NSW GOVERNMENT Health Pathology

NSWHP Research Governance Framework

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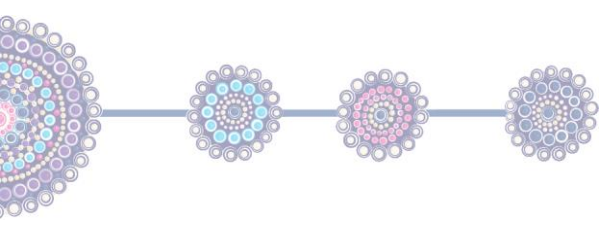

for all of us

Contents

01 Introduction

1.1 Purpose

This NSW Health Pathology (NSWHP) Research Governance Framework (Framework) reinforces the principles of the Australian Code for the Responsible Conduct of Research and applies to all research conducted at sites under the control of NSW Health Pathology (NSWHP), or involving participants, their tissue or data accessed through NSWHP.

1.2 Background

NSWHP is responsible for ensuring the people of NSW have access to the public pathology and forensic services they need.

NSWHP's vision is;

- Connecting; we listen, learn and deliver better outcomes,
- Pioneering; we have the courage and conviction to discover new and better services, and
- Caring; we put people at the centre of all we do.

NSWHP recognises that research and innovation is at the core of achieving this vision, and with the release of the NSWHP Research and Innovation Framework, aims to continue to actively engage in research activity both contributing to and supporting internal and non-NSWHP research collaborations and partnerships.

NSWHP is committed to good governance and research management practices. By operating in accordance with National Health and Medical Research Council's Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct of Human Research 2007 (updated 2018) NSWHP aims to ensure that any research activity conducted within its facilities, by its Staff or involving participants, their tissue or data accessed through NSWHP, is ethically reviewed and monitored.

Adherence to this Framework ensures the research activity conducted at sites under the control of NSWHP, or involving participants, their tissue or data access through NSWHP, meets the highest ethical, scientific, regulatory and professional standards.

This document outlines the governance requirements, roles and responsibilities for ensuring that research conducted within or involving NSWHP is conducted according to ethical principles, scientific, regulatory and professional standards. The principles of risk management, including application processes, monitoring and ongoing review and complaints management are also covered in this Framework.

1.3 Scope

This Framework applies to all research undertaken by NSWHP. This means research;

(i) conducted at sites under the control of NSWHP,

(ii) by NSWHP Staff at non NSWHP sites, and/or

(iii) involving participants, their tissue or data accessed through NSWHP or NSW Health Statewide Biobank (NSWHSB).

It applies to the full spectrum of research including biomedical, clinical, public health and health services research and provides guidance to non-NSWHP research collaborators, partners and customers who require services or materials supplied by NSWHP for research.

This Framework specifies the roles, responsibilities and accountabilities of all those who play a part in research, and demands compliance with all legislation, guidelines and codes of practice governing the conduct of research.

This Framework outlines and/or defines:

- Research quality and safety
- The key legislation that relates to the responsible conduct of research, including privacy considerations
- NSWHP's governance, application and approval processes in relation to research
- Data governance, access and storage requirements in relation to research
- Requirements for accessing NSWHP biospecimens
- Requirements for Clinical Trials conducted at NSWHP site/s
- Monitoring of research governance relevant to NSWHP
- Research collaborations including the contribution of specimens and/or data for research
- Services for non-NSWHP research
- Processes to manage research misconduct and complaints
- the roles and responsibilities of all parties involved in research, as applicable to NSWHP

02 Definitions

Adverse Events (AE): 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 (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Adverse Reaction (AR): Any untoward and unintended response to an investigational medicinal product related to any dose administered.

Chief Executive (CE): The person who holds overall responsibility for ensuring that appropriate research governance personnel, systems and structures are in place at their Public Health Organisation or Statewide Health Service.

Chief Investigator/Coordinating Investigator (CI): 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, Coordinating Investigator and Principal Investigator are synonymous.

Clinical Trial/Clinical Study: As per the TGA's Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) – annotated with TGA comments, means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics 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 objective of ascertaining its safety or efficacy. The terms clinical trial and clinical study are synonymous.

Clinical Trial Notification (CTN)/Clinical Trial Exemption (CTX): an Australian Therapeutic Goods Administration (TGA) requirement that any clinical trial conducted in Australia using unapproved therapeutic goods must be submitted to the TGA. Either by notifying the TGA of the study (CTN) or requiring TGA to review the scientific data and provide additional approval to conduct the study (CTX). The choice of which scheme to use (CTN or CTX) lies firstly with the trial sponsor and then with the HREC that approves the protocol.

Commercially sponsored research: Studies **sponsored** and **funded** by pharmaceutical companies or biotech industry for **commercial** purposes.

Consent: A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research. It must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

Designated Officer: in relation to a hospital, is a person appointed for the time being under section 5(1)(a) of the Human Tissue Act 1983 to be a designated officer for the hospital, or in relation to a forensic institution, is a person appointed for the time being under section 5(3) of the Human Tissue Act 1983 to be a designated officer for the forensic institution.

Director-General: The Director-General of the Department of Health.

Human research: Research conducted with or about people, or their data or tissue as described in the National Statement on Ethical Conduct of Human Research 2007 (updated 2018)

Human Research Ethics Application (HREA): The application form used to facilitate efficient and effective ethics review by a HREC for health and medical research involving humans. The National Health and Medical Research Council (NHMRC) have developed this national ethics form as a replacement for the National Ethics Application Form (NEAF).

Human Research Ethics Committee (HREC): A committee constituted in accordance with the National Statement on Ethical Conduct of Human Research 2007 (updated 2018) to review and where appropriate approve and monitor the ethical and scientific aspects of human research.

Multi-centre research: Research that is conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

Non-NSWHP Research: Research sponsored and conducted by non-NSWHP Staff.

NSW Health HREC: A HREC established by a NSW Public Health Organisation and registered with the National Health and Medical Research Council. As per NSW Health PD2010_055.

NSW public health system: As defined in section 6 of the *Health Services Act 1997* (NSW) consists of all the local health districts, statutory health corporations, affiliated health organisations with respect to their recognised services, and the Health Secretary with respect to the provision of ambulance services and other health services under Part 1A of Chapter 10 (which includes the provision of state-wide pathology, forensic and analytical science services).

NSWHP Authority for Data Provision: Authority to approve or deny a research project and its use of data, based on the impact of the research on site or department specific data collections, including data collections from other related departments. NSWHP Authorities for Data Provision include the Chief Medical Information Officer (CMIO), the Executive Director Forensic and Analytical Science Service (FASS), and the Director of Biobanking.

NSWHP Head of Department (HOD): Person with responsibility to approve or deny a research project and its use of resources, based on the impact of the research on clinical activity and budget, site or department resources, including those resources from related departments. NSWHP HODs include the NSWHP Directors of Operations, Executive Director Forensic and Analytical Science Service (FASS), and the Director of Biobanking.

NSWHP Staff: NSWHP employees, as well as students on clinical placement or work experience, visitors, volunteers, contractors and consultants performing authorised work within or using NSWHP facilities.

Participant Information and Consent Form: provides information about a research study or clinical trial to prospective participants and a mechanism for obtaining their written consent to participate. The information should include details such as the study or trial's purpose, duration, required procedures, risks and potential benefits.

Peer review: 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).

Principal Investigator (PI): The individual who takes responsibility for the conduct, management, monitoring and reporting of research at a site and submits the research project for site authorisation.

Quality Assurance (QA) or Quality Improvement (QI): An activity where the primary purpose is to monitor (QA)or improve (QI) the quality of service delivered by an individual or an organisation. Activities may include but are not limited to; clinical audits, management of health services, teaching activities, incident and sentinel event monitoring and investigation, root cause analysis, peer review, morbidity and mortality review and other forms of audit.

Research: Original investigation undertaken to gain knowledge, understanding and insight. In NSWHP it means research conducted at NSWHP sites or involving NSWHP Staff or access to tissue or data through NSWHP for research purposes. 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, artefacts 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 (2018). 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.

Researcher: Any NSWHP Staff member (including student) carrying out research with the permission or under the auspice of NSWHP.

Research Ethics and Governance Information System (REGIS): An online portal to help manage ethics and site governance approvals of human research projects in NSW and ACT.

Research Governance: 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. 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.

Research Governance Officer (RGO): The individual appointed within NSWHP who is responsible for the management of applications for site authorisation and oversight of authorised research projects.

Risk: The function of the magnitude of a harm and the probability that it will occur i.e. it is the potential for harm, discomfort or inconvenience that involves: the likelihood that a harm (or discomfort or inconvenience) will occur; and the severity of the harm, including its consequences. National Statement on Ethical Conduct of Human Research 2007 (updated 2018).

Scholarship: 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.

Serious Adverse Events (SAE) or Serious Adverse Drug Reaction (Serious ADR): Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

Site: A facility, location or services where the research is being conducted.

Site authorisation: The authorisation granted by the Chief Executive or delegate for the commencement of a research project at the proposed site/s.

Site-specific assessment (SSA): A process used by organisations in the NSW Public Health System to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at the proposed site. The assessment helps each site decide if there are resources available to effectively conduct a research project at a nominated site. It considers risks, impacts and practices at each research location. It is also referred to as a site approval (STE) in the REGIS system.

Sponsor: “An individual, company, institution or organisation that takes responsibility for the initiation, management and/or financing of the research.” National Statement on Ethical Conduct of Human Research 2007 (updated 2018)

Suspected Unexpected Serious Adverse Reactions (SUSAR): An adverse reaction that is both serious and unexpected.

Supporting department: A department, unit or facility which provides services or support for the conduct of a research protocol.

Tissue: Includes an organ, or part, of a human body and a substance extracted from, or from a part of, the human body (as defined in the Human Tissue Act 1983 (NSW)). Viral RNA falls within the definition of ‘tissue’ as viral RNA is intrinsically linked to human cells and is considered a substance extracted from the human body (as opposed to an organism).

Unexpected Adverse Reactions (UAR): An adverse reaction, the nature or severity of which is not consistent with the Reference Safety Information (RSI) i.e. the information contained in either an investigator’s brochure or an approved Australian Product Information that is used to determine what adverse reactions are to be considered expected adverse reactions and on the frequency and nature of those adverse reactions.

03 Research Values & Principles

3.1 Core Values

3.1.1 All NSWHP Staff will comply with the National Statement on Ethical Conduct in Human Research.

3.1.2 As per the National Statement on Ethical Conduct of Human Research 2007 (updated 2018), the design, review and conduct of research must reflect the values of; **merit, integrity, justice, beneficence,** and **respect.**

3.1.3 Research participant's rights, safety, dignity and well-being has priority over all other interests.

3.1.4 The likely benefit of research must justify any risks of harm or discomfort to participants.

3.1.5 Any risks to participants, the research team, NSWHP and others involved in research must be identified, assessed, recorded, minimised and monitored.

3.1.6 Research must:

a) be conducted with the highest scientific quality;

b) be supervised by persons with experience and qualifications that are appropriate for the research; and

c) use appropriate facilities and resources such as specialist equipment, material and support Staff suitable for the research.

3.1.7 All human research taking place in NSWHP must:

a) be reviewed and approved by a NSW Health Human Research Ethics Committee, ensuring the research meets appropriate ethical and scientific standards;

b) be reviewed and authorised by the NSWHP Chief Executive or delegate (per the NSWHP Delegations Manual), before commencement, ensuring that the research invested in is the most optimal use of NSWHP resources

Note: Authorisation is conditional on ethical and scientific approval of the project: Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations (PD_2010_055)

c) comply with the National Statement on Ethical Conduct of Research, the Australian Code for the Responsible Conduct of Research and the NSW Health Guideline on Research Governance in NSW Public Health Organisations.

3.1.8 A clinical trial using a new device or drug that is not listed by the Therapeutics Goods Administration (TGA), should be treated as a Schedule 4 drug for the purposes of storage, supply, prescribing and administration, in line with NSW Health policies; Drugs – Highly Specialised Program – Guidelines for Undertaking Clinical Trials (PD2005_078) and Medication Handling in NSW Public Health Facilities (PD2013_043).

3.1.9 NSWHP requires researchers to adopt research practices supporting a safe working environment in line with the Work Health and Safety Act 2011 No 10.

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

3.2 Core Principles

3.2.1 To ensure that all research activity is of the highest quality and is compliant with appropriate ethical, scientific, regulatory and professional standards, and something which should be supported by NSWHP, NSWHP assesses all proposed activity for the following:

3.2.2 It is the responsibility of the Head of the Department (HOD/NSWHP Director of Operations) where the research is taking place to ensure that researchers are aware of and comply with this Framework and all policies and procedures it refers to.

04 Research Requirements

4.1 Research Ethics

4.1.1 The wellbeing of research participants and their rights must be the primary consideration. Participants (living or deceased), their Tissue and medical records must be treated with respect and dignity.

4.1.2 The privacy and confidentiality of participants' personal information must always be maintained.

4.1.3 Consistent with the Human Tissue Act 1983 No 164, NSW Health Guideline 'Research Governance in NSW Health Public Health Organisations' (GL2011_001), and NSW Health Guideline 'Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research & use of tissue' (GL2006_001), ethical approval and consent may be required for use and retention of Human Tissue for purposes of research, quality assurance, audit, evaluation or education activities.

4.1.4 A HREC has no authority to approve and must reject a research proposal that intends to use tissue without obtaining consent in circumstances where the law requires consent because it involves unlawful conduct.

4.1.5 Consent may be limited to the specific project under consideration (specific informed consent) or given for the use of data or tissue in future research projects (broad-based informed consent). For broad-based informed consent, NSW Health has developed a standardised NSW Health Consent Toolkit. Materials can be accessed through the NSW Health Statewide Biobank website.

4.1.6 Pursuant to the National Statement on Ethical Conduct of Human Research, the requirement for consent may sometimes be waived, but must meet legislative requirements under the Human Tissue Act 1983 No 164, Coroner's Act (including a requirement for the Coroner's consent) and Anatomy Act.

4.1.7 The primary purpose of a Human Research Ethics Application (HREA) is to enable a Human Research Ethics Committee (HREC) to assess a research project to ensure that **respect for**, **and protection of, the safety, dignity, rights** and **well-being of research participants is upheld**.

4.1.8 All research conducted within NSWHP and involving human participants, their Tissue or data must be reviewed and approved by an appropriately National Health and Medical Research Council (NHMRC certified HREC in accordance with the NSW Health Policy Directive *Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations* (PD2010_055).

4.1.9 NSW Health CIs (and for single-centre research Principal Investigators) are required to submit applications for ethical and scientific review by NSW Health HRECs via REGIS.

4.1.10 For research that carries **only low risk** (where the only foreseeable risk is discomfort) and **does not** fall under one of the following categories, a low negligible risk (**LNR**) application to an appropriately certified HREC (as in 4.1.2) must be made.

Categories include;

a) Interventions and therapies including clinical and non-clinical trials and innovations,

b) Human genetics,

c) Women who are pregnant and the human foetus,

d) People highly dependent on medical care who are unable to give consent,

e) People with a cognitive impairment, an intellectual disability or a mental illness,

f) Aboriginal or Torres Strait Islander people,

g) People who may be involved in illegal activity.

4.1.11 All research conducted within NSWHP must, before it commences, be assessed to ensure it complies with the requirements of the National Statement on Ethical Conduct of Human Research 2007 (updated 2018) and the 'Australian Code of Conduct for the Responsible Conduct of Research 2018'.

4.1.12 Aboriginal Health and Medical Research Council (AH&MRC) of NSW Research Ethics Committee (HREC) reviews all applications for research projects to ensure views and interests align with Aboriginal people across NSW.

4.1.13 The National Mutual Acceptance (NMA) ethics scheme is a National system for the mutual acceptance of a single scientific and ethical review process for multi-centre research projects conducted in publicly funded health services. This scheme is offered across New South Wales, Queensland, South Australia, Australian Capital Territory, Western Australia and Victoria.

4.1.14 The Early Phase Clinical Trials HREC scheme is a NSW scheme that requires all early phase clinical trial HREC applications to be submitted to a dedicated NSW Health Early Phase Clinical Trial HREC for review and approval.

4.1.15 NSWHP's Research Governance Office **cannot accept the ethical approval of a University or private organisation** as this is not permitted under NSW Health Policy Directive 'Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations' (PD2010_055).

4.2 Research Governance

4.2.1 Research governance is a separate review and approval process to research ethics. Research governance refers to the processes used by institutions such as NSWHP to ensure that they are accountable for the research conducted at their sites, by their Staff and in accessing participant Tissue and data.

4.2.2 NSWHP has no authority to approve and must reject a research proposal that intends to use tissue without obtaining consent in circumstances where the law requires consent because it involves unlawful conduct and doing so would be an accessory in the unlawful conduct.

4.2.3 The Australian Code for the Responsible Conduct of Research R1 requires institutions, such as NSWHP, to ***'establish and maintain good governance and management practices for responsible research conduct'***.

Institutional Responsibilities in Research Governance

4.2.4 NSWHP is responsible for the welfare of research participants and for ensuring that research is conducted in accordance with the principles, standards and requirements

outlined in the NSW Health Guideline 'Research Governance in NSW Public Health Organisations' (GL2011_001). Such responsibilities include:

a) ensuring that arrangements are in place for monitoring and reporting on the safety of participants, in line with the requirements of the reviewing HREC and, if applicable, clinical trial sponsor;

b) 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;

c) 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; and

d) managing concerns or complaints and investigating potentional breaches as per the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018).

4.2.5 Research governance involves a process of review and approval for research projects conducted at NSWHP site/s, by NSWHP Staff or involving participants, their Tissue or data accessed through NSWHP. The review is undertaken to determine whether:

a) the project has received ethical and scientific approval, as per NSW Health Policy *Ethical and scientific review of human research in NSW Public Health Organisations* (PD2010_055).

b) the research is of public benefit and is of strategic alignment to NSWHP;

c) the investigators have the necessary skills, training and experience to undertake their role, and where necessary, appropriate training and supervision have been arranged;

d) NSWHP has the capacity to resource the project for the duration of the project i.e. experienced and qualified Staff, equipment, consumables and facilities available to undertake the research;

e) NSWHP approves the utilisation of resources for the project, above and beyond other service activity;

f) the project has been costed appropriately and there are sufficient funds to cover the costs of conducting research at the site;

g) research documents that are to be used at the NSWHP site/s, comply with NSWHP requirements (e.g. use of corporate logo, format, provision of site contact details, specific wording to be used in participant information sheet, including the contact details for complaints about a project);

h) legislative requirements have been addressed, such as the Therapeutics Goods Administration (TGA) CTN/CTX notifications, registration and license application requirements, privacy legislation and Human Tissue Act 1983 (NSW);

i) written agreements are in place with collaborating institutions for the management of joint research projects, or with recipient institutions obtaining access to Tissue or data supplied by NSWHP. The agreement should generally include obligations or restrictions relating to use of Tissue and data, management of intellectual property, confidentiality and copyright issues, sharing of commercial returns, responsibility for ethics and safety clearances, dissemination of research outcomes (including publications), management of allegations of research misconduct, management of

research data, documents and materials and financial transparency and accountability;

j) monitoring and reporting requirements are met in accordance with the National Statement on Ethical Conduct of Human Research 2007 (updated 2018).

k) adequate indemnity and insurance arrangements are in place (particularly in the case of clinical trials);

l) if the project is a clinical trial with an external sponsor, that there is a written clinical trial agreement clarifying the obligations, responsibilities and rights of the parties involved in the trial. Several standard contract templates (agreements) are available for this purpose.

NSWHP's Research Governance Office

4.2.6 NSWHP is a NSW Health Statewide specialist health service, with independent governance separate from NSW Health's Local Health Districts (LHDs) and Specialty Health Networks (SHNs). The NSWHP Research Governance Office has been operational since February 2019.

4.2.7 In accordance with the NSW Health Policy – Authorisation to commence human research in NSW Public Health Organisations (PD2010_056), **NSWHP is responsible for authorising the commencement of any human research activities conducted at sites under the control of NSWHP, or involving participants, their Tissue or data accessed through NSWHP**.

4.2.8 NSWHP supports the National Mutual Acceptance Scheme system of single ethical and scientific review for multi-centre research as outlined in Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations (PD2010_055 section 2.2).

Researcher Responsibilities in Research Governance

4.2.9 All human research that involves NSWHP Staff as research investigators must be:

a) reviewed by Site-specific Assessment (SSA) in REGIS submitted to NSWHP's Research Governance Office (RGO); and

b) authorised by the NSWHP Chief Executive or delegate,

before the research can commence.

4.2.10 Principal Investigators (PIs) should engage with NSWHP's RGO at the earliest possible opportunity if they are unsure of the process.

4.2.11 An SSA is used when research is conducted at a NSWHP site using NSWHP resources, and involves enrolling participants, carrying out protocol-specific research procedures with or on participants, or managing and analysing data, specimens and responses from surveys and questionnaires collected for or from research.

The Process

4.2.12 The SSA application can be made in parallel with (i.e. at the same time as) the HREC application.

4.2.13 The SSA application must be made through NSW Health's online Research Ethics and Governance Information System (REGIS).

4.2.14 The decision of a HREC is independent to SSA and Site authorisation. HRECs do not review SSAs and Site authorisations. Similarly, NSWHP's RGO does not undertake ethical and scientific review of the project.

4.2.15 For NSWHP Staff involved in research as an Investigator performing pathology related duties, '**NSW Health Pathology' must be selected in REGIS as the Investigator 'Site'. Ethics approval is required with NSWHP listed as the Site.**

4.2.16 For NSWHP Investigators with dual appointments outside of NSWHP, the role in the research project determines which facility/institution requires an SSA. Each site requires separate governance review and approval.

> ***Note:*** *If a NSWHP employee is listed in REGIS with the hospital as their 'Site' this will trigger an SSA for the LHD RGO to review, and subsequently the LHD CE to sign-off & take responsibility for.*
>
> *This must be corrected as soon as possible to avoid delays in project commencement.*
>
> ***NSWHP is a separate entity to all LHDs and has full responsibility for the research occurring within its facilities and by its staff.***
>
> *If this occurs, please contact the Research Governance Office for guidance.*

4.2.17 Regardless of whether a research project has undergone full or expedited (Low Negligible Risk) HREC review, **the project must not commence at any site until research governance authorisation has been obtained from the Chief Executive or delegate of each Institution under whose auspices the research will be conducted at.**

4.2.18 For research projects conducted by NSWHP investigators an SSA must be submitted by a NSWHP Principal Investigator (PI) through REGIS. The PI takes collective responsibility for the project team across NSWHP.

4.2.19 The NSWHP PI should discuss the project with the relevant local laboratory manager, clinical director and/or Local Pathology Director prior to submitting for NSWHP Head of Department (HOD) sign-off. A copy of this communication as evidence of local support is to be uploaded into the SSA (in REGIS).

4.2.20 In REGIS, the SSA applications will be reviewed and a decision made by HOD/s. The HOD/s consult and confirm the impact of the research project on service activity and resources with the relevant local laboratory manager, clinical director and/or Local Pathology Director. The HOD may request further information from the NSWHP PI if the SSA requires clarification.

4.2.21 When the relevant HOD/s has made a decision, the SSA will be submitted to the RGO for their review and recommendation for authorisation. The RGO may request further information from the NSWHP PI if the SSA requires clarification.

4.2.22 When the RGO is satisfied the application is complete, a recommendation is provided to the Chief Executive (CE) or the CE Delegate for a final determination.

4.2.23 If pathology, forensic or biobank data is required, the application must be reviewed in alignment to PD2015_037 with endorsement by the; Director General under the Health Administration Act 1982, the Chief Health Officer under the Health Administration Act 1982 or the relevant NSWHP delegate as under NSWHP Delegation of Duties Manual.

4.2.24 Only once Site authorisation has been granted can the research project commence at the site.

4.2.25 To avoid duplication, for research projects that are conducted by NSWHP Staff across multiple departments or NSWHP site locations, investigators only need to apply for a single SSA across all NSWHP in REGIS.

4.2.26 For human research conducted within NSWHP that requires use of data from NSWHP collections, the NSWHP PI must ensure that the use of data is approved by the NSWHP Authority for Data Provision through the SSA HOD (NSWHP – Clinical Services – Data; NSWHP – FASS – Data; NSWHP – Biobank – Data).

4.2.27 A research project that does not involve the conduct of research activities by NSWHP investigators and only requires support from NSWHP in the form of:

a) access to participants, facilities or equipment, or

b) supply of Tissue or data,

will not be required to undergo SSA through NSWHP RGO via REGIS (see 4.2.27).

4.2.28 As per 4.2.26 in lieu of NSWHP SSA via REGIS, a NSW Health Access Request form must be completed and submitted by non-NSWHP Staff to NSWHP's RGO, together with a copy of:

a) the HREC letter of approval;

b) the HREA form;

c) the project protocol or method;

d) all documents to be distributed through NSWHP's facilities, locations or operational/clinical services; and

e) written confirmation of support from the relevant NSWHP Staff, Clinical Stream Lead, Director of relevant Statewide service or Director of Operations supporting the access to participants, Tissue, data and/or equipment.

4.3 Animal care and ethics

4.3.1 NSWHP Staff involved in animal research must ensure the research project has been approved by an NSW University or LHD Animal Ethics.

4.3.2 Where a NSWHP site is conducting or involved in animal research, NSWHP is responsible for:

a) responding promptly and effectively to recommendations from the relevant University or LHD Animal Ethics Committee (AEC) to ensure the welfare of animals; and

b) conducting audits/inspections of animal research projects as considered appropriate.

4.3.3 For projects involving animals, the investigator/s must seek peer review from an appropriate AEC, 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.

4.3.4 All care and use of animals for research is to be conducted in compliance with:

a) the NSW Animal Research Act 1985 No 123;

b) NSW Animal Research Regulation 2010, and

c) the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.

4.3.5 The use of animals in research, including the use of genetically modified or cloned animals, must be ethically justified, and such research must provide for the welfare of the animals and incorporate the principles of replacement, reduction and refinement.

4.4 Data Management, Storage & Privacy

4.4.1 NSWHP owns the data related to patient attendances and material tested at NSWHP.

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

a) confidentiality and privacy are maintained;
b) methods and results are open to scrutiny;
c) outcomes can be validated;
d) materials can be accessed for further research if that is within the scope and intent of the original participant consent, ethics approval and privacy laws and policies; and
e) responsibilities of NSWHP under NSW legislation and NSW Health policies in relation to privacy and records management are met.

4.4.3 Applications for the release of NSWHP statewide unit record data (comprising personal health information) for the purposes of management of health services or research should be submitted to the NSW Population and Health Services Research Ethics Committee (PHSREC) in alignment to PD2015_037.

4.4.4 Non-NSWHP requests to access NSWHP data containing patient information must apply to NSWHP's RGO (NSWPATH-RGO@health.nsw.gov.au).

4.4.5 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; General Retention and Disposal Authority – Health Services, Public: Patient/Client records (GDA17); NSW Health Electronic Information Security Policy (PD2013_033); NSW Health policies and guidelines; NSW Privacy Manual for Health Information and NSWHP policies and procedures.

4.5 Quality Assurance and Quality Improvement

4.5.1 NHMRC states that QA is:

'*An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation is a QA activity. Terms such as 'peer review', 'quality assurance', 'quality improvement', 'quality activities', 'quality studies' and 'audit' are often used interchangeably. The term 'quality assurance' is used to include all of these terms.'*

4.5.2 QA is a routine activity and is also a requirement for the accreditation of pathology facilities and services. The aim is to monitor the accuracy and performance of laboratory testing; minimise the risk of issuing erroneous results that may lead to patient harm; and to improve the overall performance of the pathology service.

4.5.3 QA for laboratory testing is supported by a specific exemption in the Human Tissue Act 1983 for the use of small amounts of Tissue samples lawfully removed from the human body (living or deceased) for the purpose of carrying out analyses or tests that are:

a) part of QA, or
b) necessary for the delivery of services.

Refer to section 4.6.5 for additional requirements.

4.5.4 For activities such as QA, the management of health services and teaching activities, such projects must be screened for ethical risks and legal requirements to ensure compliance with:

a) NSW Health Privacy Manual for Health Information (2005) and Health Records and Information Privacy Act 2002 (NSW);
b) NSW Human Tissue Act 1983 No 164
c) Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practice Guide for NSW (GL2007_020) 'Model Checklist'
d) NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities (March 2014)
e) NHMRC National Statement on Ethical Conduct of Human Research 2007 (updated 2018)

4.5.5 NSWHP recognises the value in the co-design of a research proposal and recommends the involvement of consumers and/or consumer advocate groups when developing research projects.

4.5.6 The form and degree of community involvement must be appropriate to the research activity and requires consumers and community members with differing backgrounds, interests and perspectives.

4.5.7 NSWHP is committed to enabling the capacity of consumers and community members to engage in research design, conduct and translation through a range of practical measures such as education and training, to promote the value and uptake of consumer and community member involvement.

4.5.8 Peer review is an essential tool for researchers and institutions in maintaining standards of excellence and integrity. In compliance with the *Australian Code on the Responsible Conduct of Research (2007)*, researchers should:

a) act in confidence;

b) declare all conflicts of interest;

c) not permit personal prejudices to influence the process;

d) not take undue or calculated advantage of knowledge obtained;

e) ensure their awareness of and compliance with the criteria to be applied;

f) not participate in peer review outside their area of expertise; and

g) give proper consideration to findings that challenge accepted ways of thinking.

4.5.9 A Quality Improvement Committee (QIC) will be established to provide operational support and advice to researchers around quality improvement projects. The QIC review will provide quality improvement determinations, issuing letters of approval as a quality improvement initiative for use when applying to journals for publication.

4.6 Biospecimen Access, Use and Retention

4.6.1 NSWHP Staff must meet any relevant legislative requirements that relate to the collection, retention, use and disposal of Human Tissue, including the general prohibition on trade in human tissue (National Statement on Ethical Conduct in Human Research (2007)), Human Tissue Act 1983, Coroner's Act 2009, Anatomy Act 1977), and the NSW Privacy and Personal Information Protection Act 1998; NSW Health Records and Information Privacy Act 2002; NSW State Records Act 1998; NSW State Records General Retention and Disposal Authority – Public Health Services: Patient/Client Records (2011); NSW Health Electronic Information Security Policy (PD2013_033).

4.6.2 **Tissue removed from the body of a living person specifically for therapeutic, medical or scientific (research) purposes must have the person's consent to the removal**.

4.6.3 The use of Tissue removed from the body of a living person during medical, dental or surgical treatment after 1 November 2003 for any therapeutic, medical or scientific (including research) purpose generally requires consent in writing from the patient (subject to section 4.6.4). Consent may be given by;

- the patient (Human Tissue Act Section 21X);
- the Senior available next of kin of a child (Human Tissue Act Section 21Y);
- a person responsible for a person who is a patient under Part 5 of the Guardianship Act 1987 (Human Tissue Act Section 21Z);
- the Senior available next of kin of a person who is deceased.

4.6.4 The consent referred to in section 4.6.3 is not required for the use of small samples of tissue, retained in the form of a tissue slide or tissue block, for medical or scientific purposes (Human Tissue Act section 34(1)(b1)). However, release of tissue slides or blocks outside of NSWHP must be approved by a NSWHP Delegate in accordance with NSW Health Pathology's Delegations Manual, and be subject to a Material Transfer Agreement – see further section 4.6.10.

4.6.5 In addition (and as previously indicated in section 4.5.3), the consent referred to in section 4.6.3 is not required for the use of small samples of any tissue lawfully removed from the body of a person for the purpose of carrying out analyses or tests that are part of a quality

assurance, quality control, audit or evaluation program that ensures or improves the quality of services or, are necessary for the delivery of services (Human Tissue Act section 34(1)(b3)). However, internal use of tissue for these purposes by NSWHP staff must be approved by the local Clinical Director and/or Laboratory Manager in accordance with NSW Health Pathology's Delegations Manual. Use of tissue for these purposes by external entities or individuals must be approved by a NSWHP Delegate in accordance with NSW Health Pathology's Delegations Manual, and be subject to a Material Transfer Agreement – see further section 4.6.10.

4.6.6 Tissue may be removed from the body of a deceased person (other than a deceased child) at a hospital if a Designated Officer (appointed for the hospital under Human Tissue Act section 5(1)(a)) authorises the removal of tissue for use in therapeutic, medical or scientific (including research) purposes (Human Tissue Act section 23). If the body of a deceased person (other than a deceased child) is at a place other than a hospital, the removal of tissue from the body for the purpose of its use for other therapeutic, medical or scientific purposes is authorised if the deceased person had, during their lifetime, given consent in writing to the removal of tissue from the person's body for that purpose, or the removal is authorised by the person's senior available next of kin in accordance with section 24 of the Human Tissue Act.

*Note: A Designated Officer for a hospital or a senior available next of kin **must not** authorise the removal of tissue from the body of a deceased person in respect of whose death a coroner has jurisdiction to hold an inquest under the Coroners Act 2009 unless a coroner has given consent to the removal of the tissue (Human Tissue Act section 25).*

4.6.7 Where a post-mortem examination has been authorised under section 28 or 29 of the Human Tissue Act in respect of the body of a deceased person (other than a deceased child) at a hospital or forensic institution, use of Tissue removed for the purposes of the post-mortem examination for therapeutic, medical or scientific (including research) purposes may be authorised by a Designated Officer for a hospital or forensic institution (appointed for the hospital or forensic institution under Human Tissue Act section 5(1)(a) or 5(3)) pursuant to section 31A of the Human Tissue Act if:

a) the deceased person had, during their lifetime, given their consent in writing to the use after the person's death of tissue from the person's body for therapeutic, medical or scientific purposes and the consent has not been revoked; or

b) the deceased person had not, during their lifetime, expressed an objection to the use after their death of tissue from the person's body for therapeutic, medical or scientific purposes, and a senior available next of kin has given their consent in writing and there is no objection to the removal of tissue, and

c) provided that, in the circumstances of both a) and b), if a Coroner has jurisdiction to hold an inquest under the Coroners Act 2009 in respect of the death of the person, a Designated Officer for a hospital or forensic institution must not authorise the use of any tissue removed from the person's body unless a Coroner has given consent to the use of the tissue (Human Tissue Act section 31B). The consent of a Coroner is not required for the use of small samples of tissue removed for the purposes of the post-mortem examination and retained in the form of a tissue slide or tissue block for medical or scientific purposes (Human Tissue Act section 34(1)(b1); Coroner's Act section 90(3)(c)(v).

4.6.8 Where an anatomical examination of the body of a deceased person (other than a deceased child) at a hospital or forensic institution body for medical or scientific purposes

has been authorised under section 8 of the Anatomy Act, the body or tissue of the deceased person may be transferred to and used by the holder of an anatomy licence for further medical or scientific purposes unless there is reason to believe that to do so would be contrary to the wishes of the deceased or the senior available next of kin of the deceased (Anatomy Act sections 11 and 11A). In the case of tissue transferred to a licence holder, arrangements must be made for the return of the tissue to the holder of the licence (Anatomy Act section 11A).

4.6.9 **Tissue collected and stored for clinical diagnostic purposes** (such as medical, dental or surgical treatment) must be retained in NSWHP sites for durations specified by the National Pathology Accreditation Advisory Council's (NPAAC) 'Requirements for the retention of laboratory records and diagnostic material (Seventh Edition 2018)'.

4.6.10 Accordingly, use of Tissue for research, quality assurance or improvement purposes in any of the circumstances described in sections 4.6.2 – 4.6.8 above requires the internal approvals in accordance with NSW Health Pathology's Delegations Manual, with the use of Tissue by external entities or individuals being subject to a Material Transfer Agreement entered into between NSWHP and the recipient (*which includes terms dealing with the permissible use of the Tissue and requirements for the Tissue to be returned to NSWHP for storage if necessary due to NPAAC specimen retention requirements*).

4.6.11 Where the research involves the handling and transfer of Tissue, researchers must also comply with air, road and rail transport safety legislation, including:

a) International Air Transport Association Dangerous Goods Regulations (IATA DGRs);

b) Australian Civil Aviation Act 1988;

c) Australian Civil Aviation Safety Regulations 1998,

d) CASR part 92 – Consignment and carriage of dangerous goods by air (including part 92 advisory documents)

e) NSW Dangerous Goods (Road and Rail Transport) Act 2008 No 95; and

f) NSW Dangerous Goods (Road and Rail Transport) Regulation 2014

g) NHMRC National Statement on Ethical Conduct of Human Research 2007 (updated 2018)

4.7 Expedited research

4.7.1 NSWHP's RGO must be notified as early as possible if there are research projects related to a public health emergency so that they can prioritise the expedited review of the SSA and Site authorisation process.

4.8 Risk Management, Privacy & Safety

4.8.1 NSWHP complies with the NSW Health Risk Management - Enterprise-Wide Policy and Framework. In addition, all NSWHP Staff are required to comply with NSWHP's Enterprise Risk Management Procedure NSWHP_PR_026 which provides direction and support to NSWHP Staff regarding the management of enterprise risks.

4.8.2 Researcher/s have a primary responsibility to ensure the safety of all participants in research conducted within NSWHP, acting in accordance with and adhering to the *National Statement on Ethical Conduct in Human Research (2007)*.

4.8.3 NSWHP researchers must ensure they follow good work, health and safety practices adhering to NSW Health Policy Directive Work Health and Safety: Better Practice Procedures PD2018_013 and NSWHP's Work, Health and Safety Procedure (NSWHP_PCP_004) and for research visits conducted off-site work in accordance with NSWHP_PR_041 Home Collection Procedure and NSWHP_PD_025 Home Collection Services.

4.8.4 NSWHP requires that investigator/s assess all local safety events and act on any events as clinical care dictates. Safety monitoring and reporting must be conducted in accordance with the requirements of the NHMRC Position Statement on the Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods, NSW Health PD2017_039, the Therapeutic Goods Act (1989), and the Therapeutic Goods Administration Australian Clinical Trial handbook

4.8.5 NSWHP researcher/s are responsible for reporting all AEs and SAEs to the approving HREC, TGA, study Sponsor (for commercial clinical trials) and NSWHP RGO in accordance with the requirements of:

a) National Statement on Ethical Conduct in Human Research (2007) (Chapter 5.5 c)
b) ICH Guidelines for Good Clinical Practice (ICH GCP E6(R1) (Section 4.11)
c) NHMRC's Safety monitoring and reporting in clinical trials involving therapeutic goods.
d) Therapeutic Goods Administration (TGA) Act
e) TGA's Australian Clinical Trial Handbook
f) NSW Health Incident Management Policy (PD2020_020); and
g) NSW Health Operational Manual Research Governance Officers Guideline (GL2010_015)

4.8.6 AEs and SAEs also constitute 'incidents' which need to be managed in accordance with the NSW Health Incident Management Policy PD2020_020, including taking immediate action to minimise harm, notification in approved incident management systems, consideration of notification to Treasury Managed Fund and external regulators, and investigation. If an AE is determined to be a 'reportable incident' it will require a Root Cause Analysis (RCA) in accordance with Division 6C of the Health Administration Act 1982, and NSW Health Patient Safety and Clinical Quality Program PD2005_608.

4.8.7 Other incidents arising from research which do not consistute AEs (such as a privacy breach) will also need to be managed in accordance with the NSW Health Incident Management Policy PD2020_020, including taking immediate action to minimise harm, notification in approved incident management systems, consideration of notification to Treasury Managed Fund and external regulators, and investigation.

4.8.8 For all critical incidents (clinical or corporate) the NSWHP Critical Incident Policy NSWHP_PR_021 must also be followed.

4.8.9 Reporting timelines for any clinical trial-related events such as Adverse Events, Unexpected Reactions to Serious Adverse Events, Sudden Unexpected Serious Adverse Reactions, Serious Adverse Events, are set out in the NSW Health Operations Manual for Research Governance Officers and the NHMRC Safety monitioring and reporting in clinical trials involving theraputic goods

Biosafety, chemical and radiation safety

4.8.10 All projects involving biological materials, chemicals or radiation must be carried out while following specific safety and containment requirements. Some biological materials and chemical substances may be subject to further regulations or controls, including the Occupational Health and Safety Regulation Act 2001, Chapter 6 Hazardous substances.

4.8.11 All NSWHP research must be conducted in compliance with the Gene Technology Amendment Act 2007, National Health Security Act 2007 and applicable Australian Standards in Microbiological Practices.

4.8.12 Any research involving genetically modified organisms or organisms that cause Listed Human Diseases under the Biosecurity Act 2015 requires Insitutional Biosafety Commitee (IBC) approval.

4.8.13 In lieu of NSWHP's own IBC, University or Local Health District IBCs must be approached for IBC review and approval.

4.8.14 NSWHP researchers who are Sponsors of clinical trials involving Genetically Modified Organisms (GMOs) should discuss the details of their research with the Office of Gene Technology Regulator (OGTR) before submitting an application to the Regulator under section 92 of the Gene Technology Act 2000. A list of OGTR accredited organisations can be found at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accredorg-1#nsw.

4.8.15 Research involving the administration of cytotoxic drugs must be conducted consistent with the SafeWork NSW Guideline Cytotoxic Drugs and Related Waste – Risk Management.

4.9 Clinical Trials – Research Agreements, Insurance & Indemnity

4.9.1 As part of the review of the SSA for clinical trials, the indemnity arrangements and any agreements between the sponsors/granting bodies and the investigators will be reviewed against the NSW Health Clinical Trials – Insurance & Indemnity policy directive (PD2011_006)

4.9.2 Each clinical trial to be conducted at a NSWHP site and sponsored by an external entity to NSWHP must be governed by a written agreement clarifying the obligations, responsibilities and rights of the parties involved in the trial, in accordance with Research – Authorisation to Commence Human Research in NSW Public Health Organisations (PD2010_056) and Clinical Trial Research Agreements for Use in NSW Public Health Organisations (PD2011_028).

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

4.10 Financial Management

4.10.1 NSWHP is 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, as outlined in NSW Health's Research Governance in Public Health Organisations (GL2011_001).

4.10.2 The NSW Health Policy Directive 'Group Services/Commercialisations Policy – Revenue Policy, Revenue Standard' (PD_2005_522) requires all external funds from research

activities to be paid into the general revenue fund. This occurs unless funds are scheduled as a Restricted Financial Asset (RFA) fund, otherwise known as a Special Purpose and Trust Fund (SP&T). Research cost centres are to be established in accordance with NSW Health's Research Governance in Public Health Organisation (GL2011_001).

4.10.3 In alignment to NSW Health Accounting Manual and the Guidelines for research funding (GL2011_001), requirements apply for the accounting of research and clinical trials funding, these include;

a) **Commonwealth Grants**: should be accounted for in RFA (SP&T) to allow NSWHP to meet the reporting requirements.

b) **State Government Grants**: these must be maintained within the General Fund (Revenue), allocated to appropriate cost centres.

c) **Clinical Trials**: a RFA (SP&T) account may be used for clinical trials that are funded in advance through a returnable grant from a third party and are approved in line with the NHMRC requirements as published at the time the trial account is established in the RFA fund. Note: Clinical Trials falling outside of this criteria must be accounted for within the General Fund.

d) **Other Grant giving bodies:** to be managed within the RFA (SP&T) Fund

e) **Donations and Bequests (Philanthropic funds):** to be managed within Australian Taxation Office (ATO) endorsed RFA (SP&T) Fund, in consultation with the NSWHP Research Office and NSWHP Finance

f) **International Grants:** to be managed within the RFA (SP&T) Fund

g) **Capital funding:** Finance will provide advice when/ if funding is provided as this will depend on the source of the funds and the agreement with the funding body

4.10.4 Philanthropic and Sponsorship funding for research activity must align to the NSW Health Sponsorship policy (PD2005_415), NSW Health Fundraising (covers Philanthropy) policy (PD2009_067) and NSW Health Group Services/Commercialisations Policy – Revenue Policy, Revenue Standard' (PD 2005_522). All NSWHP Staff should ensure that;

a) A written sponsorship agreement is entered into with the sponsor before the research commences, which contains appropriate terms and does not impose or imply conditions that would limit, or appear to limit, NSW Health's ability to carry out its functions fully and impartially;

b) There should be no real or apparent conflict between the mission and objectives of NSW Health and those of the sponsor

c) Full disclosure of sponsorships must be made to the Board and approval for their application should be contained in the Board Minutes with a clear indication if the sponsorship includes research (PD 2005_522)

d) Deductible donations received by NSWHP and endorsed by the ATO as a deductible gift recipient is managed in accordance with the ATO DGR fund rules, as approved by the ATO

e) There are no prohibited sponsorship and conflicts, such as companies that own,

control or is involved with the manufacture and production or promotion of tobacco-related products, which includes cigarettes, cigars and pipes.

4.11 Collaborative Research

4.11.1 NSWHP is committed to collaborative research with non-NSWHP researchers and institutions.

4.11.2 For collaborative research between NSWHP investigator/s and non-NSWHP investigator/s, NSWHP must be added as a site in the Human Research Ethics Application (HREA) and have an SSA reviewed through NSWHP's RGO and a Site authorisation before commencement.

4.11.3 In addition, collaborative research must be governed by a written agreement clarifying the obligations, responsibilities and rights of the parties involved in the research. The agreement should be reviewed by NSWHP's Legal Counsel before signature.

4.12 Services for Non-NSWHP (external) Research

4.12.1 All external requests for services for research (service orders) must go through a NSWHP Research (Services) Coordinator.

4.12.2 The NSWHP Research (Service) Coordinator conducts due diligence on the request, developing a quote for service and service level order based off the Statewide Pricing schedule and feedback/approval from the relevant Local Clinical Director.

4.12.3 Where a request to access data has been made, the NSWHP Research (Service) Coordinator will work with NSWHP's RGO to develop and arrange sign-off of a Disclosure of Information and Confidentiality Undertakings, as per section 5.2 and the Data Collections – Disclosure of Unit Record Data for Research or Management of Health Services policy directive (PD2015_037).

4.12.4 NSWHP Staff must not sign 'supporting department' declarations on LHD Site Specific Assessments, as NSWHP is no longer a Department in a hospital but a Statewide Health Service. NSWHP must take responsibility for all research it is involved in.

4.12.5 In alignment to NSW Health Policy Directive PD2008_030 HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research, NSWHP may charge for research governance review of commercially sponsored research (site specific assessments and amendments).

4.12.6 Any services provided by NSWHP in support of research must be subject to a written agreement. The agreement should be reviewed by NSWHP's Legal Counsel before signature.

4.13 Authorship, Acknowledgement and Affiliation

4.13.1 NSWHP acknowledges the importance of communicating the findings of its research to peers, professional organisations, stakeholders, participants in the research and the wider community, and that communication about research findings needs to be aligned to the

research publication requirements set down by the Australian Code on the Responsible Conduct of Research 2018 and the International Committee of Medical Journal Editors.

4.13.2 NSWHP encourages the wide dissemination of research findings in line with the provisions of the *National Statement on Ethical Conduct in Human Research* and all NSWHP Staff, students, and other non-NSWHP research colleagues must follow NSWHP's *Research Publications Authorship, Affiliation and Acknowledgements Policy* (NSWHP_PD_026).

4.14 Confidentiality and Intellectual Property (IP)

4.14.1 NSWHP supports the development and commercialisation of intellectual property (IP) in accordance with NSWHP's Intellectual Property Framework (NSWHP_CG007) and NSW Health Policy Directive 'Intellectual Property Arising from Health Research' (PD2005_370).

4.14.2 As outlined in PD2005_370, all IP created by NSWHP Staff in the course of their employment, is owned by NSWHP.

4.14.3 Following deduction by NSWHP of any establishment costs and protection costs, any net commercialisation proceeds will be distributed as follows;

a) one third to the creator/s of the IP;

b) one third to the department or section of NSWHP which originated the IP; and

c) one third to NSWHP.

4.14.4 NSWHP shall divide the one third share of net commercialisation proceeds payable to the creators amongst the individual creators in accordance with the contributions identified by written agreement from each creator as to the relative contribution of each of them to the creation of the IP. If no such agreement has been made, NSWHP shall distribute the one third share in accordance with its own reasonable estimate of the relative contributions of each creator.

4.14.5 Where NSWHP is providing substantial resources for research conducted with independent research institutes, public or private organisations, a Research Collaboration Agreement must be put in place. This protects the rights of NSWHP and ensures the benefits of the research undertaken by NSWHP (funded or resourced) is preserved for the public health system. The agreement should be reviewed by NSWHP's Legal Counsel before it is signed.

4.14.6 Staff must complete NSWHP's Intellectual Property Disclosure Form (NSWHP_F_00013) and forward it to the NSWHP IP Coordinator as soon as IP is created, when anticipated creation is imminent, or as soon as it comes to light.

4.15 Research Reporting / Oversight

4.15.1 All NSWHP research activity will be reviewed by the NSWHP Research and Innovation Advisory Committee (RIAC).

4.15.2 The RIAC reviews annually the number of:

a) research projects approved and commenced;

b) research publications, reports and clinical guidelines;

c) new grants and scholarships/fellowships;

d) philanthropy donations for research and their utilisation

e) NSWHP Staff acting as research student supervisors;

f) clinical trials and research projects supported i.e. through data provision or ad hoc services;

g) Intellectual Property, copyright registrations and commercialisation events.

4.16 Research Misconduct, Disputes & Complaints Management

4.16.1 Research team member disputes or grievances arising out of the conduct of any research should be referred to the Principal Investigator for resolution or to the academic supervisor where relevant.

4.16.2 Grievances between research teams or individuals will be dealt with under NSW Health's mandatory Policy Directive 'Resolving Workplace Grievances' (PD2016_046)

4.16.3 Anyone may notify an issue of research misconduct, that a researcher has not acted responsibly, including any potential breach of research policy, contractual obligations and/or ethical-legal issues surrounding research projects and publication of research.

4.16.4 Complaints and allegations should be first dealt with at the departmental level and if circumstances make this difficult or not possible, the NSWHP Research Integrity Officer should be contacted at NSWPath-Research@health.nsw.gov.au.

4.16.5 Serious research incidents escalated to the Research Integrity Officer will be reported to the Critical Incidents Committee.

4.16.6 For potential breaches, NSWHP aligns to the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research.

4.16.7 Upon receiving a written complaint form, the NSWHP Research Integrity Officer will assess whether the complaint if proven, would constitute ***a breach of the*** Australian Code for the Responsible Conduct of Research.

4.16.8 Research participants must have available the contact details of the NSWHP RGO (NSWPath-RGO@health.nsw.gov.au) via site specific documents or Patient Information and Consent Forms (PICF) for matters or complaints relating to NSWHP site. Depending on the nature of the complaint, the NSWHP RGO may be required to liaise with the reviewing HREC Coordinator. The NSWHP RGO will record the details of the complaint and deal with the complaint in a prompt manner.

05 Implementation of the Framework

5.1.1 Implementing the NSWHP Research Governance Framework is the responsibility of NSWHP through NSWHP's Strategic Leadership Team.

5.1.2 The NSWHP Research and Innovation Advisory Committee (RIAC) provides strategic advice to NSWHP and oversees the implementation of NSWHP's Research and Innovation Framework. The role of the RIAC is to advocate, lead, advise, support and promote NSWHP's research activity, encouraging a culture of research and innovation and a forum for evaluating emerging technologies.

5.1.3 The implementation of the Research Governance Framework is reviewed annually by the Audit and Risk Management Committee (ARMC).

5.1.4 The Research Governance Framework is monitored by the;

a) **Research Governance Office** – all site-specific requirements including; timelines from application receipt to SSA sign-off, project tracking, and annual activity reporting.

b) **Executive Director of Finance** – accounting and reporting annually all research-related funding.

c) **Research Activity Report and Researchers** – are to report all associated outcomes, including publications, on their annual report to NSWHP as part of annual governance, which will be collated by the Research and Innovation Office and reported annually through the NSWHP Research Activity Report.

5.1.4 Compliance monitoring and reporting must be in accordance with the NSWHP's Compliance Management Framework. This includes;

a) Ensuring a risk assessment is conducted for each research-related compliance obligation in accordance with the NSWHP's Enterprise Risk Management Procedure (NSWHP_PR_026).

b) Monitoring of key (research-related) compliance obligations and associated controls to ensure risk ratings and controls remain appropriate and effective.

c) Identification and resolution of any control gaps (instances of actual or potential non-compliance)

d) Reporting compliance issues or incidents

06 Roles and Responsibilities

The following is a summary of the roles and responsibility of NSWHP, Site/Head of Department (managers) and researchers in relation to effective research governance.

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

Role	Responsibilities
6.1 NSWHP	• Foster high quality research and provide career advancement opportunities. • Research strategy and governance • Monitoring performance of research strategy and governance • Developing systems for research outcomes reporting • Developing systems for research financial accounting and reporting • Supporting NSW Health's REGIS processes and reporting • Authorisation of research project approval following ethical and site-specific approval • Responding to results of audits of research and complaints • Supporting and facilitating QA/QI project approval • Ensuring systems and procedures are in place for reporting and managing research misconduct and complaints • Providing opportunities for ongoing education in research ethics and governance requirements. • Support the research objectives of our LHD and Specialty Network partners
6.2 NSWHP Researchers	• Conduct of research in line with research protocols and management of research resources; • Ensuring compliance with: - Legislative and regulatory requirements including the Australian Code for the Responsible Conduct of Research (2007); - Conditions of ethical and scientific approval; - Conditions of site approval; - Contractual requirements such as those under a clinical trial;

Role	Responsibilities
	• Ensuring research protocols are subject to scientific and peer review prior to submission for ethical approval; • Reporting of adverse or serious adverse events and IBC breaches; • Ensuring data collection reflects principles of confidentiality, and is in line with the consent provided by the participant/s; • Effective data management and disposal; • Declaring conflicts of interest; • Reporting any concerns relating to research misconduct or complaints; • 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); • Supervision and mentoring of research students and Staff; • Ensuring students and Staff have appropriate training and credentialing in research protocols and in policies and conditions for conducting research in NSWHP; • Publishing results of research with integrity, including positive and negative results; and • Ensuring compliance with NSWHP employment, safety and other procedures and conditions including the NSW Health Code of Conduct (PD2015_049).
6.3 NSWHP Clinical Directors	• Support research as part of their role to maintain the department and the laboratory service as a model of excellence in diagnosis, consultation, research and teaching. • Support research as part of providing high quality diagnostic, consultative, procedural specialty services in Specialty area. • Encourage an academic environment which supports research and development. • Provide leadership, direction, clinical governance, and overall supervision within the relevant laboratory department/s, and provide support, advice and cooperation to the Executive Medical Directory of NSW Health Pathology that assists achievement of overall organisational goals and objectives. • Responsible for accuracy, quality, relevance, timeliness and cost effectiveness of all services provided by the specialty department including services for research.

Role	Responsibilities
6.4 NSWHP Directors of Operation; Executive Director FASS; Director of Biobanking (as Head of Department (HOD) in REGIS)	• Review and approval of Site-specific Assessments (SSA) components in the full knowledge of the impact of the research project on service activity and resources. • Escalate any research projects that may have concern regarding the impact on the organisation to their delegated manager. • 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. • Approving or denying a research project and its use of resources, based on the impact of the research on clinical activity and budget, site or department resources, including those resources from related departments. • Ensuring that research is conducted in accordance with relevant national research ethics and conduct guidelines, e.g. National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, updated 2018) and the Australian Code for the Responsible Conduct of Research (2018), and any specific conditions of its approval imposed by the local research and ethics governance process. • Ensuring ethical and scientific approval has been obtained in accordance with NSW Health (PD2010_055). • Ensure that researchers are aware of and comply with all policies and procedures included in this Research Governance Framework. • Ensuring researchers and research Staff have the appropriate experience, qualifications and competence to manage the research project. • Ensuring all Staff or volunteers (contingent workers) working on the research project in NSWHP facilities have undertaken orientation to the site and comply with all NSWHP policies. • Ensuring the research project has been costed appropriately with sufficient funds identified to cover all aspects of the project. • Documenting agreement with external entities on the management of collaborative research. • Ensuring all parties in a research project have appropriate indemnity insurance cover. • Ensuring intellectual (collaboration) agreements are in place prior to commencement of the research project. • Supporting effective data management.

Role	Responsibilities
6.5 NSWHP Chief Medical Information Officer (CMIO); Executive Director FASS; Director of Biobanking (as Authority for Data Provision)	• Review and approval of Site-specific Assessments (SSA) where the project requires access to data collections held at NSWHP, in the full knowledge of the impact of the research project on NSWHP data collections. • Management and oversight of the data collections within their delegated authority (Clinical; FASS; NSWHSB). • Consideration of privacy requirements and confidentiality of research data including appropriate collection, storage, retention, security and disposal of data and records prescribed by the NSW Privacy and Personal Information Protection Act 1998; NSW Health Records and Information Privacy Act 2002; NSW State Records Act 1998; General Retention and Disposal Authority – Health Services, Public: Patient/Client records (GDA17); NSW Health Electronic Information Security Policy (PD2013_033); NSW Health policies and guidelines; NSW Privacy Manual for Health Information and NSWHP policies and procedures. • Understanding of the full impact of the proposed research throughout the life of the project on site or department specific data collections, including data collections from other related departments. • Approving or denying a research project and its use of data, based on the impact of the research on site or department specific data collections, including data collections from other related departments. • Ensuring that use, collection or findings of data for research is conducted in accordance with relevant national research ethics and conduct guidelines, e.g. National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, updated 2018) and the Australian Code for the Responsible Conduct of Research (2018), and any specific conditions of its approval imposed by the local research and ethics governance process. • Ensuring ethical and scientific approval has been obtained in accordance with NSW Health (PD2010_055). • Ensure that researchers are aware of and comply with all policies and procedures included in this Research Governance Framework. • Documenting agreement with external entities on appropriate data management for collaborative research.
6.6 NSWHP Chief Executive (CE)	• Championing high ethical integrity in research and innovation • Understanding the requirements of research governance and the implications of approving the conduct of research. • Authorising the commencement of research at NSWHP as set out in NSW Health PD2010_056. • Approval of Intellectual property agreements as set out in NSW Health PD2005_370

Role	Responsibilities
6.7 NSWHP Research and Innovation Program Director	• Deep understanding the requirements of research governance and the implications of approving the conduct of research. • Authorising the commencement of low negligible risk (LNR) research at NSWHP as set out in NSWHP Delegation Manual. • Granting site authorisation through the NSW Health Request to Access process whereby access is granted to NSWHP participants, tissue or data for research to be conducted at another site; • Working with NSWHP Finance to ensure accounting of research funds in accordance with NSW Health Guideline (GL2001_001). • Preparing and disseminating reports on research activities undertaken in NSWHP. • Ensuring NSWHP meets all research expectations set out in the MoH Statement of Service (Service Level Agreement). • Managing Bequests and Donations targeted for Research via a RIAC subcommittee, who will appropriately process and report on the management of these funds and utilisation in accordance with the NSW Health PD2005_415 and PD2009_067 on philanthropic funding. • Ensuring actions of the Research and Innovation Advisory Committee and its subcommittees are delivered in accordance with the Research Governance Framework.
6.8 NSWHP Research Governance Officer	• 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; • 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 (SSA) approvals; • Documenting research activities via a database of research studies; • Review qualifications of researchers requiring certification for their roles.
6.9 NSWHP Strategic Leadership Team (SLT)	• Implementation of the Framework and associated procedures; • Ensure regular review and update of the Framework; • Ensure financial management of research funding in accordance with NSW Guideline GL2011_001; • Ensure relevant audits of research practices are included in the Audit & Risk schedule”

Role	Responsibilities
	• Review qualifications of researchers requiring certification for their roles.
6.10 NSWHP Corporate Governance	• Maintaining NSWHP's Compliance Management Framework and Register, and receiving notifications of non-compliance from Compliance Owners (SLT members) and coordinating notification to governance committees and relevant external bodies such as; the NHMRC, Office of Health and Medical Research, NSW Information and Privacy Commission, Independent Commission Against Corruption • Providing legal review of research agreements and advice in relation to legislative compliance • Ensuring that research compliance and risks are considered as part of the development of annual Internal Audit Plans, and monitoring compliance by management with improvement actions arising from completed audits • Providing advice and assistance to the NSWHP Research Integrity Office in relation to the notification, investigation and resolution of research misconduct or complaints
6.11 NSWHP Audit and Risk Management Committee (ARMC)	• Ensure that the Framework aligns to NSWHP's Compliance Management Framework • Review the effectiveness of the Framework in ensuring NSW Health Pathology's compliance with Compliance Obligations.
6.12 NSWHP Finance and Performance Sub-Committee of the Board	• Review the effectiveness of the Framework in ensuring NSW Health Pathology is delivery on key strategic objectives outlined in Priority 5 of NSWHP's Strategic Direction Towards 2025
6.11 NSWHP Research Integrity Officer(s)	• Discussing complaints or allegations of misconduct with the notifier and explaining the options for taking action as provided under the Australian Code for the Responsible Conduct of Research (2007) and NSWHP procedures. • Liaising with researchers on, and investigating, potential breaches to ascertain a thorough understanding of an alleged misconduct or complaint. • Conduct a risk assessment and log alleged breach. • Work with the Director of Corporate Governance to notify breaches and determine the course of action for resolution of misconduct or complaints.
6.12 NSWHP Research (Services) Coordinators	• Ensuring that external (non-NSWHP) requests for NSWHP clinical and/or forensic services are reviewed and responded to in a timely manner, ensuring they meet requirements of the National Statement on Ethical Conduct of Human Research 2018

Role	Responsibilities
	• Coordinating the provision of a quote for contracted research services using NSWHP Statewide Pricing Model with guidance from local Clinical Directors. • Ensuring a signed Service Level Order, i.e. a Service Level Agreement, is in place prior to providing the requested research services. • Ensuring appropriate account is setup by Finance and invoicing of research services is based on the research Service Level Agreement.”.

07 Legal and Policy Frameworks

For a detailed overview and the links to all policies, procedures, guidelines and supporting documents governing research in NSWHP, please go to:

https://www.pathology.health.nsw.gov.au/research-and-innovation/research-governance/research-policies

International Guideline

- WMA Declaration of Helsinki – Ethical Principles for Medical Research involving Human Subjects

National Guidelines

- AIATSIS (Australian Institute of Aboriginal and Torres Strait Islander Studies) Guideline for Ethical Research in Indigenous Studies)
- Australian Civil Aviation Act 1988;
- Australian Civil Aviation Safety Regulations 1998, part 92 – Consignment and carriage of dangerous goods by air (including part 92 advisory documents)
- Australian Standards in Microbiological Practices
- Biosecurity Act 2015
- Gene Technology Amendment Act 2007
- ICH GCP (Therapeutic Goods Administration Annotated Note for Guidance on Good Clinical Research Practice)
- International Air Transport Association Dangerous Goods Regulations (IATA DGRs);
- National Health Security Act 2007
- National Pathology Accreditation Advisory Council's (NPAAC) 'Requirements for the retention of laboratory records and diagnostic material *(Seventh Edition 2018)'*
- NHMRC Australian Code for the Responsible Conduct of Research 2018
- NHMRC Australian Code for the care and use of animals for scientific purposes (8th edition)
- NHMRC Authorship
- NHMRC Collaborative Research
- NHMRC Disclosure of interests and management of conflicts of interest
- NHMRC Ethical considerations in quality assurance and evaluation activities
- NHMRC Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance
- NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research
- NHMRC Management of Data and Information in Research
- NHMRC National Statement on Ethical Conduct of Human Research
- NHMRC Peer Review

- NHMRC Research Governance Handbook: Guidance for the national approach to single ethical review
- NHMRC Research Integrity and Policy Misconduct
- NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods
- NHMRC Statement on Consumer and Community Participation in Health and Medical Research (the Statement on Participation).
- NHMRC Supervision
- NHMRC Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research.
- NPAAC Publications.
- NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material (Seventh Edition 2018
- NPAAC Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices (IVDs) (Fourth Edition 2018)
- Therapeutic Goods Act (1989)
- Therapeutic Goods Administration Australian Clinical Trial handbook

NSW Government Acts and Regulations

- NSW Dangerous Goods (Road and Rail Transport) Act 2008 No 95
- NSW Dangerous Goods (Road and Rail Transport) Regulation 2014
- NSW Health Administration Act 1982.
- NSW Guardianship Act 1987
- NSW Health Records and Information Privacy Act 2002
- NSW Health Records and Information Privacy Regulation 2012
- NSW Human Tissue Legislation Amendment Act 2012 No.72
- NSW Information and Privacy Commission Information and Privacy Commission Statutory Guidelines on Research
- NSW Occupational Health and Safety Regulation Act 2001, Chapter 6 Hazardous substances
- NSW Privacy and Personal Information Protection Act 1998
- NSW SafeWork NSW Guideline Cytotoxic Drugs and Related Waste – Risk Management
- NSW State Records Act 1998
- NSW State Records General Retention and Disposal Authority – Health Services, Public: Patient/Client records (GDA17) (2019)
- NSW Work Health and Safety Act 2011 No 10

NSW Health Policies

- NSW Health Clinical Trial Research Agreements for Use in NSW Public Health Organisations (PD2011_028)
- NSW Health Data Collections – Disclosure of Unit Record Data for Research or Management of Health Services (PD2015_037)
- NSW Health Drugs – Highly Specialised Program – Guidelines for Undertaking Clinical Trials (PD2005_078)
- NSW Health Fundraising Policy (PD2009_067)
- NSW Health Group Services/Commercialisations Policy – Revenue Policy, Revenue Standard' (PD 2005_522)
- NSW Health HREC and Research Governance: Fee Policy for Review of Commercially Sponsored Research (PD2008_030)
- NSW Health Intellectual Property Arising from Health Research Policy (PD2005_370)
- NSW Health Medication Handling in NSW Public Health Facilities (PD2013_043)
- NSW Health NSW Clinical Trials – Insurance and Indemnity (PD2011_006)
- NSW Health Electronic Information Security Policy (PD2013_033)
- NSW Health Incident Management Policy (PD2020_020)
- NSW Health Patient Safety and Clinical Quality Program (PD2005_608)
- NSW Health Privacy Manual for Health Information
- NSW Health Research – Authorisation to Commence Human Research in NSW Public Health Organisations (PD2010_056)
- NSW Health Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations (PD2010_055)
- NSW Health Resolving Workplace Grievances (PD2016_046)
- NSW Health Risk Management – Enterprise-Wide Policy and Framework – NSW Health (PD2015_043)
- NSW Health Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations (PD2017_039)
- NSW Health Sponsorships Policy – NSW Health (PD2005_415)
- NSW Health Work Health and Safety: Better Practice Procedures (PD2018_013)

NSW Health Guidelines

- NSW Health Accounting Manual and the Guidelines for research funding (GL2011_001)
- NSW Health Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research and use of tissue (GL2006_021)
- NSW Health Operations Manual: Research Governance Officers (GL2010_015)

- NSW Health Quality Improvement & Ethical Review: A Practice Guide for NSW (GL2007_020)
- NSW Health Research Governance in NSW Public Health Organisations (GL2011_001)

NSWHP Frameworks and Procedures

- NSWHP Conflicts of Interest and Gifts and Benefits Procedure (NSWHP_PCP001)
- NSWHP Home Collection Procedure (NSWHP_PR_041)
- NSWHP Home Collection Services (NSWHP_PD_025)
- NSWHP Intellectual Property Framework & (NSWHP_F_00013) Intellectual Property Disclosure Form (NSWHP_CG007)
- NSWHP Delegations Manual (NSWHP_CG_001)
- NSWHP Enterprise Risk Management Procedure (NSWHP_PR_026)
- NSWHP Work, Health and Safety Procedure (NSWHP_PCP_004)
- NSWHP Publications Affiliation and Acknowledgement (NSWHP_PD_014)
- NSWHP Research and Innovation Framework (NSWHP_CG006)
- NSWHP Compliance Management Framework (NSWHP_CG_010)

Review

A preliminary review of the Framework will be undertaken by the NSWHP Research Governance Office within 6 months of initial approval and otherwise on an ad hoc basis where required due to any changes or additions to regulatory requirements or NSWHP's risk exposure. Formal review of the Framework will occur by 31/12/2022.

Risk

Risk Statement	The research governance framework will support our staff and sites with meeting International, National and State regulatory and legislative requirements when conducting research activity. Failure to do so could lead to potential risks to patient safety and safety for our workforce.
Risk Category	Clinical Care and Patient Safety

Further Information

For further information, please contact:

Policy Contact Officer	Position: Research Governance Officer
	Name: Andrew Harre
	Telephone: 02 9464 4766
	Email: Andrew.Harre@health.nsw.gov.au

Version History

The approval and amendment history for this document must be listed in the following table.

Version No	Effective Date	Approved By	Approval Date	Policy Author	Risk Rating	Sections Modified
1.0	04/01/2021	The Board & Strategic Leadership Team (SLT)	16/12/2020	Amanda Koegelenberg/ Andrew Harre	Medium (L)	New Framework
1.1	11/06/2021	Director Clinical Operations	11/06/2021	Amanda Koegelenberg/ Andrew Harre	Medium (L)	Additional reference to Section 7 – NHMRC Australian Code for the care and use of animals for scientific purposes (8th edition)