 **Research projects** – there are policies and procedures in place at each SVHA health care facility to ensure that financial management supports the research function. This

includes:

- Annual financial reporting to funding bodies
- Annual auditing of St. Vincent's Hospital financial records by the Auditor General

3.4.2 **Research applications** – the SVHA facility governance processes must ensure that sufficient funds are available so that each project can be completed.

3.5 Data management

3.5.1 **Record of projects** – each SVHA facility must maintain a database/s in regard to research projects, departments and related information to enable research to be monitored and reported in an ongoing manner.

3.5.2 **Research records** -

- Research records are retained in accordance with State and Commonwealth guidelines.
- Human research records are maintained in accordance with State and Commonwealth privacy legislation.

3.6 Ethics/Project Approval Processes

3.6.1 Research involving animals does not commence until full approval has been granted by an appropriately credentialed Animal Ethics Committee

3.6.2 Research involving humans, human biospecimens and/or human data does not commence until full approval (both ethics and governance) has been granted by appropriately credentialed Human Research Ethics Committee and by the individual SVHA facility governance processes or other review body and any other relevant external body eg Therapeutic Goods Administration (TGA), Radiation Safety Committee.

3.6.3 Research involving genetically modified organisms does not commence/facilities are not used until full approval has been granted by appropriately credentialed Institutional Biosafety Committee and the OGTR, if relevant.

3.7 Consumer and Community Participation in Research

All ethics committees operating under the auspices of SVHA facilities have 'Lay' members who represent the community and take part in the decision-making process.

Where research specifically involves Aboriginal and Torres Strait Islander participants, assessment and advice must be sought from people familiar with the culture and practices of the Aboriginal and Torres Strait Islander people with whom participation in the research will be discussed.

3.8 Intellectual Property Rights and Publications Practices

SVHA facility staff are bound by the Intellectual Property Policy at the individual facility.

3.9 Project and risk management

All research must comply with the relevant State and Commonwealth legislation, guidelines and codes of practice as well as the Code of Ethical Standards of Catholic Health Australia and state jurisdictional guidelines.

- The application forms to HREC, AEC and IBC are developed and maintained to ensure compliance and risk management matters are addressed.
- Projects are monitored by the various committees and facilities inspected in accordance with State and Commonwealth requirements.

3.10 Complaints/Grievances and conflict of interest process

3.10.1 **Human Research** - Research recruits are advised of the complaints process via the information and consent form for the project

3.10.2 **Research involving animals** – appropriate complaint and grievance processes are in place for researchers and staff members.

3.10.3 **Research involving genetically modified organisms** – all research involving genetically modified organisms must be assessed by a credential Institutional Biosafety Committee and comply with the guidelines and legislation of the Office of Gene Technology Regulator.

4. Relevant References:

1. Australian Code for the Responsible Conduct of Research (2018).

Human Research

2. National Statement on Ethical Conduct in Human Research; NHMRC 2007 (Cth), updated December 2018.

3. Code of Ethical Standard, Catholic Health Australia 2001

4. Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)

5. Therapeutic Goods Act 2001

6. ARPANSA: Exposure of Humans to Ionizing Radiation for Research Purposes; 2005.

7. Guardianship and Administration Act 1986 (Vic)

8. Human Tissue Act 1982 (Vic)

9. Privacy Act 1998 (guidelines under Sections 95 and 95A) (Cth) (Revised 2015)

10. Health Records Act 2001 (Vic)

11. Statutory Guidelines on Research (under the Health Records Act 2001)

Research involving animals

12. Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 8th edition 2013

13. Gene Technology Act 2000 (Cth)

14. Australian Quarantine Act 1908 (Cth)

15. Prevention of Cruelty to Animals Act 1986 (Vic)

16. Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits 2004

Research involving genetically modified organisms

17. Gene Technology Act 2000 (Cth)

18. Gene Technology Regulations 2001 (Cth)

Policy Title:	Research Policy
TRIM Number:	D/2021/83300
Version:	*V1*
Portfolio:	Research
Keywords	*Research; Human Research; Animal Research; Genetically Modified Organisms*
Policy Applicable to	This policy applies to all SVHA group services, divisions, facilities, services, and the workforce involved in research.
Status	Current
Review Officer/Author(s):	Group Chief Research Officer
First Introduced:	*March 2020*
Last Review Date:	*N/A*
Summary of changes:	*N/A*
Next Review Date:	*March 2022*
Approval Committee:	SVHA Board Research and Education Committee
Approved Date:	*20 March 2020*