**INTERNAL ONLY**

**ISLHD POLICY**

**COVER SHEET**

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| **NAME OF DOCUMENT** | Responsible Conduct of Research |
| **TYPE OF DOCUMENT** | Policy |
| **DOCUMENT NUMBER** | ISLHD CORP PD 25 |
| **DATE OF PUBLICATION** | November 2017 |
| **RISK RATING** | Low |
| **REVIEW DATE** | November 2022 |
| **FORMER REFERENCE(S)** | ISLHD OPS PD 25 |
| **EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR** | Chief Executive<br>Illawarra Shoalhaven Local Health District |
| **AUTHOR** | Clinical Director<br>Health & Medical Research |
| **KEY TERMS** | Research, Ethics, Research Governance, Research Integrity |
| **FUNCTIONAL GROUP OR HUB** | District |
| **NSQHS STANDARD** | Standard 1 |
| **SUMMARY** | This document sets out the principles that govern the conduct of research in the ISLHD and the responsibilities of the parties involved. |

**COMPLIANCE WITH THIS DOCUMENT IS MANDATORY**

Feedback about this document can be sent to ISLHD-CorporateGovernance@health.nsw.gov.au

# Responsible Conduct of Research — ISLHD CORP PD 25

## 1. POLICY STATEMENT

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

1.2 Research within the ISLHD 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

1.3 Research conducted within the ISLHD 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.

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

## 2. AIMS

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

## 3. TARGET AUDIENCE

All Clinicians and Managers

## 4. RESPONSIBILITIES

**ISLHD Management 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 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
- Conduct clinical research in accordance with the *National Statement on Ethical Conduct in Human Research* and affiliated guidelines and *The National Statement on Ethical Conduct in Human Research and Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*
- 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 and ensure that they acknowledge 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 institutions 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 (Updated May 2015)* and affiliated guidelines
(iii) *National Statement on Ethical Conduct in Human Research and Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)*
(iv) *Relevant legislation, regulations and policies, and*
(v) *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, 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 59th WMA General Assembly, Seoul (2008).*
- *National Statement on Ethical Conduct in Human Research. NHMRC* 2007 (Updated May 2015)
- *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. NHMRC (2003).*
- *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* (2007)

**Related Policies and Guidelines:**

- *Research – Human and Animal Research and the National Health and Medical Research Council Act 1992. NSW Health PD2010_057*
- *Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations. NSW Health PD2010_055*
- *Research – Authorisation to Commence Human Research in NSW Public Health Organisations. NSW Health PD 2010_056*
- *Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials. NSW Health PD2007_035.*
- *Human Research Ethics Committees: Quality Improvement & Ethical Review. NSW Health GL2007_020*
- *Human Research Ethics Committees: Standard Operating Procedures for NSW Public Health Organisations. NSW Health GL2013_009*
- *Operations Manual: Human Research Ethics Committee Executive Officers. NSW Health GL2010_014*
- *Clinical Trials: Insurance and Indemnity. NSW Health PD2011_006*
- *Research Governance Handbook. NHMRC (2011)*
- *Research Governance in NSW Public Health Organisations – NSW Health GL2011_001*
- *Operations Manual: Research Governance Officers. NSW Health GL2010_015*

### 7.2 Legislation – Human Research:

- *Privacy and Personal Information Protection Act 1998 (NSW)*
- *Privacy Act 1988 (Cth)*
- *Guardianship Act 1987 (NSW)*
- *Health Records and Information Privacy Act (2002)*
- *State Records Act 1998 (NSW)*
- *Therapeutic Goods Act 1989 and Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)*
- *Anatomy Act 1997 (NSW)*
- *Human Tissue Act 1983 and Regulation 2010 (NSW)*
- *Research Involving Human Embryos (NSW) Act 2003*
- *Gene Technology Act 2000 and Regulations 2001 (Cth)*

**Related Policies and Guidelines:**

- *Privacy Management Plan. NSW Health PD2015_036*
- *Statutory Guideline on Research. Health Records and Information Privacy Act 2002 (NSW). Information and Privacy Commission NSW (2004)*
- *Data Collections – Disclosure of Unit Record Data Held for Research or Management of Health Services. NSW Health PD2015_037*
- *Access to Unapproved Therapeutic Goods – Clinical Trials in Australia. Therapeutic Goods Authority (2004)*
- *Human Research Ethics Committees and Therapeutic Goods Legislation. Therapeutic Goods Authority. (2001)*
- *The Australian Clinical Trial Handbook. Therapeutic Goods Authority (2006)*
- *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Therapeutic Goods Authority (2000)*
- *Human Tissue – Requirements of the Human Tissue Act in relation to research and use of tissue. NSW Health GL2006_021*
- *Intellectual Property Arising from Health Research. NSW Health PD2005_370*
- *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 |
|---|---|---|
| May 2012 | 0 | Director Research Governance<br>Approved ISLHD Executive Clinical Management Committee April 2013. |
| May 2014 | 1 | Director Research Governance |
| September 2017 | 2 | Clinical Director, Health & Medical Research. |
| November 2017 | 2 | Approval - Chief Executive |