

**CENTRAL COAST LOCAL HEALTH DISTRICT (CCLHD)**  
*Research Governance Framework for the  
Responsible Conduct of Research*



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Local Health District

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## Table of Contents

<b>1 Introduction</b> .....	1
1.1 Purpose .....	1
1.2 Objective.....	2
1.3 Scope.....	2
1.4 Definitions .....	2
1.5 Distinction between Research Governance and Ethical Review.....	4
1.6 Principles of Research Governance .....	5
<b>2 Implementing the Research Governance Framework</b> .....	7
2.1 Research Committees.....	7
2.2 Process for Governance Review CCLHD .....	7
2.3 Monitoring Research Governance.....	8
<b>3 Research Quality</b> .....	9
3.1 Peer Review.....	9
3.2 Safety.....	9
<b>4 Research Outcomes</b> .....	14
<b>5 Ethical Considerations</b> .....	14
5.1 Monitoring Ethical Requirements.....	15
5.2 Multi-Centre Ethical Review .....	15
5.3 Low and Negligible Risk Research .....	15
5.4 Quality Improvement Activities .....	16
5.5 Audits.....	16
5.6 Data Management.....	17
5.7 Long Term Storage of Data and Materials.....	18
5.8 Privacy .....	19
<b>6 Publication and dissemination of research findings</b> .....	20
6.1 Communication with the Community .....	20
6.2 Research Publication .....	20
6.3 Authorship.....	21
6.4 Clinical Trials.....	21
<b>7 Collaborative Research Across Institutions</b> .....	23
<b>8 Building Research Capacity</b> .....	24
8.1 The Role of Research Supervisors.....	24
8.2 The Role of the Department .....	24
<b>9 Financial Management</b> .....	26
9.1 Joint Venture Contractual Agreement.....	26
<b>10 Risk Management</b> .....	27
10.1 Indemnity .....	30
10.2 Clinical Trial Research Agreements .....	30
10.3 Disclosure of Conflict of Interest.....	31
10.4 Disputes.....	31
<b>11 Roles and Responsibilities</b> .....	33
11.1 CCLHD Responsibilities .....	33
11.2 Researcher Responsibilities .....	33
11.3 Research Manager Responsibilities .....	34
<b>12 Appendices</b> .....	35
12.1 CCLHD Research Committee Terms of Reference (TOR). <b>Error! Bookmark not defined.</b>	

## 1 Introduction

Central Coast Local Health District (CCLHD) is committed to research and to its proper governance and conduct. It recognises the critical role that research plays in informing clinical practice and the health of the community. It also recognises that the experience of clinicians, patients and the community is essential in shaping the research agenda.

CCLHD seeks to develop and promote a research culture that reflects the organisation's core values: teamwork, honesty, respect, ethics, excellence, caring, commitment and courage, and that supports the goals of its strategic plan.

To assist CCLHD achieve its goals in the area of research, CCLHD has identified specific research strategic initiatives designed to:

- Encourage, support and coordinate research and innovation across the Central Coast Local Health District;
- Recognise and reward innovation and, wherever relevant, facilitate its application across the CCLHD; and
- Contribute to the evidence-base through research and evaluation.

Through these initiatives the CCLHD will ensure that the quality of the research undertaken within CCLHD services and facilities is first class and that it uses the available resources appropriately, while recognising that the primary focus of CCLHD is the quality of the care it offers its community, clients and patients.

This Research Governance Framework (the Framework) provides for the proper management and conduct of research within CCLHD. It supports the integration of research and health practice in the hope that patients and the community of the Central Coast area will receive clinical care and service delivery that reflect evidence and that research will address the health needs of the community.

### 1.1 Purpose

The Framework has been developed to define the requirements for and mechanisms by which effective governance of research is undertaken within its organisation. It reflects and reinforces the principles of the *Australian Code for the Responsible Conduct of Research* (2007).

The *Australian Code for the Responsible Conduct of Research* (2007) is supported by a range of policy and other documents (listed within this framework), which should also be read in conjunction with this document.

In June 2012, the *NSW Health and Medical Research Strategic Review* was released by NSW Health. The Review made 40 recommendations in relation to eleven themes, grouped under two strategies: foster translation and innovation from research; and build globally relevant research capacity. Whilst the recommendations indicate responsibility for a number of bodies, there are 10 for which Local Health Districts will have a direct responsibility. Specifically, in relation to Theme 11: Improve NSW Health Research Administration, recommendations were made to reform and enhance the research

governance functions within the NSW Local Health Districts. The Office of Health and Medical Research (OHMR) within the NSW Ministry of Health will be responsible for the implementation of many of the recommendations from the Review, which will flow on to the LHDs for implementation.

## 1.2 Objective

CCLHD seeks to establish a *Governance Framework for the Responsible Conduct of Research* which meets the specifications of the *Australian Code for the Responsible Conduct of Research (2007)*.

The framework specifies the roles, responsibilities and accountabilities of all those who play a part in research, and demands compliance with the laws, regulations, guidelines and codes of practice governing the conduct of research.

## 1.3 Scope

The Framework applies to the conduct of all research carried out within CCLHD facilities, by any CCLHD employee, or involving CCLHD employees, clients or patients, and research student placements in CCLHD. It also applies to individuals who have a contractual arrangement with CCLHD such as Visiting Medical Officers who conduct research within CCLHD facilities or whose research involves CCLHD clients or patients. It will not apply to the same individuals when they conduct research, or part thereof, in their private rooms, or without involving CCLHD clients or patients. In such cases the individuals will be responsible for their own research.

## 1.4 Definitions

In the context of this document the following definitions apply:

### ***Associate Investigator (AI)***

Associate Investigator means an investigator who provides intellectual input into the research and whose participation warrants inclusion of their name on publications.

### ***Coordinating investigator (CI)***

Coordinating investigator means an investigator who takes overall responsibility for the research project and submits the project for ethical and scientific review. The individual is responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators. For single centre research, Coordinating Investigator and Principal Investigator are synonymous.

### ***Department***

Department means a Department, Unit or Facility of CCLHD where the research will be conducted, including from where participants will be recruited.

### ***Principal Investigator (PI)***

Principal Investigator means the individual who takes responsibility for the conduct, management, monitoring and reporting of research at a CCLHD site.

**Research**

Research means original investigation undertaken to gain knowledge, understanding and insight. In the CCLHD it means research conducted at CCLHD sites, involving participants, their tissue or data accessed through NSW Health.

It includes “work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artifacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. (*Australian Code for the Responsible Conduct of Research, 2007*)

It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research. (*Research Assessment Exercise 2008: Guidance on submissions, 2005*)

**Researcher**

Researcher means any staff member or student carrying out research with the permission or under the auspice of CCLHD.

**Research Governance**

Research governance means the framework of principles, processes and standards of good practice set in place to achieve and continuously improve research quality. Appropriate governance of research requires institutions, their managers and their researchers to share responsibility and accountability for research conducted according to ethical principles, scientific and regulatory standards, and the principles of risk management. A research governance framework should describe the roles, responsibilities and accountabilities of all parties, and define the processes to be used for compliance, monitoring and on-going review of the quality of research. (*Harmonisation of Multi-centre Ethical Review (HoMER) Enabling System - Consultation Document, 2008*)

**Research Manager**

Research Manager means the individual appointed within the Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects and compliance with the CCLHD research governance framework.

**Scholarship**

Scholarship means the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines, in forms such as dictionaries, scholarly editions, catalogues and contributions to major research databases. (*Research Assessment Exercise 2008: Guidance on submissions, 2005*)

**Supporting Department**

Supporting Department means a department, unit or facility which provides services or support for the conduct of a research protocol, for example: medical records, pharmacy, pathology, imaging, radiology.

## 1.5 Distinction between Research Governance and Ethical Review

Research governance includes a range of accountabilities for the management and conduct of research; ethical review is only one element in research governance.

### ***Research Governance Accountabilities***

Research governance requires an organisation to undertake a variety of governance roles including:

- Determination and management of the resourcing of research;
- Management of contracts associated with research, including those contracts with collaborating institutions;
- Management of intellectual property, authorship and the publication of research results evolving from research in the organisation;
- Assessment of site capacity and operational approval to undertake research;
- Assessment of indemnity and/or insurance arrangements for clinical trials;
- Reporting to internal and external bodies in relation to the management, outputs and outcomes of research;
- Handling of complaints related to all aspects of the conduct of research;
- Auditing of research (to ensure adherence to relevant processes/requirements);
- Establishment, composition and monitoring of institutional Human Research Ethics Committees (HRECs); and
- Oversight and review of compliance with ethical review procedures.

### ***Ethical Review Accountabilities***

The accountabilities for ethical review bodies include:

- Assessment of the risks and benefits of proposed research;
- Assessment of the requirements for participants' consent;
- Evaluation of specific research methods, fields and participants;
- Determination of compliance with the requirements of the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007) of each research project; and
- Ensuring respect for, and protection of, the rights of research participants.

### ***Cross Over-Accountabilities***

There are a number of accountabilities which the organisation and the ethics committee share. These include:

- Consideration of the researcher's experience and/or qualifications;
- Monitoring of approved research; specifically, approving or authorising amendments, reviewing serious adverse events; and reviewing annual and final reports;
- Handling of complaints relating to all aspects of the conduct of research; and

- Establishing levels of ethical review for internal Medical Records (MR) reviews, Database Research (DR) Requests and Clinical Practice Improvement (CPI)/ Quality Improvement (QI) activities requiring ethical review.

These differences and synergies are important in determining the functions and mechanisms by which the Research Governance Framework is implemented and monitored within CCLHD.

## 1.6 Principles of Research Governance

The following principles reflect CCLHD's commitment to excellence in research and compliance with codes of conduct: (*Australian Code for the Responsible Conduct of Research, 2007; Harmonisation of Multi-centre Ethical Review (HoMER) Enabling System - Consultation Document, 2008; Responsible Conduct of Research Policy, 2008*):

- CCLHD requires that prior to its conduct, all research to be conducted by CCLHD staff within CCLHD facilities, directly or indirectly utilising CCLHD resources or involving CCLHD staff, clients or patients as participants is assessed for the following:
  - Scientific integrity
  - Quality
  - Safety
  - Feasibility
  - Risk management
  - Financial management
  - Ethical acceptability.
- CCLHD expects researchers to maintain high standards of responsible research which foster a research environment, distinguished by intellectual honesty and integrity, and scholarly, theoretical and scientific rigor.
- CCLHD encourages respect for freedom of expression and the open exchange of ideas.
- CCLHD expects researchers to ensure that they remain familiar with relevant legislation, policy and procedures relating to the responsible conduct of research.
- CCLHD will support access to appropriate induction, training, credentialing and mentoring of researchers.
- CCLHD requires researchers to adopt research practices which support a safe working environment in line with the New South Wales Occupational Health and Safety Act (2000), associated legislation and CCLHD's, safety and environment policies and procedures. (New South Wales Occupational Health and Safety Act (2000), 2009)
- Respect for the human participants involved in research and for the environment is a fundamental principle to be applied by all researchers. Researchers will comply with the National Statement on Ethical Conduct in Human Research and related codes of practice and legislation and all human research ethics policies current at any time. (National Statement on Ethical Conduct in Human Research, 2007)
- Where there is a suspicion that a breach of the Australian Code for the Responsible Conduct of Research (2007) or research misconduct has occurred

- there is a requirement to inform the Chief Executive or relevant Executive Director.
- Where allegations of a breach of the Code or research misconduct appear to be justified the Chief Executive or relevant Executive Director will determine whether a prima facie case exists in accordance with the Research Misconduct Allegation Guidelines. (To be developed).
  - In line with CCLHD's commitment to Indigenous peoples and culture, researchers will exercise sensitivity in any research associated with Aboriginal and Torres Strait Islander peoples. Researchers will comply with the guidelines under the NSW Aboriginal Health and Medical Research Committee and also the National Health and Medical Research Councils Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) and associated guidelines.(Hayes, Rowbottom, Davies, Parker, & Bashford, 2003) Further detail may be obtained in the Aboriginal Health Information Statement and Guidelines (Policy Directive) Where appropriate, CCLHD encourages and supports consumer involvement in research in line with the principles outlined in the NH&MRC Statement on Consumer and Community Participation in Health and Medical Research. (A Model Framework for Consumer and Community Participation in Health and Medical Research, 2004)
  - CCLHD supports the development and commercialisation of intellectual property in accordance with the CCLHD Intellectual Property Policy and Procedure, which is under development and the NSW Health policy (Intellectual Property Arising from Health Research - Policy - PD2005\_370, 2005).

## **2 Implementing the Research Governance Framework**

Implementing the CCLHD Research Governance Framework is the responsibility of CCLHD, through its Executive, the Research Committee, the Research Manager, department heads and researchers.

### **2.1 Research Committees**

#### **2.1.1. Research Committee**

A CCLHD Research Committee has been formed as a sub-committee of the CCLHD Board. The committee provides oversight of research governance activity in the CCLHD and strategic advice on the development of research capacity to the CCLHD Board and Executive. The committee performs the functions outlined in the attached Appendices (see attached Terms of Reference in Appendix 1).

#### **2.1.2 Research Operations Committee**

A Research Operations Committee will be developed to provide operational assistance and advice to researchers and for monitoring of compliance with governance for reporting to the Executive and Board sub-committee.

### **2.2 Process for Governance Review CCLHD**

As a participant in the NSW Health model for single ethical and scientific review of multi-centre research, CCLHD retains responsibility for authorising the commencement of research to be undertaken within the organisation. This authorisation is given in accordance with the *NSW Health Policy PD2010\_056 Authorisation to commence human research in NSW Public Health Organisations*.

CCLHD will undertake a site-specific assessment (SSA) of each research project, thereby allowing CCLHD to consider whether it has the organisational, human and financial capacity for the research in question to be conducted at that site. This SSA will involve consideration of such matters as human and financial resource implications, impacts on staff, and patient availability. This assessment however, does not constitute another ethics review.

#### ***Investigators***

Principal Investigators (PI) and Associate Investigators (AI) are responsible for the conduct of the research project at the site. They will ensure:

- That appropriate and timely approvals are obtained from the head of department and where relevant from the supporting department involved in the research project, thereby ensuring that each department is aware of the research project,
- That the researcher(s) involved in the project have the necessary skills and expertise to undertake their role, and
- That the department supports the conduct of the project and the associated use of departmental resources.

#### ***Chief Executive and T2 Executives***

The Chief Executive and Tier 2 Executives are responsible for understanding the requirements of research governance and the implications of approving the conduct of research. Managers of facilities will therefore be required to sign off the SSA, having read and understood the research proposal and accepted the implications of approving the conduct of the research for their services, facilities and human and financial resources.

### **2.3 Monitoring Research Governance**

The implementation of the Research Governance Framework will be monitored through the following mechanisms:

- All research funding will be accounted for and reported annually through the Director of Finance.
- All HREC and Site Specific requirements will be reported annually through the Research Manager.
- All research and associated outcomes including publications will be reported by researchers on their annual report to the CCLHD, which will be collated by the Research Manager and reported annually through the Director Clinical Governance.

CCLHD will also implement internal audits of research processes and research funding as per *NSW Health Guidelines, GL2011-001*.

### **3 Research Quality**

CCLHD is committed to ensuring that research undertaken by researchers is of the highest quality. The following processes are designed to ensure research quality.

#### **3.1 Peer Review**

Peer review refers to the impartial and independent assessment of research by others working in the same or a related field. (*Australian Code for the Responsible Conduct of Research, 2007*) It is an essential tool for researchers and institutions in maintaining standards of excellence and integrity. CCLHD acknowledges the importance of peer review and requires its researchers to participate in this process.

Those participating in peer review must undertake this process in a fair and timely manner, with due regard for the ethical and professional responsibilities the process demands.

Researchers should therefore:

- Act in confidence;
- Declare all conflicts of interest;
- Not permit personal prejudices to influence the process;
- Not take undue or calculated advantage of knowledge obtained;
- Ensure their awareness of and compliance with the criteria to be applied;
- Not participate in peer review outside their area of expertise; and
- Give proper consideration to findings that challenge accepted ways of thinking. (*Australian Code for the Responsible Conduct of Research, 2007; Responsible Conduct of Research Policy, 2008*)

Researchers in receipt of research funding have a responsibility to participate in peer review processes. Supervising researchers must assist trainee researchers in developing the necessary skills for peer review and in understanding their obligation to participate in the process.

CCLHD staff undertaking research as part of post graduate qualification (or similarly in the case of undergraduate students) must undertake and provide evidence of appropriate supervision by university staff pertaining to their research.

#### **3.2 Safety**

Research conducted within CCLHD must adhere to all safety requirements related to both the research procedures and the conduct of the research. The safety of both the participants and the researchers is paramount. This includes safety requirements when the research is to be conducted off-site; for example, at the participant's home or within the community. Such visits should be conducted in accordance with any relevant CCLHD departmental policies or procedures, any specialist-based home visit protocols and, where relevant, any University policies.

Researchers who are not current employees of CCLHD must undertake:

- Orientation in relation to relevant NSW and CCLHD Policies; and
- Adequate site orientation training when undertaking research on a CCLHD site (e.g. fire, manual handling, Work, Health and Safety).
- Provide evidence of a current Criminal Record Check (CRC) and Working with Children Check (where applicable).

### ***Participant Safety***

Researchers have the primary responsibility to ensure the safety of all participants in research conducted within CCLHD in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* and other relevant guidelines. (*National Statement on Ethical Conduct in Human Research, 2007*)

Where the participants in research are also patients of CCLHD, any policy and process relating to patient safety pertains.

Researchers are responsible for reporting all Adverse Events (AEs) and Serious Adverse Events (SAEs) to the approving Human Research Ethics Committee (HREC), TGA and Research Manager (acting as the Research Governance Officer RGO) CCLHD in accordance with the requirements of:

- Section 3.3.20 of the *National Statement on Ethical Conduct in Human Research (2007)*;
- Section 4.11 of the ICH *Harmonised Tripartite Guidelines for Good Clinical Practice (ICH Harmonised Tripartite Guideline - Guideline For Good Clinical Practice E6(R1) 1996; National Statement on Ethical Conduct in Human Research, 2007)*;
- The National Health and Medical Research Council's (NHMRC) Position Statement on the Monitoring and Reporting of Safety for Clinical Trials (June 2009);
- The Therapeutic Goods Administration (TGA) Act (1989);
- The TGA's Australian Clinical Trial Handbook (March 2006);
- NSW Health Policy Directive PD2007\_061; Incident Management (July 2007); and
- NSW Health Guideline GL2010\_015 Operational Manual Research Governance Officers (Sept 2010).

Serious adverse events are clinical incidents which will also need to be managed in accordance with PD2007\_061 Incident Management. Where serious adverse events occur to a CCLHD patients at a CCLHD site and the event is deemed to be a 'clinical incident' the event will require reporting through the Incident Information Management System (IIMS). Additionally, if an adverse event is determined to be a 'reportable incident' it will require a root cause analysis in accordance with Division 6C of the [Health Administration Act 1982](#).

The *NSW Patient Safety and Clinical Quality Program* defines the roles and responsibilities of Clinical Governance within CCLHD in relation to incident management, the establishment of sustainable incident reporting systems, and the investigation of incidents, including root cause analysis. (*Patient Safety and Clinical Quality Program - PD2005\_608, 2005*) Clinical Governance Staff, provide leadership, support and facilitation in these endeavors, working collaboratively with clinical staff, executives and managers to address issues relating to patient safety.

## **Clinical Trials Involving Therapeutic Products**

**In the case of** single centre research projects, the Principle Investigator is required to provide safety reports to the reviewing HREC.

For multi-center research projects, the principal investigator is required to report SAEs and Suspected Unexpected Serious Adverse Reactions (SUSARs) directly to the reviewing HREC with a copy of these to the Research Governance Officer (for CCLHD this is the Research Manager) and Co-ordinating Investigator. All other safety reports should be submitted to the reviewing HREC by the Co-ordinating Investigator.

Depending on the complexity, design and risk perceived, the reviewing HREC and/or CCLHD as the Public Health Organisation (PHO) have the discretion to require that additional information be reported, particularly for investigator initiated clinical trials. This is in accordance with the [NSW Operations Manual for Research Governance Officers, GL2010\\_015 \(September 2010\)](#)

The timelines for reporting the events are as set out in the [TGA's Australian Clinical Trial Handbook \(March 2006\)](#) and [GL2010\\_015 \(September 2010\)](#).

## **Other Human Research**

For research other than clinical trials involving therapeutic products, the reviewing HREC will determine the minimum requirement for safety reporting, including adverse event reporting.

Depending on the complexity, design and risk perceived, CCLHD as the PHO also has the discretion to require that additional information be reported. This is in accordance with the [NSW Operations Manual for Research Governance Officers GL2010\\_015 \(September 2010\)](#).

## **Reports**

Any reports received by the Research Manager which pertain to a CCLHD site will be tabled at the Operational Research Committee in the Risk Register. The Principal Investigator will then be advised of any subsequent action required as a result of an AE or SAE.

## **Bio Safety**

The CCLHD will establish formal agreements with established Institutional Bio-safety Committees (IBC). Given the relationship of CCLHD researchers with the University of Newcastle an arrangement will be established with the university's Institutional Bio-safety Committee (IBC) as a designated IBC for CCLHD. The ICB is responsible for the assessment, recommendations for management, and monitoring of the risks to the health and safety of people and the environment from activities undertaken for research and teaching purposes, which make use of genetically modified organisms, pathogenic micro-organisms, and other biological hazards.

The Institutional Bio-Safety Committee assists the CCLHD to meet the legislative requirements of the Gene Technology Act 2000. See link below:

<http://www.comlaw.gov.au/Series/C2004A00762>

As well as monitoring microbiological practice against *Australian Standards* and other aspects of Bio-safety related to research, particularly in the life sciences.<sup>15</sup>

### **Animal Care and Ethics**

At present research conducted under the auspices of the CCLHD does not involve animals. If required in the future an agreement will be established for peer review to be undertaken by the Animal Care and Ethics Committee of the University of Newcastle or any other appropriate partner.

This committee would be responsible for the consideration of ethical and welfare aspects of research involving animals as well as the scientific or educational value of the use of animals for research and teaching purposes.

Specifically it would be responsible for ensuring on behalf of the CCLHD that all care and use of animals for research was conducted in compliance with the *NSW Animal Research Act and Regulations*,<sup>16</sup> and the “*Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*”<sup>17</sup> The role of the committee would be to ensure that the use of animals was justified, and that the research provided for the welfare of the animals and incorporated the principles of replacement, reduction and refinement.

### **Radiation Safety**

The Radiation Safety Officer for CCLHD and Northern Sydney Local Health District (NSLHD) is responsible for ensuring CCLHD meets the legislative requirements of the *OH&S Regulation 2001, Chapter 6 Hazardous Substances, Radiation Control Act (NSW) 1990, The Code of Practice for the exposure of Humans to Ionizing Radiation for Research Purposes, Radiation Protection Series 8, May 2005 (Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)) and the ARPANSA Radiation Protection Series.*

The Radiation Safety Officer sits on the Joint Radiation Safety Assurance Committee of NS and CCLHD's along with the Director of Clinical Governance, CCLHD. The Director of Clinical Governance will feed any radiation issues identified within the CCLHD up to this Committee.

The Radiation Safety Officer will attend both the Gosford and Wyong sites one day per month and will be the main point of contact for Radiation Safety for CCLHD and the point of referral for Education & Training; Safety Reporting; Personal Dose Records; Compliance Checks; the Radiation Management Plan; and Research.

### **Occupational Health and Safety**

Researchers must adhere to CCLHD Occupational Health and Safety policies, any other relevant policies or regulations relating to health and safety and must obtain any safety clearance necessary for the conduct of their research. Specific examples of compliance include the following:

- Research involving the administration of cytotoxic drugs must reflect the NSW WorkCover Guidelines document for the handling of cytotoxic drugs and contaminated waste as outlined in NSW Health policy directive: Cytotoxic Drugs and Related Waste. (Cytotoxic Drugs & Related Waste - Safe Handling in the NSW Public Health System PD2008\_059, 2008).
- Where the research involves the handling and transfer of tissue samples, researchers must adhere to IATA (International Air Transport Association) Dangerous Goods Regulations (DGRs) and the requirements of the Australian Civil Aviation Act. (Civil Aviation Safety Regulations - Consignment and carriage of dangerous goods by air 1998; Dangerous Goods Regulations, 2008).. In addition to; the NSW Human Tissue Legislation Amendment Act 2012 No.72; the requirements of the National Health and Medical Research Council's (NHMRC's) National Statement on Ethics Conduct of Human Research (2007) and the Privacy Act 1988 (Australian).
- Researchers who conduct research requiring visits to families' homes must follow the procedures for ensuring their safety as set out in CCLHD Home Visiting Guidelines.

It is the responsibility of head of the department where the research is taking place to ensure that researchers are aware of and comply with these policies and procedures.

## 4 Research Outcomes

The CCLHD Research Committee will report annually on research activity for:

- Number of research projects (and title) approved and commenced in CCLHD
- Research educational activities undertaken in CCLHD
- Quantum of research grant funding (competitive and philanthropic) to CCLHD
- Number (and title) of research publications, reports and guidelines involving CCLHD staff
- Intellectual property commercialisation in CCLHD
- Number of research students and research fellowships employed by CCLHD or supported/supervised by CCLHD staff; and number of academic research higher degree completions at each tertiary organisation
- Research awards to CCLHD staff or students

## 5 Ethical Considerations

As part of its role in supporting research, CCLHD must demonstrate a collective responsibility for achieving high standards of professional conduct.

Researchers have an individual duty to ensure that their work enhances the reputation of CCLHD and the professional discipline to which they belong.

All research conducted within CCLHD must, before it commences, establish its compliance with the requirements of:

- [The National Statement on Ethical Conduct in Human Research \(2007\)](#); and
- [The Australian Code for the Responsible Conduct of Research \(2007\)](#)

and be reviewed and approved by an appropriately accredited lead HREC in accordance with the [NSW Health Policy PD2007 044 Research - Model for Single Ethical and Scientific Review of Multi-Centre Research](#) or an accredited HREC under the [Mutual Acceptance Initiative \(February 2012\)](#). The Mutual Acceptance initiative includes the acceptance of ethical and scientific review of multi-centre clinical trials in New South Wales, Queensland and Victorian Public Health Organisations.

Researchers must observe CCLHD's legislative responsibilities and policies relating to privacy of personal information used in research. It is the obligation of the researcher to enquire whether confidentiality applies and of the Principal Investigator to inform team or co-researchers of their obligations with respect to any such confidentiality requirements.

Research results and methods should be open to scrutiny by colleagues within CCLHD and, through appropriate publication, to peer review. Where confidentiality provisions apply, data must be kept in a way that access by third parties can occur without breaching confidentiality.

Confidentiality provisions in research contracts or separate confidentiality agreements may be entered into by CCLHD, the researcher and the client or sponsor of research.

Where such agreements limit publication and discussion, limitations and restrictions must be explicitly stated in the agreement.

All researchers should ensure that they are familiar with and comply at all times with the confidentiality obligations in research contracts.

## 5.1 Monitoring Ethical Requirements

All research conducted within CCLHD will be monitored in accordance with the requirements of the [National Statement on Ethical Conduct in Human Research \(2007\)](#) which in turn stipulates conditions of approval. These requirements from a site perspective for researchers include :

- Submission to the Research Governance Officer (RGO) of approved amendments and variations to the approved protocol by an approved NSW Health HREC prior to their implementation.
- Submission to the RGO of any Serious Adverse Events acknowledged by the approving HREC in addition to any other regulatory authorities, including the Therapeutic Goods Administration and trial sponsor or co-operative group.
- Submission of progress reports to the funding body annually from the date of initial approval as per the contractual requirements.
- Compliance with any special requirements of the approving HREC or RGO as set out in the letters of approval from both the HREC and site

## 5.2 Multi-Centre Ethical Review

Research undertaken under the auspices of CCLHD must be approved by a [Lead NSW Human Research Ethics Committee](#) under the [NSW Health System for Single Ethical and Scientific Review of Multicentre Research](#) or one of the HRECs accredited under the [Mutual Acceptance Initiative](#) from QLD or Victoria .

## 5.3 Low and Negligible Risk Research

Low and Negligible Risk Research undertaken under the auspices of CCLHD must be approved by a [Lead NSW Human Research Ethics Committee](#) under the [NSW Health System for Single Ethical and Scientific Review of Multicentre Research](#) or one of the HRECs accredited under the [Mutual Acceptance Initiative](#) from QLD or Victoria .

As per the [Operations Manual: Human Research Ethics Committee Executive Officers \(September 2010\)](#), HRECs will undertake an expedited review of Low/Negligible Risk Research. These will be reviewed by the HREC Executive Committee, comprising of a minimum of two members including the Chairperson or delegate and a member of the research office. The Executive will be at the discretion to request a full National Ethics Application (NEAF) if it deems a project to be considered more than low/Negligible Risk.

CCLHD cannot accept the ethical approval of a University or private organisation as these are not covered under the NSW Health model.

In addition, all projects will undergo Site Specific Assessment (SSA) prior to commencement at a CCLHD site.

## 5.4 Clinical Practice Improvement, Quality Improvement, and Research

Clinical Practice Improvement Projects (CPI) and Quality Improvement (QI) projects may sometimes require ethical review, for example:

- Where the project involves direct contact with patients
- Where the project involves the accessing of health information by those who are not members of the clinical care team
- Where the project is likely to generate data that may lead to publication.

CPI & QI Projects undertaken by CCLHD staff and participants of CCLHD will undertake a registration process. Participants will have their projects approved by appropriate managers prior to commencement of the project in line with the CCLHD Clinical Practice Improvement Projects (CPI) and Quality Improvement (QI) Policy.

If there is a need to publish a CPI or QI project or if the CCLHD CPI and QI Policy registration process identifies a project entails ethical risks these projects will be submitted to the Hunter New England (HNE) Lead NSW Health Human Research Ethics Committee for consideration. The HNE HREC will determine whether an exemption from ethics approval applies, proof of this exemption may be needed for publication purposes.

This process complies with the CCLHD's requirements under the [Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practice Guide for NSW \(GL2007 020\)](#).

## 5.5 Audits

CCLHD will submit Medical Records (MR) Research Reviews and Database Research (DR) Requests to the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC) for ethical review.

The NSLHD HREC Executive undertakes an expedited review of these types of applications. The HREC Executive consists of a minimum of two members including the Chairperson of the HREC or delegate and a member of the research office. The Executive is at the discretion to request further application if it is deemed that the project requires further ethical review.

## 5.6 Data Management

Research data and primary materials must be managed and stored securely to ensure that:

- Confidentiality and privacy are maintained;
- Methods and results are open to scrutiny;
- Outcomes can be validated;
- Materials can be accessed for further research if that is within the scope and intent of the original participant consent and ethics approval; and
- Responsibilities of CCLHD under NSW legislation and under its own policies in relation to privacy and records management are met.

CCLHD will provide appropriate policy, systems, facilities and procedures for the safe and secure storage of research data and materials, and for the maintenance of accurate records in relation to where these are stored. Research data and materials can be stored in electronic form.

Data management guidelines and procedures will comply with the relevant protocols for the collection, storage, retention, security and disposal of data and records including those prescribed by the *NSW Privacy and Personal Information Protection Act 1998*; *NSW Health Records and Information Privacy Act 2002*; *NSW State Records Act 1998* and CCLHD's policies and procedures. (*NSW Health Records and Information Privacy Act 2002, 2004*; *NSW Privacy and Personal Information Protection Act 1998, 2009*; *NSW State Records Act 1998, 2009*)

Data must be recorded in a durable and appropriately referenced form. Each department or research unit must establish procedures appropriate to their needs and requirements for the retention of data and for the keeping of records of data held. Data must be kept in a way that reference to them by third parties can occur, except where confidentiality applies.

Research data collected by researchers in CCLHD need to be safely held in CCLHD in accordance with the CCLHD policy for *Management of Clinical and Non Clinical Research Data (currently under development)*. A copy of this policy will be provided to the principal researcher following approval of the research application. Researchers are also required to comply with the CCLHD's legislative responsibilities and policies with respect to record keeping.

Research records that may be relevant to allegations of research misconduct must be retained until the matter is resolved.

Researchers, including those who leave CCLHD, may retain copies of their research data and primary materials, excluding patient records, but originals must be retained by the department/unit/service/centre and ultimately by the CCLHD Records Management Office to ensure protection of the researcher and CCLHD. Researchers are also responsible for making arrangements in relation to the management of their data, if the researchers leave CCLHD.

Researchers will be responsible for the security and confidentiality of the copies of data and materials that they retain. All copies produced must be clearly marked as “COPY” and must not be used as an original record in terms of adding further notations or documentation on the copy; otherwise this will no longer be a copy of the original record. Ownership of research data and primary materials will be determined in accordance with the CCLHD’s *Managing Research Data and Materials Policy Compliance - Procedure* currently under development) Ownership of and access to databases and archives will be determined in accordance with the [NSW Health Electronic Information Security Policy, PD2008\\_052](#) (September 2008) and CCLHD’s Security Information Plan as well as the *Managing Research Data and Materials Policy Compliance Procedure*.

The systems and specific services for the retention and storage of research data and materials implemented by CCLHD may be audited by CCLHD’s internal auditors. Individual researchers are able to hold copies of the data for their own use. Nevertheless, it should be understood that retention solely by the individual researcher provides little protection to the researcher or the institution in the event of an allegation of falsification of data.

## **5.7 Long Term Storage of Data and Materials**

Data and research records should be stored for 15 years for Clinical Research, at least five (5) years for non-clinical research ([NSW State Records 8.0.0 Research Management \(GDA17\)](#)) and until participants are at least 25 years if age for research involving children/adolescents under the age of 16 ([NSW State Records General Retention and Disposal Authority – Public Health Services: Patient/Client Records \(2011\)](#)). The data should be kept under secure conditions, after the completion of the research. This storage may be in as electronic or paper copies.

Materials of a biological origin must be retained in a suitable long term storage facility in accordance with state and national retention periods. Appropriate storage and management will be provided by CCLHD.

Researchers will be responsible for the security and confidentiality of the copies of data and materials they retain, particularly in relation to long term storage, including payment of archive costs. It is recommended where a project involves a commercial sponsor or funding partner that the researcher negotiates an appropriate budget for archiving costs to cover the duration of the study and record retention period. Researchers are also responsible for making arrangements in relation to the management of their data, if the researchers leave CCLHD.

National Health and Medical Research Council (NH&MRC) guidelines recommend that where materials of a biological origin are being used in a clinical trial or research project, records should be retained for appropriate periods of time to monitor effects and trace all participants in the event that late or long term effects emerge. Where the data are crucial to the substantiation of research findings and cannot readily be duplicated elsewhere, longer retention periods than those listed in the CCLHD Policy Compliance Procedure *Managing (Clinical and non-clinical) Research Data and Materials* may also be appropriate, (currently under development)

## 5.8 Privacy

CCLHD acknowledges and supports the importance of privacy and requires researchers to respect the privacy, confidentiality and cultural sensitivities of participants and, where relevant, of their communities. Participants are often easily identifiable, and the information they provide may be sensitive. Special care should be taken to protect the identity of participants when disseminating information and storing material.

The research, and specifically the management of the data from the research, must adhere to the NSW Privacy & Personal Information Protection Act, 1998, the NSW Health Records and Information Privacy Act (2002), and the *NSW Health Privacy Policy*. ([NSW Health Records and Information Privacy Act 2002, 2004; NSW Privacy and Personal Information Protection Act 1998, 2009; NSW State Records Act 1998, 2009](#)).

## 6 Publication and dissemination of research findings

Publication and dissemination of research findings are important parts of the research process supporting the translation of research into benefits for the community. At the same time, research findings that demonstrate the experimental treatment has no effect should also be reported.

Dissemination may take many forms from formal publication of the results in academic journals to web publishing or discussion in a public form. CCLHD acknowledges the importance of communicating the findings of its researchers to peers, professional organisations, stakeholders, participants in the research and the wider community. CCLHD encourages the wide dissemination of research findings in line with the provisions of the *National Statement on Ethical Conduct in Human Research 2007*.

### 6.1 Communication with the Community

Communication of research findings is supported by CCLHD's policies in relation to the media. The CCLHD Research Office and Corporate Communications units will provide assistance to researchers seeking to promote their findings including assistance with the media when required. CCLHD acknowledges that communication about research findings needs to be aligned to the research publication requirements set down by the *National Code on the Responsible Conduct of Research (2007)*.

### 6.2 Research Publication

Researchers must comply with national *Publication Guidelines* in relation to the identification of authors in peer-reviewed journals, and the presentation of results in a public forum. CCLHD staff are required to acknowledge their affiliation with CCLHD and comply with the criteria for authorship set out in the:

- Australian Code for the Responsible Conduct of Research (2007);
- Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (International Committee of Medical Journal Editors); (Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication 2008) and
- JAMA Authorship Responsibility, Financial Disclosure, Copyright Transfer and Acknowledgement (Graham, Bartholomeusz, Taboonpong, & La Brooy, 1988)

Accurate and professional publication of research findings is incumbent on all CCLHD researchers. In general, research findings must be correct, complete, comprehensive, sensitive to cultural differences, and mindful of ownership, attribution and confidentiality issues.

In disseminating research findings researchers must respect the rights of all parties to confidentiality, privacy and ownership of intellectual property.

The intellectual property rights of CCLHD, its researchers, research trainees and sponsors, and the rights to confidentiality of the parties involved, will be protected under the NSW Health, Intellectual Property Policy and Procedure (PD 2005\_370) and the Privacy Management Plan (PD2005\_554).

### 6.3 Authorship

To be acknowledged as an author, researchers must have made a substantial scholarly contribution to the work, and be prepared to take responsibility for that part of the work which they contributed. Substantial scholarly contribution to the work will be made through one or more of the following:

- Conception and design of the research; and/or
- Determination, analysis and interpretation of research data; and/or
- Drafting or revision of significant parts of the work so as to contribute to the interpretation.

Researchers must adhere to the authorship criteria identified above and must offer authorship to all and only those who meet those criteria. A person who qualifies as an author must not be included or excluded as an author of a publication without their permission, in accordance with the *Authorship of Research Policy*.(under development).

Where there is more than one author of a publication, one author (by agreement among the authors) should formally accept overall responsibility for the entire publication. Such formal acceptance must be in writing and kept on file in the department or research unit of that author, together with the names of all other authors.

A proper research process gives due recognition to all those who contribute to research. Authors should ensure that the work of research students/trainees, research assistants, technical officers and other staff is properly acknowledged. Reference in publications must be made to CCLHD contribution to the research.

The named authors of the publication must read the final paper and sign a statement:

- Indicating that each of them has met the minimum requirements for authorship;
- Acknowledging the author with overall responsibility for the publication.

Such a statement must include a declaration that there are no other "authors" of the publication according to the criteria in the CCLHD policy. If, for any reason, one or more co-authors is/are unable to sign the statement, the Head of the research unit or department may sign on their behalf, noting the reason for their unavailability. This statement should accompany the work to the publishers; a copy should be retained in the department or unit.

Publication of multiple papers based on the same set(s) or sub-set(s) of data is improper unless there is full cross-referencing (for example, by reference to a preliminary publication at the time of publication of the complete work which grew from it). Simultaneous submission to more than one journal or publisher of material based on the same set(s) or sub-set(s) of data should be disclosed at the time of submission.

### 6.4 Clinical Trials

Researchers must register clinical trials with a recognised register to promote access to information about all clinical trials. All clinical trials authorised within CCLHD after February 2013 should be registered with the NHMRC Australian and New Zealand

Clinical Trials Registry which is administered by the Clinical Trials Centre of the University of Sydney.

## **7 Collaborative Research Across Institutions**

Collaboration between researchers, between institutions, across state borders and with international researchers is recognised as supporting high quality and innovative research. There are however, particular research governance issues in relation to ownership of intellectual property, conflicts of interest and commercialisation of findings which must be addressed as part of participating in collaborative research. There must be clarity on all these issues prior to commencement of the research if the benefits of collaboration to all parties and to the community, are to be realised.

In any collaborative research arrangement an agreement will be put in place to outline the responsibilities of each party.

In general, issues of intellectual property and conflict of interest will be managed under the relevant NSW Health Policies (PD 2005\_370 and PD 2005\_554) and in accordance with external arrangements such as sponsorship.

## 8 Building Research Capacity

CCLHD is committed to building the CCLHD's research capacity. It recognises the role of supervisors in building that capacity. Appropriate mentoring and supervision of research trainees is critical to developing a research culture distinguished by excellence, integrity and professionalism.

- CCLHD will collaborate with external organisations, and any university involved in higher degree candidate supervision and training, to assist in facilitating appropriate training, supervision, mentoring and education of its research trainees.
- CCLHD will make available on-line resources i.e. Policies & Procedures etc. to research trainees including the Australian Code for the Responsible Conduct of Research (2007), the National Statement on Ethical Conduct in Human Research (2007) and all related policy documents.
- CCLHD will ensure research trainees are provided with basic training in all relevant CCLHD policies and procedures to encourage excellence, integrity and professionalism in research undertaken within CCLHD.

### 8.1 The Role of Research Supervisors

Research supervisors have a number of important roles and responsibilities. These include:

- Supervision of each research student/trainee (including honours, masters and doctoral students and postdoctoral fellows)
- Ensuring as far as possible that:
  - The ratio of research students/trainees to supervisors is small enough to ensure effective interaction, and effective supervision of the research at all stages;
  - The work submitted by research students/trainees is their own and that data collected is reliable and valid;
  - Professional relationships are encouraged at all times;
  - Peer review of research methodology and findings is undertaken;
  - Staff working on research projects are provided and comply with all relevant policies and conditions, and relevant CCLHD policies – outlined in a letter from the principal investigator when team members are engaged; and
  - Any intellectual property embodied in the research is protected appropriately according to the relevant CCLHD policies.
- Advising each research student/trainee of applicable government and institutional guidelines for the conduct of research, including those covering ethical requirements for studies on human or animal subjects, and requirements for the use of potentially hazardous agents.
- Acting as the primary source of guidance to research students/trainees in all matters of sound research practice.

### 8.2 The Role of the Department

In so far as researchers carry out their research within departments, departmental staff have a responsibility to adhere to the *Australian Code of Conduct for the Responsible*

*Conduct of Research and the CCLHD adaption of this policy of this under development).* The Head of Department has a responsibility to put in place procedures to facilitate and monitor the issues raised in this document.

Research undertaken in specific departments, facilities, units or divisions also has implications for supporting departments such as Pharmacy, Imaging and Pathology. The Head of Department has a responsibility to ensure that these supporting departments are aware of the research and have agreed to the research and its implications for their department.

## **9 Financial Management**

The NSW Health Policy Directive *Revenue Policy*, [Revenue Standard on Group Services/Commercialisation \(PD 2005 322\)](#) requires all external funds from research activities to be paid into the general revenue fund. This occurs unless funds are scheduled as a Special Purpose and Trust fund.

The NSW Health Policy Directive on [Research Governance in Public Health Organisations \(GL2011 001\)](#) states that Public Health Organisations are responsible for being aware of all research taking place within their premises, and reporting these activities to the public on an annual basis through their annual report.

CCLHD will instigate procedures for the accurate recording of all research income and expenditure for CCLHD including those funds paid into the general revenue funds or into special purpose and trust fund accounts. These will enable accurate reporting of all research income and expenditure. The accurate reporting of all research funds will support the securing of research infrastructure funds.

Recipients of research funds will therefore be required to inform CCLHD Finance that funds are specifically for research, CCLHD Finance will be required to identify funds as research funds in accounting procedures to enable accurate reporting.

All researchers will manage and account for the funding received in accordance with the relevant financial management practices. All records should be available for reporting and auditing purposes.

### **9.1 Joint Venture Contractual Agreement**

The development of any Joint Venture Contractual Agreements will be the responsibility of the Chief Executive and the CCLHD Board in consultation with the CCLHD Research Committee.

## 10 Risk Management

The NSW Health [Risk Management - Enterprise-Wide Policy and Framework, PD2009\\_039](#) - articulates the requirement for NSW Health entities to establish risk management practices in accordance with the [Australian/New Zealand Standard 4360:2004, Risk Management](#).

Under this framework all health entities are required to:

- Have a risk management plan that identifies how the organisation will manage, record and monitor risk, including procedures for escalating risk reports to the Chief Executive;
- Include risk management planning as a part of the strategic, operational and annual business planning activities of the organisation, its facilities and/or networks.
- Have a risk register that is used to record, rate, monitor and report risk; and
- Have an established process for monitoring and reviewing risk control and governance systems. (Risk Management - Enterprise-Wide Policy and Framework - NSW Health - PD2009\_039, 2009)

Within CCLHD, the Chief Executive is required to:

- Champion risk management within the organisation;
- Ensure appropriate resources are allocated to managing and monitoring risk and to implementing risk mitigation strategies identified through risk planning activities;
- Implement and keep current a risk management plan for the organisation;
- Consider risk in strategic planning and decision making;
- Ensure communication of risk management requirements to management and staff;
- Establish a risk register for the organisation that provides for the recording, monitoring and management of risk;
- Review and take appropriate action on risk reports escalated from within the organisation; and
- Determine the formal delegation of authority for various levels of management within the entity to accept risks or take – up opportunities.

CCLHD has an Audit and Risk Management Committee which operates in accordance with the [Model By-Laws](#), this Committee is Chaired by the Chief Executive of CCLHD. Additionally the Executive Risk Management Committee (See attached TOR in Appendices) has been established to oversee the framework, facilitate its implementation, monitor its effectiveness and report on outcomes.

The Audit and Risk Management Committee has the following core responsibilities:

- **Risk Management**

- Review whether management has in place a current and appropriate ‘enterprise risk management’ process, and associated procedures for effective identification and management of the organisation’s financial and business risks, including fraud and corruption
  - 
  - Review whether a sound and effective approach has been followed in developing strategic risk management plans for major projects or undertaking
  - Review the impact of the organisation’s risk management process on its control environment and insurance arrangements
  - Review whether a sound and effective approach has been followed in establishing the organisation’s business continuity planning arrangements, including whether disaster recovery plans have been tested periodically
  - Review the organisation’s fraud control plan and satisfy itself that the organisation has appropriate processes and systems in place to capture and effectively investigate fraud related information.
- **Control framework**
    - Review whether management’s approach to maintaining an effective internal control framework, including other external parties such as contractors and advisors, is sound and effective
    - Review whether management has in place relevant policies and procedures, and that these are periodically reviewed and updated
    - Determine whether the appropriate processes are in place to assess, at least once a year, whether policies and procedures are complied with
    - Review whether appropriate policies and procedures are in place for the management and exercise of delegations
    - Consider how management identifies any required changes to the design or implementation of internal controls
    - Review whether management has taken steps to embed a culture which is committed to ethical and lawful behaviour.
- **External accountability**
    - Review the financial statements and provide advice to the Chief Executive (including whether appropriate action has been taken in response to audit recommendations and adjustments), and recommend their signing by the Chief Executive
    - Satisfy itself that the financial statements are supported by appropriate management signoff on the statements and on the adequacy of the systems of internal controls
    - Review the processes in place designed to ensure that financial information included in the organisation’s annual report is consistent with the signed financial statements

- Satisfy itself that the organisation has a performance management framework that is linked to organisational objectives and outcomes.
- ***Compliance with applicable laws and regulations***
  - Determine whether management has appropriately considered legal and compliance risks as part of the organisation’s risk assessment and management arrangements.
  - Review the effectiveness of the system for monitoring the organisation’s compliance with applicable laws and regulations, and associated government policies.
- ***Internal audit***
  - Act as a forum for communication between the Chief Executive, senior management and internal and external audit
  - Review the internal audit coverage and annual work plan, ensure the plan is based on the organisation’s risk management plan, and recommend approval of the plan by the Chief Executive
  - Advise the Chief Executive on the adequacy of internal audit resources to carry out its responsibilities, including completion of the approved internal audit plan
  - Oversee the coordination of audit programs conducted by internal and external audit and other review functions
  - Review all audit reports and provide advice to the Chief Executive on significant issues identified in audit reports and action taken on issues raised, including identification and dissemination of good practice
  - Monitor management’s implementation of internal audit recommendations
  - Review the internal audit charter to ensure appropriate organisational structures, authority, access and reporting arrangements are in place
  - Periodically review the performance of internal audit
  - Consult with the Chief Executive when the Director of Internal Audit is to be appointed or removed from their position. In the case of an in-house internal audit function (where that function is the predominant role of that officer), consultation will include either the Chair of the Committee providing advice, or an independent member of the Committee participating in the selection process.
- ***External audit***
  - Act as a forum for communication between the organisation, senior management and internal and external audit
  - Provide input and feedback on the financial statements and performance audit coverage proposed by external audit and provide feedback on the audit services provided

- Review all external plans and reports in respect of planned or completed audits and monitor management’s implementation of audit recommendations
- Provide advice to the Chief Executive on action taken on significant issues raised in relevant external audit reports and better practice guides.

CCLHD requires that researchers include, in their research design, mechanisms to manage risk by preventing and dealing adequately with any harm that might occur, and implementing a monitoring process in the event of such harm.

The greater the risk to participants in any research project for which ethical approval is granted, the more important it is that:

- The risks are managed as well as possible, and
- The participants clearly understand the potential risks pertaining to their involvement in the research.

## 10.1 Indemnity

As part of the review of the research governance arrangements, the indemnity arrangements and any agreements between the sponsors/granting bodies and the investigators will be reviewed.

Indemnity arrangements for CCLHD investigator initiated trials are covered by the Treasury Managed Funds and their hospital insurance for CCLHD employees. A research Indemnity Risk Assessment must be completed and submitted for consideration by the Chief Executive/Delegate for all investigator initiated trials (conducted by CCLHD staff) prior to authorisation within CCLHD.

Non CCLHD employees will be indemnified by their respective organisations and will be asked to provide evidence of this indemnity specifically for the conduct of research.

A *Medicine’s Australia Indemnity Agreement* citing CCLHD as the Authority, must be signed for all Pharmaceutical Industry sponsored clinical trials as per the NSW Health mandatory Clinical Trials Insurance and Indemnity Policy, PD 2011\_006. In addition, a Certificate of Currency must be supplied which evidences the existence of an insurance policy that covers the conduct of the relevant clinical trial in Australia, with a minimum amount of coverage of \$20 million AUD (for any one occurrence and in the annual aggregate).

## 10.2 Clinical Trial Research Agreements

Each clinical trial to be conducted at a CCLHD site(s) under the control of a NSW Public Health Organisation and sponsored by an entity external to that Public Health Organisation must be governed by a written agreement clarifying the obligations, responsibilities and rights of the parties involved in the trial, in accordance with NSW Health, *Policy Directive PD2010\_056 Research – Authorisation to commence human research in NSW Public Health Organisations* and Policy Directive [PD2011\\_028, Clinical Trial Research Agreements for Use in NSW Public Health Organisations](#).

There are four Clinical Trial Research Agreements (CTRAs) that have been approved for use in NSW Public Health Organisations.

1. Standard Medicines Australia CTRA for Commercially Sponsored Trials;
2. Standard Medicines Australia CTRA for Contract Research Organisations acting as the Local Sponsor;
3. Standard Medical Technology Association of Australia CTRA; and
4. Standard Collaborative or Cooperative Research Groups CTRA.

The CTRAs are designed for use by different sponsors of clinical trials: Pharmaceutical companies; contract research organisations; medical device companies; and collaborative/cooperative research groups.

Any amendments to the standard wording in a CTRA or inclusions at Schedule 4/7 will be handled in accordance with [PD2011\\_028](#). Sponsors will have the opportunity to apply to NSW Health to have such amendments approved as standard clauses/wording or will alternatively choose to pay the cost for an external legal review of the agreement by NSW Health's preferred legal advisor.

### **10.3 Disclosure of Conflict of Interest**

Disclosure of any conflict or potential conflict of interest is essential for the responsible conduct of research.

Researchers are obliged to disclose to their academic supervisor, research team leader and co-researchers any affiliation with or financial involvement in any organisation or entity with a direct interest in the subject matter of the research or in the provision of materials for the research. The latter would include benefits in-kind, such as the provision of materials or facilities for the research and the support of individuals through the provision of benefits (for example, travel and accommodation expenses to attend conferences).

Where a research student's scholarship or studentship is funded by a company which has an interest in the research results and the academic supervisor has an interest in the company, the academic supervisor must disclose that interest at the time funds are awarded. Researchers who are staff members must disclose to their academic supervisors actual or perceived conflict between their personal interests and relationships and their duties and responsibilities as research staff of CCLHD.

### **10.4 Disputes**

Research Team member disputes or grievances arising out of the conduct of any research should be referred to the principal researcher for resolution or to the academic supervisor where relevant.

Grievances between staff members will be dealt with under NSW Health mandatory Policy Directive; [PD2010\\_007, Grievance- Effective Workplace Resolution](#).

Researchers who are not employees of CCLHD are not covered by internal procedures. A process to cover these researchers is to be developed.



## **11 Roles and Responsibilities**

The following is a summary of the roles and responsibilities of CCLHD, site managers, and researchers in relation to effective research governance.

While there are separate roles and responsibilities assigned to CCLHD, to researchers and to site or department managers, it is acknowledged that research is enhanced through a partnership approach among all those interested in, or undertaking, research within CCLHD.

### **11.1 CCLHD Responsibilities**

CCLHD is broadly responsible for the following:

- Research strategy and governance;
- Monitoring performance of research strategy;
- Developing systems for research outcomes reporting;
- Developing systems for research financial accounting and reporting;
- Ultimate authorisation of research project approval following ethical and site specific approval;
- Responding to results of audits of research ;
- Supporting and resourcing ethics approval and CCLHD Human Research Ethics Committee;
- Ensuring systems and procedures are in place for reporting and managing research misconduct; and
- Providing opportunities for ongoing education in research ethics and governance requirements.

### **11.2 Researcher Responsibilities**

Researchers have responsibility for the following:

- Conduct of research in line with research protocols and management of research resources;
- Ensuring compliance with:
  - Legislative and regulatory requirements;
  - Conditions of ethical and scientific approval;
  - Conditions of site approval;
  - Contractual requirements such as those under a clinical trial.
- Ensuring research protocols are subject to scientific and peer review prior to submission for ethical approval;
- Reporting of adverse or serious adverse events;
- Ensuring data collection reflects principles of confidentiality, and is in line with the consent provided by the participant(s);
- Effective data management;
- Declaring conflicts of interest;
- Reporting any concerns relating to research misconduct;
- Supervision and mentoring of research students and staff;

- Undertaking annual training in the Good Clinical Practice (GCP) requirements and other training in research ethics; in particular, the requirements of the NHMRC's National Statement on Ethical Conduct in Human Research (2007);
- Ensuring students and staff have appropriate training and credentialing, in research protocols and in policies and conditions for conducting research in CCLHD;
- Publishing results of research including positive and negative results; and
- Ensuring compliance with CCLHD employment, safety and other procedures and conditions.
- 12.3 Site or Department Manager Responsibilities

Site or Department Managers are responsible for:

- Approval of site specific assessments in the full knowledge of the impact of the research project on service activity and resources;
- Understanding of the full impact of the proposed research throughout the life of the project on site or department specific resources including those resources from other related departments such as pharmacy, imaging and pathology;
- Approving or denying a research project and its use of resources, on the basis of the impact of the research on clinical activity and budget, site or department resources including those resources from related departments such as pharmacy, imaging and pathology;
- Ensuring that research is conducted in accordance with relevant national research ethics (National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007) and the Australian Code for the Responsible Conduct of Research (2007)(Australian Code for the Responsible Conduct of Research, 2007; National Statement on Ethical Conduct in Human Research, 2007) and research conduct guidelines and any specific conditions of its approval by the local research and ethics governance process.
- Ensuring ethical and scientific approval has been obtained;
- Ensuring researchers and research staff have the appropriate experience, qualifications and competence to manage the research project;
- Ensuring all staff or volunteers working on the research project in CCLHD facilities have undertaken orientation to the site and comply with CCLHD policies;
- Ensuring the research project has been costed appropriately with sufficient funds to cover all aspects of project;
- Documenting agreement with external entities on the management of collaborative research; and
- Supporting and effective data management.

### **11.3 Research Manager Responsibilities**

The Research Manager is responsible for:

- Ensuring that evidence required for site authorisation is in place;
- Assessing the risk of a research project and providing a recommendation to the Chief Executive Officer or delegate;
- Authorising the commencement of Low and Negligible Risk research in CCLHD facilities;

- Granting site authorisation through the NSW Health Request to Access process whereby access is granted to participants, tissue or data for research to be conducted at another site;
- Working with CCLHD Finance in relation to the accounting of research funds;
- Ensuring that researchers are aware of contractual obligations and insurance requirements for the research project;
- Ensuring procedures are in place for review of site specific assessment approvals;
- Ensuring audits of research processes and funding occur and providing recommendations to the CCLHD Executive to address results of audits;
- Documenting research activities via a database of research studies; and
- Disseminating reports on research activities undertaken in CCLHD.
- Implementation of the Research Governance Framework for the Responsible Conduct of Research.
- Ensuring compliance with relevant policies, procedures and legislation including reporting to key bodies such as the NHMRC, Office of Health and Medical Research and Privacy NSW.
- Managing Bequests and Donations targeted for Research and ensuring there is an appropriate Committee, process and reporting mechanism for the management of these funds.
- Ensuring Action of the outcomes of both the Research Board Committee and Operational Research Committee.

## **12 Appendices**

### **12.1 Implementation Plan**