SESLHD POLICY COVER SHEET

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POSITION RESPONSIBLE FOR THE DOCUMENT	A/Prof Christopher White Director of Research
FUNCTIONAL GROUP(S)	Research
KEY TERMS	Research, ethics, research governance, research integrity
SUMMARY	This document sets out the principles that govern the conduct of research in the SESLHD and the responsibilities of the parties involved.

1. POLICY STATEMENT

Research is integral in driving quality, efficiencies and knowledge-based practice to achieve improved health care not only in delivering better treatments, therapies and services but also in supporting the development of a responsive and knowledgeable workforce.

Research within SESLHD is conducted in a culture defined by:

- Honesty and integrity
- Respect for human research participants
- Good stewardship of public resources used to conduct research
- Appropriate acknowledgement of the role of others in research
- Responsible communication of research results.

Research conducted within SESLHD is:

- Justified by its potential benefit in contributing to knowledge and understanding to improve social welfare and individual wellbeing
- Designed to ensure that respect for participants is not compromised by the aims of the research, the way it is carried out or by the results, and
- Conducted by persons qualified and competent, with experience appropriate for the research.

The responsible conduct of research is the collective responsibility of SESLHD and individual researchers.

2. AIMS

To promote high standards in the conduct of research within SESLHD and to ensure compliance with ethical standards, relevant legislation, regulations and policies.

3. TARGET AUDIENCE

All clinicians and managers

4. RESPONSIBILITIES

SESLHD will:

- Promote the responsible conduct of research – through the development and promulgation of policies and guidelines and educational activities to promote awareness of the principles outlined in these documents and to support high standards in the conduct of research

- Establish good governance and management practices – through the development of an appropriate research governance framework

- Inform and support staff – through formal training and continuing education

- Promote mentoring – through supervision of researchers and research trainees including advising on research ethics and the responsible conduct of research

- Promote and facilitate frameworks for the responsible conduct of research in collaboration with partner organisations and consistent with organisational values

- Ensure research involving human subjects for whom it is responsible whether patients or healthy volunteers will only be conducted by individuals with the appropriate scientific training and qualifications and under the supervision of a competent and appropriately qualified clinician

- Ensure a safe research environment – through implementation of Occupational Health and Safety policies and guidelines

- Ensure communities and consumers participate in the oversight of research through participation in research ethical review committees.

Researchers will:

- Conduct research in accordance with principles of responsible scientific conduct as detailed in the *Australian Code for the Responsible Conduct of Research*

- Conduct research with integrity, scholarship and scientific rigour

- Only participate in research that conforms to accepted ethical standards and that they are competent to perform

- Respect research participants and in the conduct of human research comply with ethical principles of integrity, respect for persons, justice and beneficence

- Manage conflicts of interest so that personal advantage does not affect ethical or scholarly implications

- Have a responsibility to ensure the safety of those involved in the research and follow proper practices for safety and security

- Ensure that their research findings are reported appropriately

- Acknowledge that research results and methods should be open to scrutiny by colleagues and available for peer review

- Comply with institutional procedures for research governance

- Demonstrate in all research activities accountability for good stewardship of resources to conduct research

- Comply with institutional policies in relation to research data retention, publication and authorship.

- Conduct clinical research in accordance with the
  - *(i) Principles of the Declaration of Helsinki (2008),*
  - *(ii) National Statement on Ethical Conduct in Human Research(2007)* and affiliated guidelines
  - *(iii) Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities (2018),*
  - *(iv) Keeping research on track II (2018) A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities (2018)*
  - *(v) Relevant legislation, regulations and policies* and,
  - *(vi) International Conference on Harmonisation Guideline for Good Clinical Practice(CPMP/ICH/135/95)*

- In the conduct of clinical research, the researcher who is designated as the Principal Investigator for a site will be responsible for the day to day conduct of the research and will ensure that
  - (i) written ethical and institutional approval is obtained prior to the commencement of the project
  - (ii) all aspects of the project are conducted so as to protect the interests of participants at all times and, unless a specific exemption has been given by the Human Research Ethics Committee, informed participant consent is obtained prior to recruitment into the project
  - (iii) the project is conducted in accordance with ethical and scientific approval, and
  - (iv) reports are submitted to the Human Research Ethics Committee in particular concerning the occurrence of Adverse events or information that may affect the continued ethical or scientific acceptability of the project .

5. DEFINITIONS

- **Research:** work which is undertaken on a systematic basis to create new knowledge and/or use existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings.

- **Clinical research:** is intended to produce knowledge essential for understanding human disease, preventing and treating illness and promoting health. It includes studies that either directly or indirectly involve a particular person or group of people or that uses material of human origin e.g. tissue samples or behaviour that can be linked to a particular person as well as population and epidemiological studies and health services research.

6. DOCUMENTATION

N/A

7. REFERENCES

7.1 Governing Ethical Principles:

- The Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th World Medical Association General Assembly, Helsinki, 1964 and last amended 64th WMA General Assembly, Fortaleza, Brazil (2013)
- National Statement on Ethical Conduct in Human Research. NHMRC (2007), updated 2018
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities (2018)
- Keeping research on track II (2018) A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities (2018)
- Australian code for the care and use of animals for scientific purposes, NHMRC (8th Edition 2013)
- National Framework of Ethical Principles in Gene Technology. Gene Technology Ethics and Community Consultative Committee (2012)
- Australian Code for Responsible Conduct of Research. NHMRC (2018)

Related Policies and Guidelines:

- NSW Ministry of Health Policy Directive PD2010_055 - Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations
- NSW Ministry of Health Policy Directive PD 2010_056 - Research – Authorisation to Commence Human Research in NSW Public Health Organisations
- NSW Ministry of Health Policy Directive PD2007_035 - Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials
- NSW Ministry of Health Guideline GL2007_020 - Human Research Ethics Committees: Quality Improvement & Ethical Review
- NSW Ministry of Health Guideline GL2013_009 – Human Research Ethics Committees: Standard Operating Procedures for NSW Public Health Organisations
- NSW Ministry of Health Guideline GL2010_014 - Operations Manual: Human Research Ethics Committee Executive Officers
- NSW Ministry of Health Policy Directive PD2011_006 - Clinical Trials: Insurance and Indemnity
- Research Governance Handbook. NHMRC (2011)
- NSW Ministry of Health Guideline GL2011_001 - Research Governance in NSW Public Health Organisations
- NSW Ministry of Health Guideline GL2010_015 - Operations Manual: Research Governance Officers

7.2 Legislation - Human Research:

- Anatomy Act 1997(NSW)
- Gene Technology Act 2000 and Regulations 2001 (Cth)

- Guardianship Act 1987 (NSW)
- Health Records and Information Privacy Act 2002 (NSW)
- Human Tissue Act 1983 and Regulation 2015 (NSW)
- Privacy Act 1988 (Cth)
- Privacy and Personal Information Protection Act 1998 (NSW)
- Research Involving Human Embryos Act 2003 (NSW)
- State Records Act 1998 (NSW)
- Therapeutic Goods Act 1989 and Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)

Related Policies & Guidelines:

- Privacy Manual for Health Information 2015 (NSW Health)
- Statutory Guideline on Research. Health Records and Information Privacy Act 2002 (NSW). Office of the Privacy Commissioner (2004)
- NSW Ministry of Health Policy Directive PD2015_037 - Data Collections – Disclosure of Unit Record Data Held for Research or Management of Health Services
- Accessing unapproved products (https://www.tga.gov.au/accessing-unapproved-products) (website accessed 03 Dec 2020)
- The Australian Clinical Trial Handbook. Therapeutic Goods Authority V2.2 (2018)
- Integrated Addendum to ICH E6(R1):Guideline For Good Clinical Practice E6(R2) (2016)
- NSW Ministry of Health Guideline GL2006_021 - Human Tissue – Requirements of the Human Tissue Act in relation to research and use of tissue
- NSW Ministry of Health Policy Directive PD2005_370 - Intellectual Property Arising from Health Research
- Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (RPS No. 8). Australian Radiation Protection and Nuclear Safety Agency.

7.3 Animal Research:

- Animal Research Act 1985 and Regulations 2010 (NSW) and related policies and guidelines (www.animalethics.org.au)

8. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
August 2013	1	Developed by Professor Margaret Rose, Research Governance
September 2013	2	Re-formatted by Scarlette Acevedo, District Policy Officer.
December 2020	3	Minor review. References updated by Andrew Bohlken, Research Development Manager. Approved by Executive Sponsor. Published by Executive Services.