

## Research Governance in NSW Public Health Organisations

**Summary** This guideline summarises the principles, standards and requirements for the responsible conduct of quality research. It also clarifies the responsibilities and accountabilities of key parties involved in research taking place in NSW Public Health Organisations.

**Document type** Guideline

**Document number** GL2011\_001

**Publication date** 25 January 2011

**Author branch** Office for Health and Medical Research

**Branch contact** 9391 9920

**Review date** 31 December 2024

**Policy manual** Patient Matters

**File number** 05/7283-4

**Previous reference** N/A

**Status** Review

**Functional group** Corporate Administration - Governance  
Clinical/Patient Services - Research, Governance and Service Delivery

**Applies to** Local Health Networks, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Public Health Units

**Distributed to** Public Health System, NSW Ambulance Service, Ministry of Health

**Audience** Research office staff; Directors of Research; Heads of Depts hosting & supporting research

## RESEARCH GOVERNANCE IN NSW PUBLIC HEALTH ORGANISATIONS

### PURPOSE

The purpose of this guideline is to facilitate and support the responsible conduct of quality research in NSW Public Health Organisations through an effective research governance framework.

### KEY PRINCIPLES

Health and medical research is integral to quality health care systems. It leads to improved health outcomes through enhanced prevention and treatments, and changes in professional practice. Engaging in research activities to advance health and wellbeing is encouraged and supported by NSW Health as part of its overall commitment to improving the health of the people of New South Wales (NSW).

While investing in health and medical research can lead to far-reaching benefits for the wider community, it also has the potential to involve risk; risk to participants, institutions, and investigators. Public support, confidence and trust in research conducted in NSW Health is reliant upon an effective governance framework which manages these risks and ensures that all research meets the highest ethical, scientific, regulatory and professional standards.

### USE OF THE GUIDELINE

This guideline summarises the principles, standards and requirements for the responsible conduct of quality research. It also clarifies the responsibilities and accountabilities of key parties involved in research taking place in NSW Public Health Organisations.

Public Health Organisations are responsible for using this guideline to develop their local operating procedures which clearly define the roles, responsibilities and accountabilities of parties involved in research taking place within their premises. The local operating procedures should also define systems and processes to ensure compliance with the principles, standards and requirements of associated legislation and NSW Health policy directives as outlined in this document.

**Chief Executives** of Public Health Organisations are responsible for ensuring that appropriate research governance personnel, systems and structures are in place (section 4.1).

Specific responsibilities and accountabilities apply to **investigators** (section 4.2).

**Directors of research** or their equivalent, **Research Governance Officers**, **heads of departments** who host and support research and **managers of investigators** all play a key role in research governance (section 4.3).

**All parties** involved in research taking place in Public Health Organisations, regardless of their position, employment status and level of engagement in the research are responsible for familiarising themselves with and adhering to the principles, standards and requirements outlined in this guideline.

## REVISION HISTORY

Version	Approved by	Amendment notes
January 2011 (GL2011_001)	Deputy Director- General Population Health and Chief Health Officer	Issue of new Guideline: Research Governance in NSW Public Health Organisations. Rescinds PD2005_207 <i>Research Activities Reporting Responsibilities of AHS</i>
July 2001 (PD2005_207)	Director-General	Previously circular 2001/66

## ASSOCIATED DOCUMENTS

Research Governance in NSW Public Health Organisations: Guideline

***Research Governance in NSW Public Health  
Organisations***

**NSW**  **HEALTH**  
GUIDELINE

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**Issue date:** January 2011

GL2011\_001

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## **1 Background**

### **1.1 Research governance**

- (1) Research governance can be defined as the framework by which institutions, investigators and their managers share responsibility and accountability for research conducted according to ethical principles, scientific, regulatory and professional standards and the principles of risk management. The framework should describe the roles, responsibilities and accountabilities of all parties and define the processes used to ensure compliance, monitoring and ongoing review of the quality of research. The framework should foster an organisational culture which:
  - places the interests of research participants first;
  - promotes excellence and integrity in research through accountability, responsibility, honesty and transparency;
  - actively works to prevent or minimise adverse events, and to avert poor performance and research misconduct; and
  - encourages a research environment where ongoing education, learning and improvement are supported.
- (2) Effective research governance ultimately depends on the commitment of all parties to understand and administer their roles and responsibilities. Ethical and scientific review by an appropriately constituted Human Research Ethics Committee or Animal Ethics Committee, for example, is just one aspect of a broad system of oversight and management of the conduct of research.
- (3) In aiming to meet the principles, standards and requirements outlined in this document, it is important to remember that any systems and processes that are implemented apply to the full range of research that takes place in NSW Public Health Organisations. Systems and processes to ensure good research governance must facilitate, not hinder, quality research. This requires an exercise of judgement based on an understanding of the context, research methods and risks involved by all parties involved in the governance of research.

### **1.2 About this document**

- (1) This guideline summarises the principles, standards and requirements for the responsible conduct of quality research. It also clarifies the responsibilities and accountabilities of key parties involved in research taking place in NSW Public Health Organisations.
- (2) Section 2 of this document summarises the principles and standards articulated in key national guidelines on research ethics and governance.
- (3) Section 3 gives a summary of requirements pursuant to key legislation and NSW Health policy directives that relate to governance of research taking place in NSW Public Health Organisations.

- (4) Section 4 describes the specific responsibilities and accountabilities of investigators, Public Health Organisations and the Department of Health.
- (5) The Department may release updates to this document from time-to-time, to take account of changes in laws, policies, guidelines and codes.

### **1.3 Scope**

- (1) This document applies to all research that takes place in NSW Public Health Organisations. This means research (i) conducted at sites under the control of Public Health Organisations; and (ii) involving participants, their tissue or data accessed through Public Health Organisations. It applies to the full spectrum of research: biomedical, clinical, public health and health services research.
- (2) For the purpose of this document, the meaning of research is that used in the *Australian Code for the Responsible Conduct for Research (2007)*: “original investigation undertaken to gain knowledge, understanding and insight”.
- (3) Activities other than research are considered outside the scope of this document. These may include quality assurance or improvement activities, clinical audit, management of health services activities and teaching.

### **1.4 National context**

- (1) This Guideline is founded on three key publications which provide a national framework for research governance:
  - *National Statement on Ethical Conduct in Human Research (2007)* by the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors’ Committee (*National Statement*);
  - *Australian Code for the Responsible Conduct for Research (2007)* by the National Health and Medical Research Council, Australian Research Council, and Universities Australia (*Research Code*); and
  - *Australian code of practice for the care and use of animals for scientific purposes (2004)* by the National Health and Medical Research Council (*Animal Research Code*).
- (2) These publications, in turn, incorporate or complement established guidelines and codes of practice from national and international authorities and professional bodies. The three publications can be accessed from <http://www.nhmrc.gov.au/guidelines/index.htm>

### **1.5 Key definitions**

#### **Adverse event**

For medicines, also referred to as **adverse experience**, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign, symptom, or



disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

For devices, any undesirable clinical occurrence in a subject whether it is considered to be device related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.

[Ref: *Access to unapproved therapeutic goods via the Special Access Scheme* (2009) available from <http://www.tga.gov.au/> ].

**Animal Ethics Committee (AEC)** is a committee constituted in accordance with the terms of reference and membership laid down in the *Australian code of practice for the care and use of animals for scientific purposes* (2004).

**Animal Research Code** is the *Australian code of practice for the care and use of animals for scientific purposes* (2004)

**Clinical trial** means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

[Ref: *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments* available from <http://www.tga.gov.au/> ].

**Co-ordinating Investigator** is the individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators. For single centre research, Co-ordinating Investigator and Principal Investigator are synonymous.

**Human research** is research conducted with or about people, or their data or tissue as described in the *National Statement on Ethical Conduct in Human Research* (2007).

**Human Research Ethics Committee (HREC)** is a committee constituted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) to review and where appropriate approve and monitor the ethical and scientific aspects of human research.

**Multi-centre research** is research that is conducted at more than one site within the NSW public health system, where those sites are within the jurisdiction of more than one NSW Health HREC.

**National Statement** is the *National Statement on Ethical Conduct in Human Research* (2007).

**NSW Health** means the NSW public health system and the Department of Health.

**NSW Health HREC** is an HREC established by a Public Health Organisation and registered with the National Health and Medical Research Council.

**NSW public health system** as defined in section 6 of the *Health Services Act 1997* (NSW) consists of all the local health networks, all the statutory health corporations, all the affiliated health organisations in respect to its recognised establishment and recognised services, and the Director-General with respect to health support and ambulance services.

**Principal Investigator** is the individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the project for site authorisation.

**Public Health Organisation** as defined by section 7 of the *Health Services Act 1997* (NSW) is a local health network, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services.

**Research Code** is the *Australian Code for the Responsible Conduct for Research* (2007).

**Research Governance Officer** is 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.

**Research taking place in Public Health Organisations** means research (i) conducted at sites under the control of Public Health Organisations; and (ii) involving participants, their tissue or data accessed through Public Health Organisations.

**Reviewing HREC** is the HREC which undertook ethical and scientific review and provided ethical and scientific approval for the research project.

**Serious adverse event (SAE):**

For medicines, also referred to as **serious adverse drug reaction**, any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening;
- requires in-patient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.

NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe.

For devices is any adverse medical occurrence that:

- led to a death;
- led to a serious deterioration in health of a patient user or other. This would include:
  - a life threatening illness or injury;
  - a permanent impairment of body function or permanent damage to a body structure;
  - a condition requiring hospitalisation or increased length of existing hospitalisation;
  - a condition requiring unnecessary medical or surgical intervention; or
  - foetal distress, foetal death or a congenital abnormality/birth defect;
- might have led to death or a serious deterioration in health had suitable action or intervention not taken place. This includes:
  - a malfunction of a device such that it has to be modified or temporarily/permanently taken out of service; or
  - a factor (a deterioration in characteristics or performance) found on examination of the device.

[Ref: *Access to unapproved therapeutic goods via the Special Access Scheme* (2009) available from <http://www.tga.gov.au/> ].

**Site** is a facility, location or service where research is actually conducted.

**Site authorisation** is the authorisation granted by the Chief Executive or delegate of the Public Health Organisation for the commencement of a research project.

**Therapeutic good** is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under section 7 of the *Therapeutic Goods Act 1989*). Therapeutic use means use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
- influencing inhibiting or modifying a physiological process;
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; or
- replacement or modification of parts of the anatomy.

[Ref: <http://tga.gov.au/docs/html/tga/tgaginfo.htm>, last accessed 12/10/2010]

## 2 Principles and standards

### 2.1 Introduction

- (1) This section summarises the principles and standards articulated in the *National Statement*, *Research Code* and *Animal Research Code*. They are presented under the following broad areas: ethics, science, dissemination of research outcomes and findings, and research management.
- (2) All parties involved in research taking place in NSW Public Health Organisations are responsible for being familiar with and adhering to the *National Statement*, *Research Code* and *Animal Research Code*.

### 2.2 Ethics

#### 2.2.1 Human research

- (1) The safety, dignity, rights and wellbeing of research participants must be given priority over all other interests at all times.
- (2) Research must be designed, reviewed, and conducted according to the values of respect for human beings, research merit and integrity, justice, and beneficence.
- (3) The likely benefit of research must justify any risks of harm or discomfort to participants.
- (4) A person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. Research must meet the requirement for consent – that participation be the result of choice made by participants – based on this principle. Where the individual lacks the capacity to consent, a person or appropriate statutory body exercising lawful authority for the individual must be provided with sufficient information to decide whether that individual will participate. That decision should be in the participant's best interests.
- (5) Pursuant to the *National Statement*, the requirement for consent may sometimes be waived justifiably, but respect for human beings must always be shown in any alternative arrangements. Refer also to some of the legislative requirements outlined in section 3.2.6.

#### 2.2.2 Use of animals in research

- (1) Use of animals in research must be justified, taking into consideration the scientific or educational benefits and the potential effects on the welfare of animals. Research using animals must adhere to the principles of Replacement, Reduction and Refinement. Refer also to section 3.2.9.

#### 2.2.3 Conflicts of interest

- (1) Conflicts of interest must be disclosed and dealt with properly. The interest may be personal, professional, financial or institutional. Both actual and apparent conflicts

of interest that could compromise judgements and decisions that should be made impartially must be declared and managed.

## **2.3 Science**

- (1) Research must be of high scientific quality. It must be:
  - designed or developed using methods appropriate for achieving the aims of the research proposal; and
  - based on a thorough study of current literature, as well as previous studies.
- (2) Research must be conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research. Investigators and supervisors must ensure that the role model they provide to junior colleagues is positive and conducive to a research culture of excellence, integrity, professionalism and mutual respect. In return, research trainees must understand that in undertaking research they are joining an endeavour that requires dedication and accountability.
- (3) Research must be conducted using appropriate facilities and resources, such as specialist equipment, material and support staff suitable for the research.

## **2.4 Dissemination of research outcomes and findings**

- (1) Publication and dissemination of research outcomes and findings, whether favourable or unfavourable, is an important aspect of the research process, passing on the benefits to other investigators, professional practitioners and the wider community.
- (2) Research outcomes and findings must be accurate and should be subject to peer review.
- (3) Research outcomes and findings should be made accessible to research participants in a way that is timely and clear.
- (4) Clinical trials should be registered with a recognised register to promote access to information.
- (5) In some cases, sponsors or research funders may seek to delay or otherwise restrict the release of research outcomes and findings. Any such delay should not be beyond the time needed to protect intellectual property and other relevant legitimate interests.
- (6) Authorship on publications should be based on substantial contribution in a combination of:
  - conception and design of the project;
  - analysis and interpretation of research data; and
  - drafting significant parts of the work or critically revising it so as to contribute to the interpretation.

- (7) A person who qualifies as an author must not be included or excluded as an author without their written permission.
- (8) Refer also to *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications* by the International Committee of Medical Journal Editors.

## **2.5 Research management**

### **2.5.1 Management of research material and data**

- (1) While it may not be practical to keep all primary research material (e.g. biological material, questionnaires, recordings, clinical and other records), durable records derived from them (e.g. assays, test results, transcripts, laboratory notes) must be stored, retained and disposed of in compliance with legislation, policies and guidelines.
- (2) Research material and data must be accessible, unless this is prevented by ethical, privacy or confidentiality reasons. Individuals requesting access must be informed of relevant confidentiality agreements and restrictions on use.
- (3) Where the research uses materials of biological origin, or other materials where there is limited experience of their long-term use, records should be preserved for long enough to enable participants to be traced in case evidence emerges of late or long-term effects.
- (4) If the results from research are challenged, all relevant data and primary materials should be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.
- (5) Refer also to section 3.2.10.

### **2.5.2 Finance**

- (1) There must be good stewardship of public resources used to conduct research. Refer also to section 3.3.6.

### **2.5.3 Risk**

- (1) Risks to participants, research team, organisation and others involved in research must be identified, gauged and minimised. Mechanisms must be put in place to monitor and manage harm that occurs. Refer also to section 3.3.7.

## 3 Legislation and NSW Health policies

### 3.1 Introduction

- (1) This section provides a summary of key legislation and NSW Health policy directives that relate to the responsible conduct of research, as at the date of publication of this document. Other legislation, NSW Health policy directives and guidelines may apply to research taking place in NSW Public Health Organisations. This document should not be read as a substitute to referring to current version of the enacted legislation, available online at the NSW Parliamentary Counsel website. <http://www.legislation.nsw.gov.au>
- (2) Section 3.2 summaries the main legislation. NSW Health policy directives or guidelines that directly relate to a piece of legislation are also listed under the appropriate heading in this section.
- (3) Section 3.3 covers NSW Health policy directives that specifically relate to governance of research taking place in Public Health Organisations.
- (4) All parties involved in research taking place in Public Health Organisations are responsible for complying with all relevant legislative and NSW Health policy requirements.

### 3.2 Legislation

#### 3.2.1 National Health and Medical Research Council Act

- (1) The National Health and Medical Research Council (the NHMRC) operates under the *National Health and Medical Research Council Act 1992 (Cth)*. Under that Act, provision of assistance from the Medical Research Endowment Account (including funding through the NHMRC Funding Schemes) is conditional on recipients complying with guidelines issued by the NHMRC relating to the conduct of medical and health research.
- (2) Policy Directive PD2010\_057 *Research - Human and Animal Research and the National Health and Medical Research Council Act 1992* outlines the requirement to comply with the *National Statement, Research Code, Animal Research Code* and other relevant guidelines published by the NHMRC (Refer also to section 3.3.1).
- (3) The *NSW Supplement to the National Statement on Ethical Conduct in Human Research* provides guidance on how NSW laws and other requirements of NSW Health relate to requirements of the *National Statement*.

#### 3.2.2 Privacy

- (1) Privacy obligations for NSW Health arise from two separate laws: the *Privacy and Personal Information Protection Act 1998 (NSW)*, which regulates personal information; and *Health Records and Information Privacy Act 2002 (NSW)*, which regulates personal health information in the NSW public and private sector.

- (2) Policy Directive PD2005\_593 *Privacy Manual (Version 2) – NSW Health*, provides a guide to the legislative obligations imposed on the health system by the *Health Records and Information Privacy Act 2002 (NSW)*.
- (3) Other pieces of legislation also impose specific controls on when and how information can be used and disclosed in the health system. These include:
  - *Health Administration Act 1982 (NSW)*;
  - *Mental Health Act 2007 (NSW)*;
  - *Public Health Act 1991 (NSW)*;
  - *Government Information (Public Access) Act 2009*; and
  - *Health Care Liability Act 2001*.
- (4) The Commonwealth *Privacy Act 1988* binds the private sector in NSW including non-government organisations and private health sector providers (such as individual medical practitioners and private hospitals). These organisations and providers may conduct research with, or using information provided by, Public Health Organisations.
- (5) Research involving the collection, use and disclosure of personal health information must satisfy the conditions set out in the *Statutory Guidelines on Research* issued by the NSW Privacy Commissioner under the *Health Records and Information Privacy Act 2002 (NSW)*. This applies to both the NSW public and private sector.
- (6) Policy Directive PD2006\_077 *Data Collections – Disclosure of unit record data held for research or management of health services*, provides guidance on disclosure of unit record data relating to the health of an individual or individuals, which are held in data collections owned by the NSW Department of Health, including those data collections that are managed by an external agency on behalf of the Department.

### **3.2.3 Human tissue**

- (1) Research involving human tissue in NSW is governed by the *Human Tissue Act 1983 (NSW)* and *Human Tissue Regulation 2010 (NSW)*. In this Act, except where the context or subject-matter otherwise indicates or requires, the definition of tissue includes blood, ova and semen, and foetal tissue.
- (2) Where anatomical examination precedes the removal of human tissue, including for research purposes, the *Anatomy Act 1977* applies. The *Anatomy Act* imposes a consent and authorisation regime for the anatomical examination of the body of a deceased person. A license is required for anatomical examinations under the Act. If the body is subject to the *Coroners Act 1980 (NSW)*, or the *Coroners Act 2009 (NSW)* which is currently replacing in stages the 1980 Act, it must be accompanied by a document authorising the disposal of the remains.
- (3) Policy Directive PD2005\_341, *Human Tissue-Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters* outlines the requirements of the *Human Tissue Act 1983 (NSW)* and incorporates Department of Health policy in relation to the provision of information and obtaining consent for use of human tissue.



- (4) Guideline GL2006\_021, *Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research and use of tissue* outlines the requirements of the Act in relation to research and provides guidance for HRECs.
- (5) Policy Directive PD2010\_054 *Coroner's Cases and the Coroners Act 2009* provides information regarding the Coroners Act and the implications for medical practitioners, healthcare workers and managers in the public health system.

### **3.2.4 Ionising radiation**

- (1) Control of radiation in NSW is governed by the *Radiation Control Act 1990 (NSW)*, and *Radiation Control Regulation 2003 (NSW)*.
- (2) Clause 22 of the *Radiation Control Regulation 2003 (NSW)* places limits on how much ionising radiation humans can receive during research, in accordance with the document published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (RPS No. 8)*.
- (3) The NSW Department of Environment, Climate Change and Water is the regulatory authority responsible for ensuring compliance with the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (RPS No. 8)*.

### **3.2.5 Use, manufacture, sale and distribution of therapeutic goods**

- (1) The Commonwealth *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulations 1990*, and *Therapeutic Goods (Medical Devices) Regulations 2002* establish a national system of regulatory controls of therapeutic goods for human use. Responsibility for the regulatory controls lies with the Therapeutic Goods Administration (TGA).
- (2) Clinical trials that involve the following must be conducted through the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) scheme, regulated by the TGA:
  - use of any product not entered on the Australian Register of Therapeutic Goods.
  - use of a product beyond the conditions of its marketing approval.
- (3) The TGA has adopted the CPMP/ICH *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95)* in principle. It has reproduced CPMP/ICH/135/95 annotated with comments, indicating which sections have not been adopted to reflect local (Australian) regulatory requirements. Clinical trials regulated by the TGA must comply with *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments* or *ISO 14155 Clinical Investigation of Medical Devices*, whichever is applicable.

### **3.2.6 Guardianship**

- (1) The *Guardianship Act 1987 (NSW)* establishes who can give valid substitute consent in circumstances where a person is unable to consent to medical or dental treatment. Part 5 of the Guardianship Act applies to a patient who is of or above the

age of 16 years and who is incapable of giving consent. Section 33(2) of the Act provides that a person is incapable of giving consent if the person is incapable of understanding the general nature and effect of the proposed treatment, or is incapable of indicating whether or not he or she consents or does not consent to the treatment.

- (2) The Act has special provisions relating to clinical trials. A clinical trial is defined in the Act as a trial of drugs or techniques that necessarily involves the carrying out of medical or dental treatment on the participants in a trial. This includes the administration of placebos to participants. Note that this is different from the definition of clinical trial used in this document (see section 1.5), which is in line with the definition used by the Therapeutic Goods Administration.
- (3) A person unable to consent may not participate in a clinical trial, as defined in the Act, unless the trial has been approved by the Guardianship Tribunal. In reviewing such a trial, the Guardianship Tribunal will decide whether consent can be granted by the person responsible or should be granted by the Tribunal.
- (4) Policy Directive PD2005\_406 *Consent to Medical Treatment – Patient Information* outlines how the *Guardianship Act 1987 (NSW)* applies to, among other things, clinical trials.

### **3.2.7 Human embryos and cloning**

- (1) The *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)* and *Research Involving Human Embryos Act 2002 (Cth)*, as adopted in NSW by the *Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (NSW)* and *Research Involving Human Embryos Act 2003 (NSW)*, prohibit human reproductive cloning and other specific practices associated with reproductive technology, and regulate research involving human embryos.
- (2) The activities specified under the *Research Involving Human Embryos Act 2003 (NSW)* are regulated by a licensing system overseen by the National Health and Medical Research Council (NHMRC) Embryo Research Licensing Committee.
- (3) Individuals and organisations wishing to undertake research using excess human embryos from assisted reproductive therapy or human eggs, or to create or use other embryos, must apply to the NHMRC Embryo Research Licensing Committee for a licence.

### **3.2.8 Gene technologies and related therapies**

- (1) The Commonwealth *Gene Technology Act 2000* and *Gene Technology Regulations 2001* establish a national scheme for the regulation of gene technology. The *Gene Technology (New South Wales) Act 2003* adopts the nationally consistent regulatory scheme.
- (2) The Gene Technology Regulator is the statutory office holder responsible for administering the national regulatory system for gene technology as set out in the *Gene Technology Act 2000*.

- (3) NSW Health facilities in which investigators are using gene technology or undertaking dealings with Genetically Modified Organisms must be accredited and licensed and maintain a properly constituted Institutional Biosafety Committee, or have an established link with an accredited collaborating organisation in accordance with written guidance issued by the Gene Technology Regulator.

### **3.2.9 Animals**

- (1) The supply and use of animals in research is regulated in NSW under the *Animal Research Act 1985 (NSW)*, which protects the welfare of vertebrate animals (as defined in section 3) (other than human beings) used in research. The *Animal Research Regulation 2005 (NSW)* defines the constitution and procedures for committees overseeing animal research, and the details of accreditation and licensing procedures.
- (2) All use of animals for scientific purposes in NSW must comply with the National Health and Medical Research Council's *Animal Research Code*, which is incorporated by reference into the *Animal Research Regulations 2005 (NSW)*.
- (3) Policies and guidelines developed by the Animal Research Review Panel, created by the *Animal Research Act 1985 (NSW)* and Industry and Investment NSW's Animal Welfare Unit can be accessed from <http://www.animaethics.org.au/>

### **3.2.10 Record keeping**

- (1) The *State Records Act 1998 (NSW)* provides for the retention and disposal of records held by public sector agencies.
- (2) Record keeping for NSW Health is regulated by the State Records Authority of NSW. *General Retention and Disposal Authority: Public Health Services: Patient/Client Records (GDA17)* and *Administrative Records (GDA 21)* both contain a section on research management.
- (3) The *Medical Practice Act 1992 (NSW)* (repealed) and the *Health Practitioner Regulation (NSW) Regulation 2010* are relevant for medical records created and maintained by medical practitioners.
- (4) Under *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments*, the Therapeutic Goods Administration (TGA) requires sponsors to retain records for 15 years following the completion of clinical trials regulated by the TGA. However, the TGA also notes that the overriding consideration for sponsors with respect to record retention is the issue of product liability and the potential need to produce records at any time during, and possibly beyond, the life of a product in the event of a claim as a result of an adverse outcome associated with the use of the product.

### **3.3 NSW Health policy directives relating to research governance**

#### **3.3.1 Compliance with National Health and Medical Research Council guidelines**

- (1) All human and animal research taking place in NSW Public Health Organisations must comply with the *National Statement, Research Code, Animal Research Code* and other relevant guidelines published by the National Health and Medical Research Council, in line with Policy Directive PD2010\_057 *Research - Human and Animal Research and the National Health and Medical Research Council Act 1992* (Refer also to section 3.2.1).

#### **3.3.2 Ethical and scientific review**

- (1) Human research taking place in NSW Public Health Organisations must be reviewed and approved in accordance with the *National Statement* to ensure that it meets appropriate ethical and scientific standards. Research involving animals must be reviewed and approved in accordance with the *Animal Research Code*.
- (2) The following policy directives provide further details on requirements and processes related to ethical and scientific review and approval of human research:
  - Policy Directive PD2010\_055 *Research - Ethical and scientific review of human research in NSW Public Health Organisations*;
  - Policy Directive PD2007\_035 *Human Research Ethics Committees: Standards for Scientific Review*;
  - Policy Directive PD2008\_046 *Human Research Ethics Committees: Ethical Review for External Entities*; and
  - Policy Directive PD2008\_030 *HREC and Research Governance – Fee Policy for Review of Commercially Sponsored Research*.

#### **3.3.3 Site authorisation**

- (1) All human research that takes place in NSW Public Health Organisations must be reviewed and authorised by the Chief Executive or their delegate before commencement, in accordance with Policy Directive PD2010\_056 *Research - Authorisation to commence human research in NSW Public Health Organisations*.
- (2) Authorisation is conditional on ethical and scientific approval of the project, which has been granted in line with Policy Directive PD2010\_055 *Research - Ethical and scientific review of human research in NSW Public Health Organisations*.
- (3) Applications for site authorisation may incur a fee, details of which are outlined in Policy Directive PD2008\_030 *HREC and Research Governance – Fee Policy for Review of Commercially Sponsored Research*.
- (4) A summary of routes to obtaining site authorisation is provided in Annex 1 (Refer also to section 4.3.1).

### **3.3.4 Clinical trials**

- (1) All clinical trials to be conducted at sites under the control of NSW Public Health Organisations must satisfy insurance and indemnity requirements set out in Policy Directive PD2011\_006 *Clinical Trials: Insurance and Indemnity*
- (2) If the trial is sponsored by an entity external to the Public Health Organisation, there must be a written agreement clarifying the obligations, responsibilities and rights of the parties involved in the trial. A number of standard agreements is available for this purpose: see Policy Directive PD2009\_032 *Clinical Trial Research Agreement Public Health Orgs (Collaborative or Cooperative Research Groups)* and Policy Directive PD2009\_033 *Clinical Trial Research Agreement for Public Health Organisations (Commercial Entities)*.
- (3) A clinical trial drug, which is not yet registered or listed by the Therapeutic Goods Administration, should be treated as a Schedule 4 drug for the purposes of storage, supply, prescribing and administration in line with Policy Directive PD2007\_077 *Medication Handling in NSW Public Hospitals* and pursuant to Policy Directive PD2005\_078 *Drugs – Highly Specialised Program – Guideline for Undertaking Clinical Trials*.

### **3.3.5 Intellectual property**

- (1) In line with Policy Directive PD2005\_370 *Intellectual Property Arising from Health Research Policy – NSW Department of Health*, NSW Public Health Organisations must identify, record and (if relevant) register and protect intellectual property owned by them which is derived from research (Refer also to section 4.3.9).

### **3.3.6 Financial management**

- (1) The receipt, investment and expenditure of funds used for research should comply with NSW Accounts and Audit Determinations for Public Health Organisations.

### **3.3.7 Risk management**

- (1) NSW Health entities are required to implement a risk management framework in line with AS/NZS ISO31000 and the NSW Health Risk Management Framework, in line with Policy Directive PD2009\_039 *Risk Management – Enterprise-Wide Policy and Framework – NSW Health*.
- (2) Mechanisms to manage, record and monitor risks to participants, the research team, the organisation and others involved in research should be developed in line with this policy directive.

## 4 Responsibilities and accountabilities

### 4.1 Introduction

- (1) This section describes the specific responsibilities and accountabilities of investigators, NSW Public Health Organisations and the Department of Health.

### 4.2 Investigators

- (1) Investigators are responsible for the day-to-day conduct of research taking place in NSW Public Health Organisations. They are accountable for this to: (i) the Public Health Organisation hosting the research; (ii) their employer who may or may not be the research host; and (iii) if applicable, the clinical trial sponsor.
- (2) Key responsibilities are outlined below.
  - Conducting research in accordance with:
    - a) the *National Statement*;
    - b) relevant legislation and regulations;
    - c) ethical and research arrangements of the organisations involved;
    - d) any conditions of approval stipulated by the HREC, and any other special conditions required by the HREC and the site; and
    - e) any contractual requirements such as those under a clinical trial agreement;
  - Ensuring participants' safety and welfare during the research project.
- (3) Principal Investigators, and for multi-centre research Co-ordinating Investigators, have the following additional key responsibilities:
  - Developing and submitting the proposal for ethical and scientific review and site authorisation;
  - Providing reports to the HREC and/or site on:
    - a) Adverse events;
    - b) Proposed amendments to the protocol; and
    - c) Information that might affect the continued ethical and scientific acceptability of the project;
  - Providing, at a minimum, annual progress reports and a final report to the HREC and the site; and
  - Appropriately disseminating the outcome of research, including provision of information to research participants.
- (4) Further details of the responsibilities of investigators, Principal Investigators and Co-ordinating Investigators in relation to different stages of research are provided in Annex 2.

### **4.3 NSW Public Health Organisations**

- (1) NSW Public Health Organisations undertake a number of research governance activities in their role as research host and employer of investigators. A single Public Health Organisation frequently fulfils the role of both employer and host for a given research project.
- (2) Chief Executives of Public Health Organisations are responsible for ensuring that appropriate research governance personnel, systems and structures are in place. This includes:
  - Assigning a Director of Research (or equivalent) with responsibility for the oversight of research governance matters; and
  - Identifying at least one Research Governance Officer to ensure the efficient and effective management of applications for site authorisation and oversight of authorised projects.

#### **4.3.1 Site authorisation**

- (1) Public Health Organisations must require that human research projects do not take place within their premises until authorisation has been granted by the Chief Executive or delegate.
- (2) Before granting site authorisation, the Chief Executive or delegate must be satisfied that the project has undergone appropriate review and meets the minimum governance requirements set out in Policy Directive PD2010\_056 *Research - Authorisation to commence human research in NSW Public Health Organisations*.
- (3) Research Governance Officers and, for research to be conducted at sites under the control of Public Health Organisations, relevant heads of departments (or divisional directors or other authorities) of that site are responsible for conducting the review and determining whether the project meets these minimum governance requirements.
- (4) Public Health Organisations are responsible for the efficient and effective review and processing of applications for site authorisation, and meeting benchmarks for timelines to authorisation set by the Department of Health.
- (5) Whilst site authorisation is not a requirement for animal research, Public Health Organisations must require that projects do not commence until approval has been granted by an AEC.

#### **4.3.2 Establishment and oversight of ethical review processes**

- (1) Public Health Organisations which have established HRECs and/or AECs are responsible for ensuring that the committees are sufficiently resourced to fulfil their terms of reference.
- (2) Public Health Organisations are responsible for registering the HREC with the National Health and Medical Research Council (NHMRC), and meeting NHMRC reporting requirements, including completing and submitting the Annual Report

Form. They are also responsible for ensuring that the HREC provides annual reports to the NSW Privacy Commissioner.

- (3) Public Health Organisations are responsible for conducting an annual review of the AEC it has established, including an assessment of the annual report submitted to it and meeting with the AEC chairperson.

#### **4.3.3 Provision of appropriate facilities**

- (1) For projects conducted at sites under their control, Public Health Organisations are responsible for providing the following:
  - a safe environment for research participants and staff conducting research;
  - appropriate processes and facilities for the acquisition and care of animals; and
  - access to facilities and processes for the safe and secure storage, retention, and disposal of research data, documents and materials.

#### **4.3.4 Clinical trials**

- (1) In some cases (for example, investigator-initiated projects) a Public Health Organisation may agree to sponsor a clinical trial in which case it is responsible for:
  - complying with all obligations and responsibilities of the sponsor under the *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments* or *ISO 14155 Clinical Investigation of Medical Devices*, whichever is appropriate, and to the extent relevant *Therapeutic Goods Act 1989 (Cth)*; and
  - ensuring that appropriate insurance arrangements are in place to cover for sponsor-related liabilities.
- (2) Even when it is not the sponsor, clinical trial agreements generally stipulate certain obligations and responsibilities of the site where the trial is to be conducted. Public Health Organisations are responsible for complying with their obligations and responsibilities under such an agreement.

#### **4.3.5 Reporting on research activities**

- (1) 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 or research reports.
- (2) To enable this, Public Health Organisations must require that all authorised research projects that are conducted at sites under their control provide progress reports at least annually and on completion.

#### **4.3.6 Monitoring**

- (1) Public Health Organisations are ultimately responsible for the welfare of research participants and for ensuring that research is conducted in accordance with the principles, standards and requirements outlined in this document. Where a project



is conducted at sites under their control, Public Health Organisations have the following responsibilities:

- ensuring that arrangements are kept in place for monitoring and reporting on the safety of participants, which is in line with the requirements of the reviewing HREC and, if applicable, clinical trial sponsor;
  - permitting and assisting with monitoring, audit or inspection by the reviewing HREC, clinical trial sponsor and regulatory bodies and responding promptly and effectively to any recommendations made; and
  - conducting audits/inspections of projects, such as investigator-initiated clinical trials, that were identified as requiring additional monitoring by the reviewing HREC or during review for site authorisation.
- (2) Serious adverse events are also clinical incidents which must be managed in accordance with Policy Directive PD2007\_061 *Incident Management*. If a serious adverse event is a “Reportable Incident” it requires a Root Cause Analysis in accordance with Division 6C of the *Health Administration Act 1982 (NSW)*.
- (3) For animal research, Public Health Organisations are responsible for responding promptly and effectively to recommendations from the AEC to ensure the welfare of animals. They are also responsible for conducting audits/inspections of project as it considers appropriate.

#### **4.3.7 Managing complaints and allegations of research misconduct**

- (1) Public Health Organisations are responsible for having a documented process for receiving and managing complaints about research taking place within their premises, and for taking action upon receiving complaints.
- (2) Where the complaint relates to suspected research misconduct, or it receives reports of suspected research misconduct, Public Health Organisations are responsible for ensuring that this is managed in line with the *Research Code*.
- (3) When the complaint involves the health care of patients, the Public Health Organisation is required to notify the relevant health professional body which may result in an independent investigation by the Health Care Complaints Commission.
- (4) Public Health Organisations may wish to consult the Australian Research Integrity Committee, jointly established by the National Health and Medical Research Council and Australian Research Council as a national advisory body, which will review processes by which universities and other research organisations have handled allegations of research misconduct.

#### **4.3.8 Managing conflicts of interest**

- (1) Public Health Organisations are responsible for establishing transparent processes to identify and manage actual and potential conflicts of interest involving the organisation itself, investigators, and ethical review bodies and their members or advisors.

- (2) A Public Health Organisation with a conflict of interest bearing on research is responsible for informing the relevant ethical review body about the conflict.
- (3) Clinical trials often involve dealing with large companies who sponsor the clinical trial. Public Health Organisations must comply with their obligations under NSW Health probity requirements and the *Independent Commission Against Corruption Act 1998 (NSW)*.

#### **4.3.9 Managing intellectual property**

- (1) Public Health Organisations are responsible for managing intellectual property in line with Policy Directive PD2005\_370 *Intellectual Property Arising from Health Research Policy – NSW Department of Health*. This includes identifying intellectual property rights created from health and medical research, assessing whether those intellectual property rights have commercialisation potential and where relevant, registering and protecting those intellectual property rights. Public Health Organisations should be mindful of keeping their invention, business plans, trade secrets and intellectual property secret and confidential until they have received legal advice regarding exploitation and registration.
- (2) Appropriate management of intellectual property includes ensuring that arrangements for the development, commercialisation and ownership of intellectual property are in place with other institutions (such as universities), non-employees and staff holding joint appointments with external organisations.
- (3) Public Health Organisations are also responsible for ensuring that the rights of third parties, including holders of registered patents, are not infringed by research projects undertaken within its premises or by its employees.

#### **4.3.10 Managing collaborative research**

- (1) Public Health Organisations are responsible for ensuring that written agreements are in place with collaborating institutions for the management of joint research projects. The agreement should generally include management of intellectual property, confidentiality and copyright issues, sharing commercial returns, responsibility for ethics and safety clearances, monitoring and reporting requirements, dissemination of research outcomes, management of allegations of research misconduct, and management of research data, documents and materials.

#### **4.3.11 Providing training and other support for investigators**

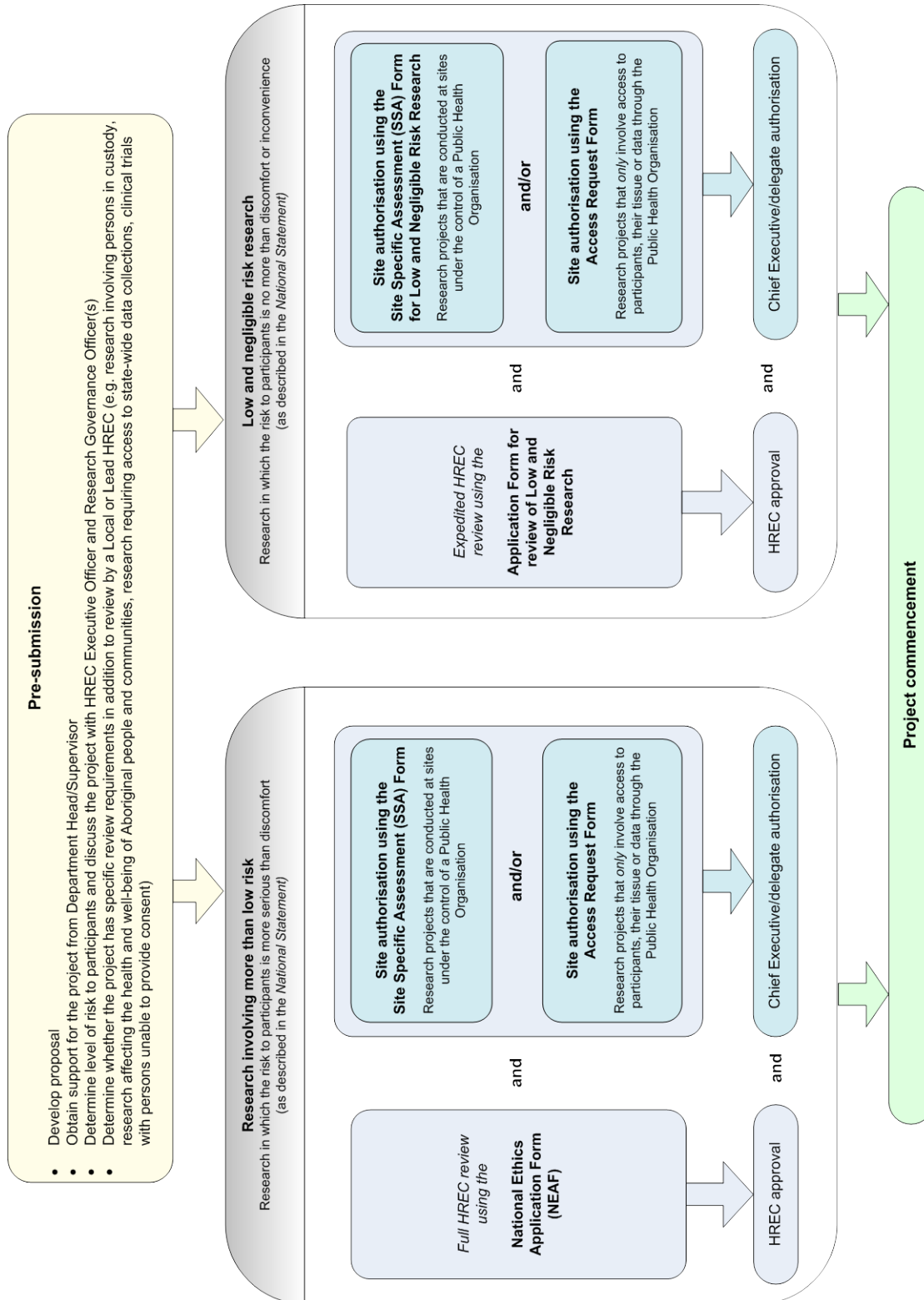
- (1) Public Health Organisations are responsible for promoting high quality research and ensuring that investigators are supported in the responsible design, conduct, management, monitoring and reporting of research. This involves promoting awareness of this document and providing:
  - codes, guidelines and policies referred to in this document, and written organisational procedures;
  - training on the principles, standards and requirements outlined in this document;

- systems to ensure students and new investigators are appropriately supervised, and there is mentoring;
  - systems to support investigators in costing research, and managing funds provided for their projects; and
  - mechanisms to support investigators in addressing and learning from mistakes made.
- (2) Managers are responsible for ensuring that investigators - whether staff, contractors or volunteers - are aware of and fulfil their responsibilities outlined in section 4.2 of this document.

#### **4.4 Department of Health**

- (1) NSW Department of Health is responsible for providing support to Public Health Organisations to ensure that research taking place in the NSW public health system is of the highest ethical, scientific, regulatory and professional standards.
- (2) It is responsible for:
- issuing policies and guidelines to assist and support the responsible conduct of high quality research;
  - working with Public Health Organisations to ensure compliance with policy and legislative requirements; and
  - reporting trends in research activity and research governance performance across the NSW public health system.

## Annex 1: Summary of routes to obtaining Human Research Ethics Committee (HREC) approval and site authorisation for research taking place in NSW Public Health Organisations



## Annex 2: Responsibilities of investigators along the research continuum

	Investigator	Principal Investigator	Co-ordinating Investigator
<b>Before research begins</b>		<p>For single centre research, developing and submitting the proposal for ethical and scientific review and site authorisation.</p> <p>For multi-centre research, developing and submitting the proposal for site authorisation.</p>	<p>For multi-centre research, developing and submitting the proposal for ethical and scientific review.</p>
<b>Conducting research</b>	<p>According the respect that is due to participants. This includes ensuring that:</p> <ul style="list-style-type: none"> <li>▪ potential participants – or a person or statutory authority exercising lawful authority for the potential participant – fully understand the purpose, methods, demands, and potential risks and benefits of the research;</li> <li>▪ no person is subject to coercion or pressure in making a decision about participation;</li> <li>▪ potential participants are provided with sufficient time to consider the research;</li> <li>▪ people who decline to participate do not suffer any disadvantage as a result of their decision; and</li> <li>▪ the entitlement of participants to withdraw from research at any time and without giving reasons is respected.</li> </ul>	See left	

	<b>Investigator</b>	<b>Principal Investigator</b>	<b>Co-ordinating Investigator</b>
<b>Conducting Research (continued)</b>	<p>Conducting research in accordance with:</p> <ul style="list-style-type: none"> <li>▪ the <i>National Statement, Research Code</i> and <i>Animal Research Code</i>;</li> <li>▪ relevant legislation and regulations;</li> <li>▪ ethical and research arrangements of the organisations involved;</li> <li>▪ any conditions of approval stipulated by the HREC, and any other special conditions required by the HREC and the site; and</li> <li>▪ any contractual requirements such as those under a clinical trial agreement.</li> </ul>	See left.	
		<p>For single centre research, providing progress reports, at least annually, to the reviewing HREC.</p> <p>For multi-centre research, providing progress reports, at least annually, to the Co-ordinating Investigator and site Research Governance Officer.</p>	For multi-centre research, providing progress reports, at least annually, to the reviewing HREC, by collating information submitted by the Principal Investigators.

	<b>Investigator</b>	<b>Principal Investigator</b>	<b>Co-ordinating Investigator</b>
<b>Conducting Research (continued)</b>	<p>Protecting the participants' welfare while they are in research. This includes:</p> <ul style="list-style-type: none"> <li>▪ recording and reviewing significant developments as the research proceeds, particularly those that put the health or safety of participants at risk;</li> <li>▪ reporting all adverse events occurring at the site to the Principal Investigator; and</li> <li>▪ taking appropriate urgent safety measures to protect participants against any immediate hazard to their health and safety.</li> </ul>	<p>See left</p> <p>For single centre research, reporting the following to the reviewing HREC and if applicable, clinical trial sponsor</p> <ul style="list-style-type: none"> <li>▪ adverse events;</li> <li>▪ proposed amendments to the protocol; and</li> <li>▪ information that might affect the continued ethical and scientific acceptability of the project.</li> </ul> <p>For multi-centre research:</p> <ul style="list-style-type: none"> <li>▪ reporting serious adverse events and suspected unexpected serious adverse reactions occurring at the site to the reviewing HREC, Co-ordinating Investigator, Research Governance Officer and if applicable, clinical trial sponsor; and</li> <li>▪ providing the outcome of HREC review to the site Research Governance Officer.</li> </ul>	<p>For multi-centre research, reporting the following to the reviewing HREC and if applicable, clinical trial sponsor</p> <ul style="list-style-type: none"> <li>▪ adverse events;</li> <li>▪ proposed amendments to the protocol; and</li> <li>▪ information that might affect the continued ethical and scientific acceptability of the project.</li> </ul> <p>For multi-centre research, providing the outcome of HREC review to Principal Investigators.</p>
	<p>Declaring any actual or potential conflicts of interest that arise during the course of research.</p>	<p>See left.</p>	
	<p>Using confidential information only in ways agreed by the participants and/or approved by the reviewing HREC.</p>	<p>See left.</p>	

	Investigator	Principal Investigator	Co-ordinating Investigator
<b>Conducting Research (continued)</b>	Ensuring that data collected is accurate and of high quality.	See left.	
	Protecting the integrity and confidentiality of primary materials and data generated by research, and storing them in a safe and secure manner.	See left.	
		Managing financial and other resources provided for conducting the project, and notifying any intellectual property arising from research.	
	Reporting any failures in carrying out the responsibilities or suspected research misconduct through appropriate systems.	See left.  Ensuring that members of the research team fulfil their responsibilities and managing any non-compliance.  Making available all data and documentation associated with the project at the request of the monitoring, inspection and auditing authorities.	
	Discontinuing the project if ethical approval or site authorisation is suspended or withdrawn. It is <i>prima facie</i> evidence of misconduct if the project is not discontinued after approval or authorisation is withdrawn.	See left.  For single centre research, notifying the reviewing HREC if the project ceases before the expected date.  For multi-centre research, notifying the Co-ordinating Investigator and site Research Governance Officer if the project ceases before the expected date.	For multi-centre research, notifying the reviewing HREC of sites where the project ceased before the expected date.



	<b>Investigator</b>	<b>Principal Investigator</b>	<b>Co-ordinating Investigator</b>
<b>Conducting Research (continued)</b>	<p>Where the research involves animals:</p> <ul style="list-style-type: none"> <li>▪ showing genuine commitment to the welfare of animals, a respect for the contribution animals make to research and a desire to promote the animals' wellbeing; and</li> <li>▪ ensuring that all research involving animals is conducted in accordance with the AEC approval.</li> </ul>	<p>See left.</p> <p>Submitting proposed changes to an approved protocol to the AEC for review and approval.</p> <p>Informing the AEC promptly when unforeseen complications / animal deaths occur.</p> <p>Providing the AEC with written reports as required, including annual reports and statistics on animal use.</p>	
<b>Research completion</b>		<p>Ensuring that project closure is orderly and systematic. This includes:</p> <p>For single centre research, providing a final report to the reviewing HREC.</p> <p>For multi-centre research, providing a final report to the Co-ordinating Investigator and site Research Governance Officer</p> <p>Appropriate dissemination of the outcome of research, including provision of information to research participants.</p>	<p>For multi-centre research, providing a final report to the reviewing HREC, by collating information submitted by the Principal Investigators</p>