NSW Health

NSW Health Research Handbook

Guidance for Conducting Research at a NSW Public Health Organisation, Specialty Health Network or Affiliated Health Organisation (NSW Health Organisation)

Last updated: 18 June 2024

This document will be revised on a regular basis. Please direct any queries or suggestions for improvements to MOH-ResearchEthics@health.nsw.gov.au.

Acknowledgement

This Handbook is the culmination of many years of development work by many parties.

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We also acknowledge Tanya Symons of TSymonsAssociates who worked extensively with the OHMR to produce the Research Office Competencies document embedded within the Handbook.

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NSW Health Research Handbook

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NSW Health Research Handbook

1. Introduction

1.1. Background

NSW Health is dedicated to performing research that meets the highest national and international standards and delivering research in a regulated environment of continuous quality improvement. This requires a governance framework that encourages and supports research.

NSW Health Organisations are accountable for the quality, safety and ethical acceptability of research conducted under their auspices which includes on their premises, by their staff and with their participants. Research conducted at a NSW Health Organisation must therefore be conducted in accordance with local, national and international ethical principles, guidelines for responsible research conduct, legislations and regulations.

It is expected that researchers follow the Australian Code for the Responsible Conduct of Research 2018 (*the Code*) which articulates the broad principles that characterise an honest, ethical and conscientious research culture. *The Code* and supporting best practice guides outline the expectations for the conduct of research in Australia or research conducted under the auspices of Australian institutions. It establishes a framework for responsible research conduct that provides a foundation for high-quality research, credibility and community trust in the research endeavour.

1.2. Purpose

The purpose of this document is to set out the overarching requirements for conducting research at a NSW Health Organisation. The document aims to give guidance to both researchers and Research Development Offices to ensure that research being undertaken is safe, valid, of high quality and fulfils all regulatory and institutional requirements.

The guidance provided in this Handbook is specific to the governance requirements for conducting research at a NSW Health Organisation. The Handbook does not provide guidance on designing a research project, such as conducting a literature review and developing a protocol that answers a given question / hypothesis, data cleaning, statistical analysis and write up.

1.3. Scope & Applicability

This document applies to all human research undertaken at a NSW Health Organisation (i.e. involving NSW Health staff, participants and/or resources), or conducted by a NSW Health Organisation (i.e. where the local health district (LHD) is the Sponsor of a research project conducted at a site under the control of a NSW Health Organisation or at another location).

It applies to all NSW Health employees, non-employed staff and to all relevant external persons and parties engaged in the research activity at NSW Health.

1.4. Getting Started

Researchers intending to conduct research at a NSW Health Organisation should first read this Handbook and familiarise themselves with:

- NSW Health Policies and Guidelines
- NSW Health and Medical Research Strategy
- NSW Health Research Standard Operating Procedures (SOPs)

Researchers must also maintain awareness of relevant laws, regulations, guidelines and directions applicable to their work, including those of other institutions, regulatory authorities, funding bodies and the government. Researchers must ensure research integrity is upheld in all research conducted and comply with *the Code*.

Where applicable, references are included throughout this document and supporting SOPs.

A summary of key documents and source locations is provided in the References and Resources Section of this Handbook.

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Abbreviations

ACTA	Australian Clinical Trials Alliance
AH&MRC	Aboriginal Health & Medical Research Council
ARPANSA	Australian Radiation & Protection Nuclear Safety Agency
ARTG	Australian Register of Therapeutic Goods
ART	Assisted Reproductive Technology
CCE	Clinical Conductor Enterprise
CCS	Clinical Conductor Suite
CIRA	Clinical Investigation Research Agreement
COMET	Core Outcome Measures in Effectiveness Trials
CPI	Coordinating Principal Investigator
CRG	Collaborative Research Group
CRO	Contract Research Organisation
CTA	Clinical Trial Approval
CTMS	Clinical Trial Management System
CTN	Clinical Trial Notification
CTRA	Clinical Trial Research Agreement
DIR	Dealings that Involve Intentional Release of a GMO Into the Environment
DMP	Data Management Plan
DMTA	Drug Misuse and Trafficking Act
DNIR	Dealings that Do Not Involve Intentional Release of a GMO Into the Environment
DSMB	Data Safety and Monitoring Board
EDD	Emergency Dealing Determination
EPCT	Early Phase Clinical Trial
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
HRIPA	Health Records and Information Privacy Act 2002
IBC	Institutional Biosafety Committee
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IIT	Investigator Initiated Trials
ICMJE	International Committee of Medical Journals Editors
IP	Intellectual Property
ISF	Investigator Site File
ISO	International Organisation for Standardisation
LHD	Local Health District
MTAA	Medical Technologies Association Australia
NaCTA	National Clinical Trial Agreement
NCAT	NSW Civil and Administrative Tribunal
NCTGF	National Clinical Trials Governance Framework
NHMRC	National Health and Medical Research Council
NLRD	Notifiable Low Risk Dealings
NMA	National Mutual Acceptance
OGTR	Office of Gene Technology Regulator
OHMR	Office for Health and Medical Research
PHO	Public Health Organisation
PHSREC	Population & Health Services Research Ethics Committee
PI	Principal Investigator
QA	Quality Assurance
REDCap	Research Electronic Data Capture
REGIS	Research Ethics and Governance Information System

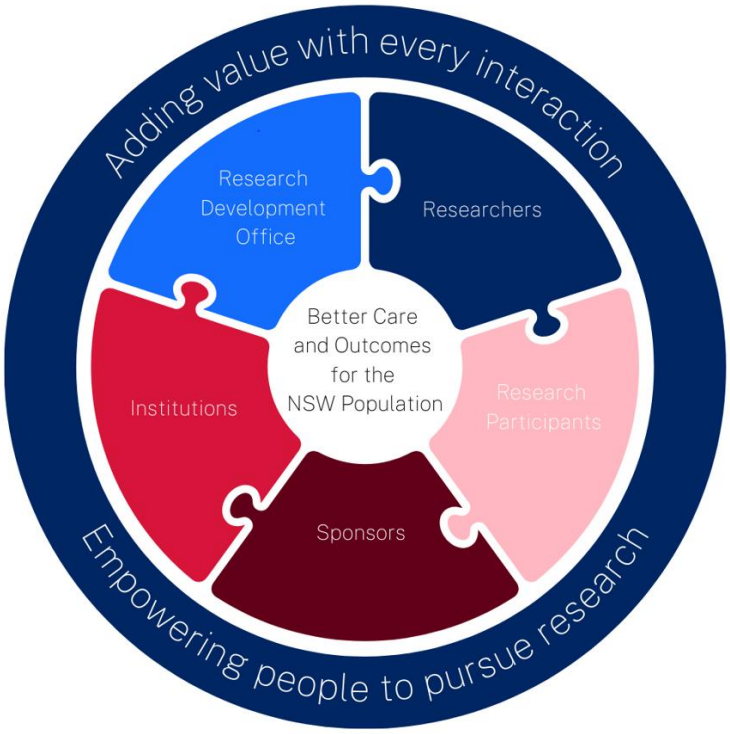
RGF	Research Governance Framework
RIHE Act	Research Involving Human Embryos Act 2002
RGO	Research Governance Officer
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SSA	Site Specific Assessment
SSI	Significant Safety Issue
SUSAR	Suspected Unexpected Serious Adverse Reaction
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TMF	Treasury Managed Fund
USADE	Unanticipated Serious Adverse Device Effects
USM	Urgent Safety Measure
WHO	World Health Organisation
WHO ICTRP	WHO International Clinical Trials Registry Platform

2. Embedding a Research Enabling Culture in NSW Health Organisations

Embedding a research culture requires a communal ethos and a multi-faceted approach that brings together all staff and patients to make a difference. By empowering our own people to pursue research and translate evidence into practice, we can make a difference to the lives of our patients and community members.

Everyone has a role to play in embedding a research culture.

- Research Development Offices should act as a system navigator to help researchers, ensuring processes are user friendly, easy to navigate and that every interaction is open, clear and helpful.
- Researchers have a responsibility to understand the requirements for undertaking research, ensuring that the ethical principles of merit and integrity, justice, beneficence and respect are applied.
- Sponsors should be aware of the impact that their commercial decisions have on the conduct of research at an institution and ensure research adheres with good clinical practice.
- Institutions should promote and foster a culture of responsible research conduct within their organisation, including the provision of safe and secure infrastructure, education and training.
- Research participants can contribute in a meaningful way to research through their engagement and involvement to ensure that outcomes are relevant and of value.



Appendix E outlines competencies Research Development Offices should actively implement to provide an effective service for health research at their institution.

3. Research Governance

Broadly, the term “research governance” means the processes that institutions, regulators, sponsors and investigators use to deliver safe and effective health and medical research involving humans.

Research governance applies to all forms of human research and addresses the protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory compliance, risk management and monitoring arrangements specific to NSW Health, whilst promoting and fostering a research culture of high integrity and good practice. At an organisational level, research governance provides assurance that studies have been designed to be feasible, financially sustainable, and delivered in a manner that minimises the impact on staff and participant’s routine clinical care (Figure 1).

NSW Health has implemented a Research Governance Framework (RGF) which ensures research conducted at, or by, NSW Health Organisations meets the highest ethical, scientific, regulatory and professional standards. Key components of the NSW Health RGF include: policies and procedures, risk management, leadership and training.

All research projects conducted at a NSW Health Organisation or sponsored by a NSW Health Organisation must meet appropriate governance standards, and be authorised by the Chief Executive of the LHD or delegate before commencement (as described in the NSW Health Organisation delegations manual). The governance processes in place ensure that ethical, legal, regulatory, strategic and logistical requirements are met in a way that is proportionate to the potential benefits and harms of the research and that all parties are aware of their responsibilities and the relevant approvals are in place.

Research Governance at a NSW Health Organisation is overseen by the Research Development Office.

Further information regarding the NSW Health Research Governance Framework and the supporting policies and procedures can be found here: https://www.medicalresearch.nsw.gov.au/policies-guidelines/.

Figure 1. An organisation's Research Governance Framework (RGF) outlines the structure and roles and responsibilities for managing research in an organisation. It is composed of research policies, procedures and training. An effective RGF includes a quality assurance program. At NSW Health Organisations this is delivered through integration with a quality management framework supporting continuous quality improvement, planning and performance, knowledge management, governance, compliance, benchmarking and risk management.

4. Researchers

4.1. Training Compliance

4.1.1. Good Clinical Practice

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, monitoring, recording and reporting trials that involve the participation of humans. GCP also ensures the roles and responsibilities of the institution, human research ethics committee (HREC), investigators and sponsor.

Compliance with GCP is incorporated by reference in the Therapeutic Goods Regulations (1990) and is a requirement for the conduct of Clinical Trials involving unapproved therapeutic goods in NSW.

The Therapeutic Goods Administration (TGA) recognises two internationally accepted GCP guidelines:

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP) with TGA annotations (for investigational medicinal products and investigational biologicals)
- Clinical investigation of medical devices for human subjects – GCP (International Organisation for Standardisation (ISO) 14155) (for investigational medical devices)

Transcelerate Biopharma Inc. have identified a minimum criteria for mutual recognition of ICH E6 GCP training. A list of courses that meet the minimum requirements can be accessed by researchers via the Transcelerate Biopharma Inc. website. Following completion of one of the courses a GCP training certificate will be provided which can be supplied to sponsors and requesting parties.

All researchers conducting regulated Clinical Trials are required to provide evidence of GCP training within the last 3 years (also a requirement of researcher credentialing). GCP training is highly recommended for all other researchers as it provides useful information related to data integrity and patient safety that can be applied across all areas of research. GCP training must be updated every 3 years.

However, it is important to note it is the individual's responsibility to ensure they are conversant with any changes that occur between the 3 year interval to GCP or laws, regulations, guidelines and directions applicable to their work.

<insert institution specific requirements around training compliance and GCP>.

4.2. Researcher Credentialing

Any researcher engaged in health and medical research involving NSW Health participants, staff and/or resources must be authorised to conduct research at a NSW Health facility.

All individuals (including NSW Health staff, external research contractors and external research students) conducting human research at or for NSW Health Organisation's are required to be:

- adequately qualified and experienced
- supervised (where applicable) and
- authorised to safely undertake the relevant research related activities.

4.3. Principal Investigator Requirements

The term Principal Investigator (PI) originates from Clinical Trials however is commonly used across all research modalities. A PI is defined as is the individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation. All research being conducted at a NSW Health Organisation must have a site PI.

There is no NSW Health policy requirement that a PI must be an employee of the site or located on the site the research is being conducted. A risk-based approach should be considered when a PI is being identified noting the responsibilities of a PI remain, regardless of their physical location.

NSW Health supports that there should always be local input and support for research taking place at a NSW Health Organisation, however this can be achieved by the inclusion of a local contact who can act as a local champion or liaison assisting with the logistics of the study.

An example of when the PI role can be adequately achieved with an external PI is a registry where the study is being driven from an external coordination centre and the support required onsite is to ensure data is transferred per an agreed schedule.

An example of when the PI role should be a locally employed role is a Clinical Trial where participants are receiving trial specific treatments.

The application of a particular investigator category (i.e., PI or Associate Investigator) for the purpose of research ethics and governance consideration does not influence or reflect the authorship nomenclature or ownership of the protocol. It is simply an indication of who is ultimately responsible for the conduct of the research at the NSW Health Organisation.

NSW Health does not have a policy position on the suitability of student researchers taking on the role of the PI. All students should be suitably supervised and not asked to perform research activity outside of their expertise and knowledge. e.g. a surgeon completing a PhD could be considered appropriate to be the PI on a surgery study. For further information regarding students, see NSW Health PD2022_049 Student Placements in NSW Health.

4.4. Student Access to Medical Records for Research Purposes

The Ministry of Health advice is that students are permitted to access LHD-owned medical records for training purposes on a clinical placement, or to deidentify and extract data for research purposes, regardless of their employment status at the LHD, provided adequate safeguards are in place and that the research has been ethically approved.

There is no requirement for students to be employed (or even claim employment status) with the LHD to access health records for either training or research purposes; nor is there a requirement for the LHD to create a contingent worker status for students on placement or conducting research.

In summary, so long as it is in compliance with general law and NSW Health policy, access to LHD-owned health records is predominantly a matter for the LHD as data custodian to determine the appropriateness of the safeguards it wishes to put in place.

For a research project where there is student involvement, Ministry policy requires:

1. HREC approval for the research, including specific approval for applying the research exemption under the Health Records and Information Privacy Act (HRIPA), if required.

While there is no determinative policy directive on point, the Ministry would highly recommend procedural safeguards such as:

1. The successful application of a Stafflink number in order to provide managed and auditable electronic medical record access;
2. Signing of a privacy undertaking. A pro forma Privacy undertaking is set out at Appendix 3 of the NSW Health Privacy Manual for Health Information. Note that this would need to be adapted for students; types of provisions which should be included for an external contractor (non-employee) are described on page 2.

Section 4.4 has been informed by advice from the Privacy Unit of Legal Services Branch at NSW Ministry of Health.

5. New Research Proposals

Research governance applies to all forms of research and addresses the protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory compliance, risk management and monitoring arrangements specific to the NSW Health Organisation whilst promoting and fostering a good research culture and practice. At an organisational level, studies must be feasible, financially sustainable and delivered in a manner that minimises the impact on staff and participant's routine clinical care.

Each NSW Health Organisation may have their own research strategy that will align with the NSW Health and Medical Research Strategy. It is important that all researchers understand these strategies and ensure that their proposed research is aligned with this and can be accommodated. To achieve this PIs need to discuss their projects with the relevant people that will be involved in any way at any NSW Health Organisation. In practice this will mean that they should speak with all heads of departments that are involved in their project i.e. medical records, radiation safety, pharmacy etc. and any staff who may need to be involved as well as senior managers and/or executives where there are significant impacts on resources or potential risks involved. NSW Health Pathology is the preferred provider of pathology services for the NSW Health system. NSW Health Pathology should be consulted prior to the commencement of any research involving their staff, services, biospecimens and/or data. Researchers are expected to identify, assess and mitigate risks associated with all new research activities.

We strongly encourage conversations about the risks and resource requirements to include all relevant stakeholders as early as possible, as experience dictates that failure to do so can result in delays or failure of the study at critical time points.

There is evidence to support that projects discussed with the local Research Development Office at time of site selection or at the concept/project design stage will reduce the site approval times. A short discussion will ensure that all relevant stakeholders have been included and assist researchers to avoid problems that may otherwise arise. The Research Development Office can also assist in all aspects of the research to be conducted at the NSW Health Organisation including research development (protocol design, statistical assistance where required) through to achieving ethical and institutional approvals as outlined in the delegation manual <insert Institution Delegations of Authority Policy or equivalent or refer to APPENDIX X for research specific delegations>.

6. Protocol Design

A high-quality and well thought out protocol will assist in smooth project implementation, the generation of quality and appropriate data, a reduction in avoidable amendments and deviations as well as facilitating efficient appraisal of the study's scientific and ethical considerations.

The team involved in protocol development should include, but is not limited to: health professionals with subject matter expertise (e.g. therapeutic area, investigational agent or class of agent), statisticians, experts with clinical research regulatory and operations (coordination, quality assurance and data management) experience and individuals or groups who can provide insight into the lived experience, values and priorities of consumers and communities.

Consumer and community engagement should be sought wherever possible throughout all stages of health and medical related research, from planning through to conduct of research and evaluation of outcomes. This ensures the research is relevant to community needs and increases opportunities to

continuously improve the quality of research (see National Health and Medical Research Council (NHMRC) Consumer and Community Engagement).

The Panel of Aboriginal and Torres Strait Islander Consumer and Community Representatives is a pool of consumer and/or community representatives drawn upon to assist in the peer review of Indigenous health research. Panel members with relevant experience are appointed to NHMRC's Targeted Calls for Research Peer Review Panels to assess Indigenous research applications against set criteria.

<insert details of relevant consumer representative groups across the district if available>

Resources, such as the Australian Clinical Trials Alliance (ACTA) Consumer Involvement and Engagement Toolkit (2022), provide practical advice on how to engage consumers in clinical research protocol development and delivery.

Use of an appropriate protocol template is essential to ensure that all risk factors and study design requirements have been considered when planning a research project. For Clinical Trials, the protocol should be based on the recommendations from the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement. Although the SPIRIT statement is designed for Clinical Trials the relevant principles can also be applied to non-interventional or health and social science research. Where appropriate, it is recommended that researchers follow the James Lind Alliance and Core Outcome Measures in Effectiveness Trials (COMET) methodology.

<insert link to institution protocol templates and whether these are recommended or must be used>

<insert details for further information for protocol development support>

7. Ethical Review

Institutions that conduct research involving humans are required to ensure that any research projects protect the rights and safety of participants, that is, it is 'ethical'. The following guidelines promote and inform the ethical conduct of human research:

- The National Statement on Ethical Conduct in Human Research (2023) (*National Statement*)
- AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (AIATSIS code), 2020
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018 and
- Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017 (the ART Guidelines)

Activities that may come within the scope defined in the *National Statement* may also encompass areas of research that are the subject of specific legislation, such as the Federal Privacy Act (1988, 2001) and the Therapeutic Goods Act (1989), as well as state and territory legislation. In these instances, those using the guidelines are also governed by federal and state legislation. Further information on the regulatory requirements for specific areas of research are provided in subsequent sections of this handbook and should be referred to where relevant.

While it is important to ensure all activities are ethically sound, not all projects require review by a HREC. The level of review will be commensurate with the level of risk to which participants are exposed.

Risks include physical, emotional, psychological, social, legal and reputational risks to participants, their families and communities, researchers, and/or institutions involved in the research. The following sections provide further guidance on the applicable HREC and non-HREC review pathways for research projects.

7.1. Risk Pathways for HREC Review or Exemption

The *National Statement* describes a variety of ways in which ethical review of research involving humans may be conducted. In 2023, the *National Statement* transitioned from three levels of risk (greater than low risk, low risk and negligible risk) to a continuum-based model from high risk to minimal risk, falling under two broad categories: higher risk and lower risk. A colour-coded table has been created to assist in understanding and applying the model (Figure 2). This enables researchers, reviewers and institutions to make relevant further distinctions in levels of risk in internal policy and practice.

All research should be assessed by an institution for its level of risk, in accordance with the guidance provided in Chapter 2.1 of the *National Statement*. This risk assessment can be conducted by a designated committee or an individual who has relevant experience and knowledge.

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

Figure 2. NHMRC National Statement on Ethical Conduct in Human Research (2023) risk profiles of research.

7.1.1. For Lower Risk Research

Research involving no more than low risk may be reviewed under other processes described in 5.1.10 to 5.1.14 of the *National Statement*. Institutions should establish processes or pathways for review of this research. Examples of such processes or pathways include, but are not limited to:

(a) review by a designated committee or person(s) within an institution;

(b) review by a sub-committee, Chair or Deputy Chair of an HREC.

NSW Health GL2023_007 Low and Negligible Risk Research provides clarification on the requirements of low risk research under the *National Statement* and is intended to provide greater consistency amongst NSW HRECs and other relevant parties.

Studies that involve the use of a waiver of the requirement for consent must be reviewed by an HREC even if they are deemed to be lower risk.

<insert details of any institution review processes for lower risk research>.

7.1.2. For Higher Risk Research

If a research project is assessed as having more than low risk, it must be reviewed by an HREC. In particular, studies that require notification or review by the TGA (i.e., Clinical Trial Notification (CTN)/

Clinical Trial Approval (CTA)) must be reviewed by a HREC that has demonstrated capacity to review these. In practice this will most likely be through a certified HREC.

The Coordinating Principal Investigator (CPI) is the individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. The CPI is responsible for ongoing communication with the HREC and passing on any outcomes from this to the PI's at each site where the research is conducted. Where the research is conducted at a single site, the CPI and PI are synonymous.

7.1.3. Research that may be Eligible for Exemption from Ethics Review

Some research may be eligible for an exemption from ethics review. This includes research that carries a lower risk to participants or the community and satisfies one or more of the conditions in section 5.1.17 (a)–(d) of the *National Statement*:

(a) the research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers and where researchers explicitly agree

(i) not to attempt to re-identify those with whom the information or data is associated;

(ii) to take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised; and

(iii) that any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data;

(b) the research is restricted to surveys and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research;

(c) is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only;

(d) the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.

Where appropriate, the institution responsible for the research may determine if an exemption is granted or not. Where there is no institution providing oversight of the research, researchers should request a grant of exemption from an ethics review body (*National Statement* 5.1.15).

Research that involves the use of personal information without consent cannot be granted an exemption from ethics review because, to conduct such research, a waiver of the requirement for consent would need to be granted by an appropriate ethics review body (*National Statement* 5.1.16).

7.1.4. Quality Improvement/Assurance and Program Evaluation

Quality assurance (QA) projects monitor and evaluate health care with the aim of improving its delivery. In almost all routine situations, QA projects will not have any ethical risks associated and should not require prior ethical review.

NSW Health GL2007_020: Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW provides a checklist for staff to assess their project against the guideline to determine if any ethical risks are present in their project.

- If all responses to the checklist are 'false', then no ethical risks have been identified with the project and no ethical review is required.
- If any of the checklist items are 'true', staff should contact a HREC or designated institutional body for further advice as ethical review may be required.

Many professional journals require evidence of ethical review before QA results will be published. If the checklist identifies no ethical risks, and only intention to publish, then ethical review is not warranted. Intending authors are encouraged to identify journal requirements on an individual basis. NSW Health has developed a letter template which an ethics review body may issue to staff in instances where a project does not involve any of the ethical risks set out in GL2007_020, advising that in accordance with NSW Health policy, there is no requirement for ethical review. Staff can then use the letter as evidence when submitting their project for publication.

For further information visit: https://www.medicalresearch.nsw.gov.au/ethical-scientific-review-2/

<insert details of any institution review processes for quality improvement/assurance projects>.

7.2 Biobanks

All biobanks must be approved by an HREC. Specifically this means that they must comply with all sections of *the National Statement* Chapter 3.2: Human Biospecimens in laboratory based research. Any biobanks that are intended for a therapeutic purpose must also comply with relevant regulatory requirements (TGA; Office of the Gene Technology Regulator (OGTR)) and any relevant state and federal laws. It is likely that research involving human biospecimens will be of a genetic nature and so researchers should ensure that they are also compliant with the *National Statement* Chapter 3.3 Genomic Research.

NSW Health have established a statewide biobank in partnership with the Office for Health and Medical Research (OHMR), NSW Health Pathology, Sydney Local Health District and Health Infrastructure. The NSW Health Statewide Biobank offers a range of educational, operational, research and best practice tools for researchers and biobankers who collect, store, study or provide access to human biospecimens. This includes a biobank certification program, SOP templates that align with best practice international biobanking standards and consent toolkit to help support and guide conversations with patients and participants. For more information visit: https://biobank.health.nsw.gov.au/.

Further to this, NSW Health Pathology have developed a set of biobanking principles to explain how their organisation supports the retrieval, processing and/or release of material and associated data. Priority is given to biobanks that use the NSW Health Statewide Biobank. For more information visit: https://pathology.health.nsw.gov.au/research/research-services/.

7.3 Specialist HREC Review

Certain human research projects must satisfy specific review requirements in addition to review by a local or lead HREC, before they take place in NSW Health Organisations. These requirements, outlined in this section, are not mutually exclusive.

7.3.1 Justice Health HREC

All research projects involving persons in custody in NSW and/or staff of NSW Justice Health require review by the NSW Justice Health HREC.
For more information: www.nsw.gov.au/health/justicehealth.

7.3.2 Aboriginal Health & Medical Research Council (AH&MRC) HREC

Approval from the AH&MRC HREC is required where the research project involves research in, or concerning, NSW and any one of the following applies:

- The experience of Aboriginal people is an explicit focus of all or part of the research;
- Data collection is explicitly directed at Aboriginal people;
- Aboriginal peoples, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal communities; or
- Aboriginal health funds are a source of funding.

For more information: www.ahmrc.org.au/ethics-at-ahmrc/.

7.3.3 NSW Population & Health Service Research Ethics Committee (PHSREC)

All research projects requiring access (including linkage) to statewide data collections owned or managed by NSW Health or the Cancer Institute NSW must be reviewed by the NSW Population & Health Services Research Ethics Committee (PHSREC).

For more information: www.cancer.nsw.gov.au/research-and-data/nsw-population-health-services-research-ethics-com.

7.3.4 Early Phase Clinical Trials

The Early Phase Clinical Trials (EPCT) HRECs Scheme was established to further support NSW's consistent, high quality scientific and ethics review and approval process for EPCT, while supporting the welfare and safety of trial participants.

All EPCT ethics applications should be submitted to one of the two NSW Health EPCT HRECs for review and approval.

For more information: www.medicalresearch.nsw.gov.au/hrec-scheme/.

7.3.5 Clinical Trials with Persons Unable to Provide Consent

Under the Guardianship Act 1987 (NSW), a person unable to consent may not participate in a Clinical Trial 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. The Guardianship Tribunal will not deal with an application for approval of a Clinical Trial until: it receives proof that the relevant ethics committees have approved the Clinical Trial; and all the centres conducting the Clinical Trial have provided the Tribunal with the patient information sheets and consent forms for the Clinical Trial.

For more information: https://ncat.nsw.gov.au/case-types/guardianship/clinical-trials.html

7.4 Research Ethics and Governance Information System (REGIS)

All NSW Health Organisation researchers are required to prepare and submit their ethics and site governance applications in the Research Ethics and Governance Information System (REGIS). REGIS is an online portal that helps to streamline the review and management of ethics and site

governance approvals of human research projects in NSW, TAS and ACT public health organisations and LHDs.

REGIS facilitates the creation, review and storage of:

- Human research ethics applications (HREA) and site specific assessment (SSA) applications
- Amendments
- Progress reports
- Safety notifications, milestones and other post approval activities

Researchers can easily track the progress of their ethics and governance applications through REGIS.

A range of guidance materials are available that offer step-by-step instructions to help users work in REGIS:

- Quick reference guides: https://regis.health.nsw.gov.au/how-to/
- Instructional videos: https://www.youtube.com/channel/UCYYI8wUSjJacGMF7pPAsIlA.

8. Site Authorisation at a NSW Health Organisation

In addition to ethical and scientific review, all human research that takes place in NSW Health Organisations, or that requires support from a NSW Health Organisation in the form of access to participants, tissue or data, must be reviewed and authorised by the organisation's Chief Executive, or their delegate before commencement. The project must not commence until the applicant has received written notification of documented authorisation.

Site authorisation enables NSW Health Organisations to:

- ensure that the proposed research project complies with appropriate ethical, scientific, regulatory and professional standards
- consider whether the project should be conducted at and supported by the organisation, and/or whether the provision of access to participants, their tissue and/or data should be supported
- be aware of all research taking place at sites under their control.

There are two pathways to site authorisation in NSW, depending on the research activities:

1. Site Specific Assessment (SSA)
2. Access Request review.

Site authorisation must be conducted in accordance with NSW Health PD2010_056: Research – Authorisation to Commence Human Research in NSW Public Health Organisations.

8.1 Site Specific Assessment (SSA)

A SSA application is required for sites under the control of a NSW Health Organisation, if the project involves one of more of the following activities:

- enrolling participants into research (e.g. obtaining informed consent, screening)
- carrying out protocol-specific research procedures with or on participants
- managing and analysing data, tissue, and responses from surveys and questionnaires collected for or from research.

The SSA process involves consideration of matters including resources (financial, in-kind and equipment/infrastructure), staff involvement, head of department support, and contract, insurance and indemnity requirements. These matters are discussed in further detail throughout the Handbook.

HREC and SSA review may occur in parallel, however the decision to authorise or to not authorise the commencement of a research project can only be made after HREC approval has been granted and the SSA has been satisfactorily completed.

All applications for site authorisation (with the exception of access requests (see Section 8.2)) must be made on the standard SSA Form in REGIS and submitted to the relevant Research Governance Officer (RGO) within the NSW Health Organisation. For instructions on how to complete the REGIS SSA, please see the Quick Reference Guide: Completing a Site Specific Assessment.

The RGO is responsible for:

- assessing site specific aspects of research applications
- making a recommendation to the Chief Executive or delegate as to whether a research project should be authorised at the site
- post-authorisation activities such as managing and reviewing amendments of authorised research projects, having oversight of authorised projects through review of annual and final reports, and managing complaints related to the conduct of projects.

For further information see *NSW Health Operations Manual: Research Governance Officers SOP*. OHMR have also developed a resource outlining the roles and responsibilities of researchers, RGO's and heads of department when reviewing and authorising an SSA (see *NSW Health SSA Roles and Responsibilities*).

8.2 NSW Health Access Requests

A research project that requires support from a NSW Health Organisation in the form of access to participants, tissue or data but does not involve the conduct of research at that NSW Health Organisation is not required to undergo the SSA application process. An access request can be submitted to the NSW Health Organisation for review before authorisation can be granted by the Chief Executive or their delegate.

Research projects suitable for review via an access request include projects that only involve one or more of the following activities at a NSW Health Organisation:

- participant recruitment through posters, leaflets and letter of invitation but not recruitment through direct contact with potential participants or enrolment;
- distribution of surveys and questionnaires through NSW Health Organisation staff but not collation and analysis of responses at that NSW Health Organisation; and
- access to data or tissue held at the NSW Health Organisation but not processing or analysis at that NSW Health Organisation.

OHMR have developed a decision tree resource to help researchers determine whether an SSA or access request is most appropriate for their research project (see *NSW Health Access Request Decision Tree).*

Only one access request per RGO is required for each research project, even if the project requires access from a number of facilities, locations or services covered by that RGO.

For further information, including a directory list of NSW Health RGOs and a copy of the access request application form, please visit: https://www.medicalresearch.nsw.gov.au/site-authorisation-access-request/.

9. Conflicts of Interest

Researchers must disclose and manage actual, potential or perceived conflicts of interest consistent with *the Code* and the NHMRC Disclosure of interests and management of conflicts of interest Guide (2019).

All NSW Health researchers must be aware of and adhere with NSW Health Conflicts of Interest and Gifts and Benefits Policy which is in alignment with t*he Code*.

10. Data and Primary Material Management and Retention

It is the responsibility of the researcher, in accordance with good data governance practice, to ensure the proper management and retention of research data during the conduct and after the completion of a research project to ensure a justification and defence of the outcomes can be provided if results are challenged. Further guidance is provided in the *National Statement*, Chapter 3.1 The Elements of Research, Element 4: Collection, Use and Management of Data and Information.

In accordance with the *Code*, researchers are strongly encouraged to develop a data management plan (DMP) at the beginning of their research to set out how data will be collected, managed and stored (see *NSW Health Research Data Management SOP* and NHMRC Management of Data and Information in Research: A guide to supporting the Australian Code for the Responsible Conduct of Research). DMPs should be developed as early as possible in the research process and should include details regarding:

- physical, network, system security and any other technological security measures
- policies and procedures
- contractual and licensing arrangements and confidentiality agreements
- training for members of the project team and others, as appropriate
- the form in which the data or information will be stored
- the purposes for which the data or information will be used and/or disclosed
- the conditions under which access to the data or information may be granted to others
- what information from the data management plan, if any, needs to be communicated to potential participants, and
- how long data will be retained for and how the data will be destroyed

<If applicable insert link to institution specific research data management plan>.

10.1. Data and Primary Materials

10.1.1. Electronic Documents and Data

NSW Health Organisation researchers (see definition on page 47 of this Handbook) are required to store and analyse electronic documents and data on NSW Health approved networks or platform servers. These servers are backed up at regular intervals and documents and data can be retrieved from the backed up copies should the need arise. Research documents or data must not be stored on local drives / desktops or removable storage devices, see NSW Health PD2020_046 Electronic Information Security Policy.

Creating, managing and using information from research databases is the responsibility of the Sponsor (or research units where a NSW Health Organisation is the sponsor).

Any person involved in the management of research data at a NSW Health Organisation, including all NSW Health employees, non-employed staff and all external persons and parties engaged in the research at NSW Health, must adhere with NSW Health policies regarding the storage and analysis of documents and data.

10.1.2. REDCap

REDCap (Research Electronic Data Capture) is a secure web application for building and managing online surveys and databases. The system was developed by Vanderbilt University and is supported by a multi-institutional consortium of administrators. The NSW Health instance of REDCap is hosted on NSW Health servers and managed by local superusers at the project level, the OHMR Administrators at the application level and eHealth at the application and infrastructure level.

REDCap can be used to collect many types and forms of data with the scope of data and collection processes designed for each project or clinical operation.

NSW Health encourages its staff to use REDCap for research purposes as the data is held within NSW and the system and security is managed in accordance with the NSW Health Information Technology systems and protocols. All data collection, storage and use of REDCap must remain compliant with NSW Health policies, guidelines and processes, regulations, project approvals (including ethics and site governance approvals), agreement and any other applicable requirement, irrespective of the data formats and tools used to collect and manage the data. It is the users responsibility to be familiar and comply with these requirements. If data is not being analysed in REDCap, data protection practices must be in place to ensure data security. See Section 10.3 of this Handbook for approved methods of data sharing.

10.1.3. Clinical Trial Management System

All NSW Health Organisations conducting Clinical Trials use a statewide clinical trial management system (CTMS). CTMS provides a shared online repository for Clinical Trials management, organising and storing all of NSW Health's Clinical Trial operational data in one secure location.

The CTMS enables the improvement of financial oversight, participant recruitment, protocol adherence, and revenue capture. Within the CTMS, trial staff can manage participants and recruitment, review budgets and forecasting, and track grants, invoices and funding milestones.

Any Clinical Trial that meets all the following criteria must be entered into the CTMS:

1. Meets the World Health Organisation (WHO) definition of a Clinical Trial which involves prospectively assigning human participants or groups to health-related interventions to evaluate the effects on health outcomes (WHO, 2020).
2. The Clinical Trial is conducted at NSW Health public facility or service, by a NSW Health employee or contingent worker, requiring a SSA within that district.
3. SSA authorisation is received on, or after, September 1st, 2023.
4. The Clinical Trial captures individual patient data.

The CTMS comprises two separate parts: Clinical Conductor Enterprise (CCE) for administration and Clinical Conductor Suite (CCS) for site/trial unit activities. Two additional CTMS components are available for use by NSW Health staff including eReg, a virtual investigator site file, and CCText, a texting application that can send appointment and reminder texts to participants.

Use of the CTMS became mandatory from September 1st, 2023, for all new Clinical Trials.

A study and patient minimum data set has been developed to assist in meeting accreditation requirements under the Australian Commission on Safety and Quality in Health Care Clinical Trial Governance Framework as well as LHD, state and national reporting. NSW Health Staff can access CTMS information, minimum data set requirements and resources through the CTMS SharePoint site: https://nswhealth.sharepoint.com/sites/NSWH-CTMS.

10.2. Confidentiality and Privacy

NSW Health Organisation staff are reminded that although they may have access to data in their clinical role, access to this data for research is for a different purpose. As such, use of data for research requires approval as outlined throughout this Handbook.

It is essential that researchers maintain a participant's privacy, wherever possible, when collecting and using personal, health or sensitive information in a research project. Researchers must ensure that study data is stored securely during the project and after its completion.

All research involving the use of personal health information must abide by the requirements outlined in:

- NSW Health Privacy Manual
- Health Records and Information Privacy Act 2002 (NSW)
- Statutory Guidelines on Research: Health Records and Information Privacy Act 2002 (NSW)
- The *National Statement*
- *The Code*

The following points must be adhered to when designing a research project involving the collection, use and dissemination of participant information:

- An individual's data should only be collected if necessary to fulfil the aims of the research.
- Obtaining informed consent from an individual when collecting, using, storing or disseminating their data or information should be the first approach used by a researcher when dealing with personal health information.
- If consent for use of an individual's data in a research project cannot be obtained from the participant, a person responsible or guardian/parent may be able to provide consent on their behalf. If consent cannot be obtained, a waiver of consent must be granted by an HREC before an individual's data can be used.
- Data should be collected, used, stored and disseminated in a manner that protects the privacy of the participant.
- Data should be stored in line with relevant state requirements (See Section 10.4: Retention).
- If data is to be transferred to another organisation, it should be in a non-identifiable or non-reidentifiable format and the participant should consent to the third party obtaining the information. It is the researcher's responsibility to ensure that the third party complies with all applicable information and privacy regulatory requirements and NSW Health requirements when receiving and managing the data.

The following aspects should also be considered when assessing the risks associated with data collection, use and retention:

- The nature of the data being collected, especially if it is personal information, health information or sensitive information.

- The format in which the data will be collected, used and stored, and whether it is identifiable, re-identifiable, non-identifiable or a mixture of all three.
- Location and length of time that the research data will be kept (See Section 10.4: Retention).
- The potential for data to be used in future research.
- If the data is to be transferred between organisations and how this will occur.
- The nature of consent obtained for the collection, use, sharing and storage of data.
- The data security measures in place to maintain individual's privacy.
- If there are any risks associated with dissemination of results.

10.3. Data Sharing

NSW Health PD2018_001 Disclosure of unit record data by Local Health Districts for research or contractor services provides direction on the procedure to be followed when identified or de-identified unit record data relating to the health of an individual or individuals is being released from the LHD for the purpose of research. It also provides a confidentiality undertaking template that is approved for use for the release of data by the authorised delegate (see Delegations manual). Under the HRIPA 2002 NSW Health Organisations are seen as a single entity for data purposes, and therefore confidentiality undertakings between NSW Health Organisations are not formally required.

The Five Safes Framework has been widely adopted across Australia, particularly in government sectors. The Framework supports data custodians to assess and describe disclosure risks according to the following elements: safe people, safe projects, safe settings, safe data and safe outputs. Further information can be found here: https://www.abs.gov.au/about/data-services/data-confidentiality-guide/five-safes-framework.

File sharing methods such as email and mobile text messaging and storage on portable media devices such as hard-drives or USBs are not considered secure and should be avoided (PD2018_001). Kiteworks (Accellion) Secure File Transfer is available for use by NSW Health Organisations for sending and receiving files over the internet or network more securely than by standard email.

Data sharing is an evolving space. As data sharing policy settings are further developed under the Ministry of Health based NSW Health Data Governance Reform Program they will be reflected in future revisions of this Handbook.

10.3.1. Secure Access Environments for Sharing Unit Record Health Data Externally

Where data sharing is permitted, NSW Health recommends sharing unit record health data intended for secondary use by external parties into a suitable Secure Access Environment. Secure Access Environments provide a single location to access and analyse datasets and help streamline access to data and allow multiple people to work on a single project, while increasing the confidence of patients and data custodians that data will be kept safe. Use of Secure Access Environments help ensure health data and information is accessible to those who need it and the data is stored and used safely.

For further information on when the recommendations apply and a list of Secure Access Environments that meet the minimum requirements see: https://www.health.nsw.gov.au/data/sharing/Pages/secure-access-environments.aspx.

10.4. Retention

Retention of data is determined by law, regulation, funding agencies, publishers, and commercial sponsors, or by standard convention. For Clinical Trials, data must be retained for a minimum of 15 years for adult studies or 25 years for paediatric studies. For areas such as gene therapy, research data must be retained permanently.

More information regarding retention of data can be found in:

* The Australian Code for the Responsible Conduct of Research, 2018 (*the Code*)

* State Record NSW General Retention and Disposal Authorities:

- GDA17 General Retention and Disposal Authority Public health services: patient/client records: This authority covers records documenting the provision of health care to patients and clients of NSW public offices, including records relating to research participants (see Function: Research Management, Reference 8.0.0, page 41).
- GDA47 General Retention and Disposal Authority Higher and Further Education and Research: This authority covers records documenting the function of higher and further education and research, including for all public offices involved in research (see Function: Research, Reference 3.0.0, page 15). This authority covers ethics committee records, grant administration and research data.

While GDA21 – General Retention and Disposal Authority Public health services: administrative records (Reference 15.0.0) is still authorised for use, advice obtained by OHMR from State Records is that this authority is under review and may be superseded in the future.

10.5. Biospecimen Access, Use, Retention and Disposal

NSW Health Pathology can provide researchers with access to biospecimens, data and/or research services. Requests can be submitted via eResearchWithUs. A list of services available can be found here: https://pathology.health.nsw.gov.au/research/research-services/accessrequest/.

NSW Health Pathology have a standardised statewide approach to pricing pathology services for research.

As outlined in Section 6.2 of this Handbook, NSW Health Pathology have a set of biobanking principles that explain how their organisation supports the retrieval, processing and/or release of material and associated data.

Researchers seeking support for their project can contact the NSW Health Pathology research office at NSWPATH-Research@health.nsw.gov.au or visit: https://pathology.health.nsw.gov.au/research/research-services/.

11. Intellectual Property

The term Intellectual Property, or 'IP', refers to the legally recognised outcome of creative effort and economic investment in creative effort. The law accords for the protection of such efforts.

The NHMRC has published a set of National Principles of Intellectual Property Management for Publicly Funded Research, which provides guidance on the ownership, promotion, dissemination, exploitation and, where appropriate, protection of IP generated through Australian Government funded research by public sector institutions.

Organisations undertaking research are required to have IP arrangements in place for employees. This is generally captured in either an employment contract, or in an IP Policy. It is the responsibility of a researcher to understand the basic principles of IP, and to understand the policies and processes in place within their organisation for managing any IP assets that may be developed by staff in the course of their work.

All NSW Health researchers must be aware of and adhere to the NSW Health Policy Directive for Intellectual Property Arising from Health Research. <insert further institution specific details including contact details for questions>.

12. Regulatory Requirements

12.1. Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) Schemes (Clinical Trials only)

The TGA is Australia's regulatory authority for therapeutic goods. The TGA is responsible for regulating the use of therapeutic goods supplied in Clinical Trials in Australia under the therapeutic goods legislation. The TGA provides a series of guidance on its requirements, with the main resource relevant to most clinical research in Australia being the Clinical Trials Handbook.

The Therapeutic Goods legislation, stipulates that a product may not be manufactured, imported, exported or supplied in Australia unless it is either entered onto the Australian Register of Therapeutic Goods (ARTG), or is "exempt" from the requirement for such entry.

The CTN and CTA schemes are two such avenues of "exemption" that allow unapproved therapeutic goods to be supplied to members of the Australian public.

All Clinical Trials involving unapproved therapeutic goods conducted under the CTN/CTA schemes must have an Australian Sponsor. Clinical Trial sponsors may be commercial entities such as pharmaceutical companies, biotech companies, Contract Research Organisations (CROs), collaborative groups or investigators or their employers.

The Sponsor is responsible for the initiation, management and financing (or arranging the financing) of the trial. The Sponsor is also the entity that is responsible for submitting a CTN/CTA.

Please refer to the TGA Clinical Trials Handbook for further information on the CTN and CTA schemes and how they may apply to your research.

The Sponsor is responsible for the submission of the CTN/CTA and any updates or reports (such as safety reporting) required to be submitted to the TGA during the conduct of the research project.

The CTN for a Clinical Trial hosted at a NSW Health Organisation must be submitted by the Sponsor to the TGA prior to commencement at a NSW Health Organisation.

The Research Development Office is not required to request the TGA acknowledgement before authorising the study at the site.

12.1.1. NSW Health as Clinical Trial Sponsor

A NSW Health Organisation may act as the Sponsor for a Clinical Trial initiated by NSW Health employees <insert visiting medical officer/honorary as applicable>. However, approval to act as the Sponsor is not automatic. The CPI (where multi-site trial), or PI (where trial is single site) must discuss the intention for NSW Health to be the Sponsor with the Research Development Office as

early as possible and prior to submission of the site governance application <or HREC submission - sequence to be confirmed>.

The CPI/PI must submit a sponsorship request through the Research Development Office. NSW Health Sponsorship must be confirmed by the <insert i.e. Clinical Trials Sponsorship Committee, Research Advisory Committee> prior to submission of a site governance application (for any site if multisite).

Where the Sponsor of a CTN/CTA, the LHD must satisfy itself that the study meets the relevant standards and ensure that arrangements are put and kept in place for management, monitoring and reporting (see TGA Clinical Trials Handbook, ICH GCP Section 5 and ISO 14155.

Where Sponsor responsibilities are being delegated to the CPI/PI e.g submission of CTN or safety reporting to TGA, this must be clearly documented.

For further information see *NSW Health Clinical Trial Sponsorship SOP*.

12.2. Authority to Prescribe Drugs of Addiction in Research

In accordance with the Poisons and Therapeutic Goods Act 1966 (NSW), researchers (medical practitioners or nurse/midwife practitioners) planning to prescribe or supply any of the following in NSW for the purposes of research must obtain authority from the NSW Ministry of Health.

- A substance in Schedule 8 (S8) of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), including a cannabis medicine, an unregistered medicine or an extemporaneously-compounded medicine
- A substance in Schedule 9 (S9) of the SUSMP
- A substance in Schedule 1 (S1) of the Drug Misuse and Trafficking Act 1985 (DMTA)

Researchers must have a NSW authority to prescribe and/or supply in place before Research Governance Authorisation can be granted for these types of research projects. For a researcher to prescribe and/or supply these drugs at a NSW Health Organisation, it is a requirement that the researcher be an employee <insert visiting medical officer/junior medical officer/honorary if applicable>.

Further information can be found on the NSW Health Website - NSW legal requirements for an authority to prescribe drugs of addiction.

12.3. Gene Technology

Gene technology (also referred to as genetic engineering, biotechnology or genome editing) is defined in the Gene Technology Act 2000 (the GT Act) as any technique for the modification of genes or other genetic material, but does not include: a) sexual reproduction; b) homologous recombination; or c) any other technique specified in the Regulations that is not gene technology.

The use of genetically modified organisms (GMOs) and other non-GMO biological hazards must be conducted in compliance with the GT Act, the Gene Technology Regulations 2001 and Australia New Zealand Standards Safety in laboratories standard AS/NZS 2243.3. Institutions and individuals must comply with the act and regulation. Sanctions apply where there is failure to comply.

The Gene Technology Regulator through the OGTR is responsible for administering the GT Act as well as the corresponding state and territory legislations. The OGTR has specific responsibilities in protecting the health and safety of people and the environment through identifying risks posed by

gene technology and managing those risks through regulating certain activities (dealings)(see Risk Analysis Framework 2013).

Dealings with GMOs are prohibited unless:

- the person undertaking the dealing is authorised by a GMO licence:
    - Dealings that involve intentional release of a GMO into the environment (DIR),
    - Dealings that do not involve intentional release of a GMO into the environment (DNIR),
    - Inadvertent dealings (dealings where a person has come into contact with a dealing without realising or intending to),
    - Emergency dealing determination (EDD) (approval of dealings with a GMO in an emergency),
    - Notifiable low risk dealings (NLRD)
- the dealing is an exempt dealing (as per schedule 2 of the GT Act); or
- the dealing is included in the GMO Register.

Institutional Biosafety Committees (IBCs) evaluate exempt and low-risk dealings and review licence applications for higher risk dealings before the applications are sent to the Regulator.

Where the dealing requires a licence the OGTR must provide authorisation before the activity can commence. Dealing with a GMO without appropriate authorisation under the GT Act is an offence and subject to criminal penalties.

A list of all approved GMO dealings can be accessed on the OGTR's GMO dealings webpage.

Accreditation of the licence holder under the GT Act is also often a condition of the licence. <insert details about institution accreditation where applicable and researcher requirements under this i.e. reference to SOPs, in conjunction with relevant approval from the relevant IBC>.

12.4. Research Involving Human Embryos

Research activities that involve the use of human embryos created by assisted reproductive technology (ART) or by other means must be conducted in compliance with the Research Involving Human Embryos Act 2002 (RIHE Act), the Prohibition of Human Cloning for Reproduction Act 2002 (PHCR Act), Research Involving Human Embryos (NSW) Act 2003, Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (NSW), Assisted Reproductive Technology Act 2007 (NSW) and the Research Involving Human Embryos Regulations 2017 (RIHER).

The NHMRC Embryo Research Licensing Committee (NHMRC Licensing Committee) is established by the RIHE Act and regulates research activities that involve the use of human embryos.

Research involving human embryos can only be conducted if authorised by a licence issued by the NHMRC Licensing Committee. A list of all licences issued by the NHMRC Licencing Committee authorising use of excess ART embryos is publicly available on NHMRC website.

Licensable activities include:

- any use of an excess ART embryo which is not an exempt use as specified in subsection 10(2) of the RIHE Act,
- research or training in ART involving fertilisation of a human egg by a human sperm outside the body of a woman,

- establishing a new human embryonic stem cell line from excess ART embryos or other embryos; or
- other activities as specified in the legislation.

Researchers must be familiar with the legislative and regulatory requirements. Information on the NHMRC Embryo Research licence application process and regulatory framework are provided on the NHMRC – Information for applicants webpage. HREC approval must be in place before applying for a licence.

If your project involves the use of human embryos please contact the Research Development Office as early as possible to discuss.

12.5. Research Involving the Use of Ionising Radiation

All research involving exposure of persons to ionising radiation above standard of care must be carried out in accordance with The Code of Practice – Exposure of Humans to Ionizing Radiation for Research Purposes Radiation Protection Series Publication No. 8 (RPS 8) set out by Australian Radiation & Nuclear Safety Agency (*ARPANSA Code*).

The *ARPANSA Code* specifies the responsibilities of:

- the researcher,
- the medical physicist assessing the effective dose and undertaking the radiation risk assessment,
- the HREC, and
- the Responsible Person (responsible for establishing systems that ensure the overall observance of this Code and its implementation (NSW Health, the Responsible Person is the Chief Executive of the LHDs).

Compliance with RPS8 is required under Section 33 of the NSW Radiation Control Regulation 2013.

The Environment Protection Authority is the regulatory authority in NSW responsible for ensuring compliance with the *ARPANSA Code*.

Before submitting a research project for ethics and governance authorisation involving the administration of ionising radiation (to research participants), the researcher must be familiar with their roles and responsibilities as outlined under the *ARPANSA Code*.

<insert institution details if applicable and the relevant contact departments and procedures. Position on review of research involving standard of care exposure vs above standard of care should also be set out here.>

12.6. NSW Civil and Administrative Tribunal (NCAT) approval

Clinical Trials involving recruitment of participants who are 16 years of age or older who are unable to provide informed consent to treatment, must have the approval of the NSW NCAT under Part 5 of the Guardianship Act 1987. For further information: https://ncat.nsw.gov.au/.

NSW Research Development Offices require NCAT approval, prior to governance authorisation. Given the requirements outlined in section 45AA(2)(e) of the Guardianship Act 1987, NCAT will not hear an application for approval of a Clinical Trial until the ethics committee application and approval have been submitted to NCAT for all nominated sites.

13. Registration of Clinical Trials

The National Statement (section 3.1.7) requires researchers to ensure Clinical Trials are registered on a publicly accessible register complying with international standards outlined by the WHO International Clinical Trials Registry Platform (WHO ICTRP) prior to the recruitment of the first participant.

Registration of a Clinical Trial on a publicly accessible register such as ClinicalTrials.gov or Australian New Zealand Clinical Trials Registry is important to ensure improved research transparency, to facilitate research participation and avoid duplication of effort. It can also aid the identification of evidence gaps and/or areas of unmet need, promote research collaboration and improve clinical research quality.

It is also a requirement of publication by the International Committee of Medical Journals Editors (ICMJE) that Clinical Trials are registered publicly prior to enrolment of the first participant.

In some instances other types of studies (i.e. non-Clinical Trials) may also need to be registered as a condition of funding.

It is the CPI/PI's responsibility to ensure Clinical Trials being conducted within NSW are registered in a publicly accessible register prior to recruitment of the first participant, ensuring that information is accurate and complete and that the record is kept up-to-date. The language used in the general title and the lay summary of the registration record should be brief, clear, and written in plain English so that it is understood by a lay person prior to commencement of the trial and that adequate evidence of this registration is available on file.

<insert contact details if institution centrally administers ClinicalTrials.gov or other account>.

(see *NSW Health Research Governance SOP*).

14. National Clinical Trials Governance Framework

To support the delivery of high-quality Clinical Trials in Australia, the National Clinical Trials Governance Framework (NCTGF) was implemented on behalf of the Australia Government Department of Health and Aged Care for all states and territories.

The NCTGF embeds Clinical Trials into routine health service provision. The framework aims to ensure Clinical Trials are conducted in a safe environment and in a high-quality manner to achieve improved health outcomes for patients and the community. The framework further aims to support health services to:

- reduce trial start up times
- optimise pre-approval and participant timeframes
- better engage trial sponsors
- improve consistency in trial service delivery and
- strengthen clinical and corporate governance arrangements.

A Clinical Trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO, 2020).

Implemented under the Australian Health Service Safety and Quality Accreditation Scheme, the NCTGF outlines actions against which health service organisations will be assessed for

accreditation. Accreditation is a formal process in which trained reviewers assess a health service's evidence of implementation of the NCTGF, providing assurance to the community that the service meets expected standards for safety and quality. For the first three-year accreditation cycle (commencing May 2023), health service organisations will be assessed against a maturity scale.

The NCTGF has five components:

- Governance, leadership and culture
- Patient safety and quality improvement systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care
- Partnering with consumers

The NCTGF does not specify how a health service organisation or trial site should develop or implement its governance systems. Instead, each health service organisation is encouraged to consider its local circumstances when developing strategies to meet the requirements of accreditation.

For further information visit: https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework.

Resources for the NCTGF are available including a user guide, video tutorial, fact sheets and case studies: https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework/resources-national-clinical-trials-governance-framework.

ClinicaltrialsNSW have established a NCTGF working group for NSW Health Organisation Research Development Office staff. To become part of the working group please contact: clinicaltrialsnsw@health.nsw.gov.au.

<insert institution contact details for NCTGF representative>.

15. Resource Management

All research projects must demonstrate that institutional costs have been adequately accounted for and agreed to by the relevant head of department. A study budget identifies the obvious costs of the research activity (including, but not limited to, estimated labour time of staff members contributing to the conduct of the study, capital equipment, review fees, statistical analysis, software, participant tests, database management, reagents, consumables, human biospecimen and animal costs etc.) in addition to regular participant intervention, as well as in-kind support. Good financial management practice requires researchers to ensure that they have adequate funding to undertake their study and therefore have a likelihood of delivering the outcomes of their project.

For Clinical Trials, funding source and finance details are to be entered into the NSW Health Statewide CTMS as part of the mandatory minimum dataset.

The Research Development Office is not responsible for ensuring that researchers have adequate funding or for the reviewing of study budgets and that they have met all of their financial and resource obligations. The Research Development Office will be checking that agreements (third party contracts and site agreements) are in place. Failure to do so will likely be identified during governance submission or routine audits and may lead to a non authorisation or suspension of the study. Where applicable a study budget must be included in the Research Agreement Payments schedule or as an appendix to the agreement (see Research Agreements Section) and will outline all

the relevant costs or grant application. Fees per the NSW Health Fee Policy should always be included in the payments schedule also.

Where research activity undertaken by a NSW LHD (commercially sponsored or otherwise) involves the contracting or subcontracting by a NSW Health Organisation of research-related clinical services, the NSW Health Organisation will engage the services of third parties consistent with its service arrangements for contracting of clinical services.

Where the CPI/PI is also the head of department, it is a conflict of interest for a CPI/PI to sign off on resource support and service provision. When this occurs sign off should be provided by a higher-level delegate or an alternate sign off allocated.

15.1. Funding Sources

Funding support for a research project can come from a variety of sources and may take many forms. This includes but is not limited to:

- Monetary payments from a commercial sponsor.
- In kind support or donated time from researchers, departments, laboratories or collaborators.
- Donated investigational products from commercial entities.
- Grant funding from NSW, commercial entities, government agencies such as the NHMRC and other not for profit organisations.

Any form of funding arrangement for the conduct of research at a NSW Health Organisation must have an appropriate and transparent financial management process in place. Any conflicts of interest must be declared before research commencement as part of the ethical review process where appropriate (see also Section 9: Conflicts of Interest).

15.2. Resource Support and Service Provisions

If a research project requires resources to be allocated from departments or providers outside of the researcher's area of direct reporting, the researcher must negotiate the terms of the service provision with a responsible party. The researcher must also meet with and obtain support from the relevant head of department/provider before the project commences at site. Proof of confirmation of support is then provided by selecting the head of department in REGIS (Part C). This is a requirement for obtaining Research Governance Authorisation at a NSW Health Organisation site (see *NSW Health Research Governance SOP*).

15.2.1. External Service Provider Agreements

The PI is responsible for ensuring an appropriate Service Agreement is in place when using an external service provider for any study related activities (i.e. a Service Agreement designed for the procurement of a service for a Clinical Trial or research study, without the Service Provider being a site). An example of this is PRP Diagnostic Imaging for computed tomography scans or magnetic resonance imaging.

15.2.2. Principal Investigator Oversight of Third Parties

For Clinical Trials, the PI must be able to demonstrate oversight and approval of third parties and any sub-contracted duties in accordance with ICH GCP (section 4.2.6 annotated by the TGA). The PI has responsibility for ensuring all third parties are appropriately qualified/accredited and will obtain

and keep copies of relevant accreditation/certification/ licenses (e.g. to manufacture/distribute medicinal product), requesting and taking up references or remote/on-site audit.

For research at a NSW Health Organisation the PI is required to obtain approval from the study Sponsor prior to engaging any third parties at the feasibility/start-up/risk assessment stage of the trial. The PI should also confirm whether the budget is in place, or has been applied for, to cover all third party activities.

In these instances the PI is required to ensure

- all relevant documentation is provided to the third party in a timely manner i.e. research protocol, approved protocol amendments, associated documentation and copies of required approvals.
- no activities are implemented by the third party until appropriate approval and contracts are in place.
- maintain regular contact with the third party/parties. Key correspondence and meeting minutes will be retained in the Investigator Site File (ISF).
- advise the third party of any protocol amendments that may impact the services that the third party has been engaged to provide.

16. Research Agreements

Where a project involves a NSW Health Organisation and any other organisation (e.g commercial sponsor, CRO, institute, or Collaborative Research Group (CRG)), an agreement on the management of the research must be in place before the project can be authorised to commence. Any such agreement is to be approved by the Chief Executive or their approved Delegate.

The type of research activity undertaken and the nature of the relationship between collaborating parties will determine the most appropriate contractual agreement.

An agreement must be in writing and include, but not limited to:

- Confidentiality and copyright issues,
- Sharing commercial returns,
- Management of conflict of interest,
- Insurance and indemnity arrangements,
- Responsibility for ethics and safety clearances and reporting to appropriate agencies,
- Protocols to be followed when disseminating the research outcomes,
- Management of primary research materials and research data, and
- Budget and Payment arrangements,
- The intellectual property rights (see also Section 11: Intellectual Property).

Where a standard Medicines Australia Clinical Trial Research Agreement (CTRA) or Medical Technology Association of Australia Clinical Investigation Research Agreement (CIRA) are used changes can only be made to the contract at Schedule 4 or 7. These changes can be sent for external legal review at the Sponsor's expense or a submission can be made to the National Clinical Trial Agreement (NaCTA) Panel. Evidence of NaCTA approval must be provided with the application.

Further details are available in Section 16.2.

16.1. Research Agreement Type

The type of research activity undertaken and the nature of the relationship between collaborating parties will guide the most appropriate contractual agreement. NSW Health Organisations are responsible for determining the form of agreement most appropriate for the trial in line with NSW Health PD2023_017 Research Agreements in NSW Health Organisations.

Commercially sponsored trials must use the Medicines Australia Clinical Trial Research Agreement (CTRA) or Medical Technologies Association of Australia (MTAA) Standard Clinical Investigation Research Agreement (CIRA) for research involving investigational medicinal products or devices, respectively.

For investigator initiated trials (IIT) and collaborative group research, a number of approved standard agreements can be used. The type of research agreement will depend on the nature of the trial and the parties involved (refer to *NSW Health Research Agreements SOP* which is aligned with PD2023_017 and includes a list of approved research agreements).

Where there is no existing standard agreement template that meets the needs of the project, a bespoke agreement may be used. NSW Health Organisations may develop their own institution specific agreements for use in situations that are not covered by the existing standard agreement templates. <If applicable insert specific standard agreement templates approved for use>.

16.2. National Clinical Trial Agreement (NaCTA) Panel

The NaCTA Panel (previously known as Southern and Eastern Border States (SEBS)) has representatives from the health departments of NSW, QLD, VIC, SA and TAS with ACT and NT as observers. NaCTA works to standardise, as far, as possible, the terms and conditions of the Medicines Australia CTRAs in an effort to streamline the administrative management of contracts for sponsors and Health Services organisations who are parties to the agreements.

Changes to the existing clauses in the body of the CTRA or CIRA should be submitted to the NaCTA panel for review. While review by the NaCTA Panel is not mandatory to amend the Schedule 4/Schedule 7 Special Conditions sections, it is highly recommended as it assists Clinical Trial sponsors with timely, standardised review, where only one negotiation is required, rather than several. The decisions made by the NaCTA are universally accepted by Institutions and Research Development Offices across the participating jurisdictions.

Application to NaCTA is through a template to request an amendment of any of the Medicines Australia Suite of CTRA's available here https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/.

16.3. Electronic Signatures

OHMR supports and encourages the valid use of electronic signatures for executing research agreements.

<insert institution specific guidelines regarding electronic signature processes and platforms used by the institution>.

17. Insurance and Indemnity

The sponsor of a Clinical Trial is the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports

the research. NSW Health Organisations must be satisfied that sponsors of Clinical Trials have insurance and compensation arrangements in accordance with applicable regulatory requirements. NSW Health Organisations must also obtain indemnity from commercial sponsors of Clinical Trials.

Insurance and indemnity arrangements are matters of research governance and are to be reviewed as part of site specific assessment which is submitted via REGIS. All insurance and indemnity on a Clinical Trial at NSW must adhere to the NSW Health PD2011_006 Clinical Trials - Insurance and Indemnity. Similarly, all other types of research should use the policy directive as a guide to ensure appropriate insurance and indemnity is obtained.

17.1. Commercially Sponsored trials

All commercially sponsored trials at a NSW Health Organisation must be indemnified and insured by an Australian sponsor, in accordance with the Medicines Australia Standard Form of Indemnity for drug trials or the MTAA Standard form of Indemnity for projects involving a device.

Where a trial is commercially sponsored, a certificate of currency for public and products liability must be submitted. The minimum requirements for insurance are:

- The insurance certificate must display the full legal name of the sponsor organisation for commercially sponsored projects.
- The full legal name of the sponsor organisation must be identical to that on the indemnity certificate.
- The certificate holder must be an Australian entity.
- The territory must mention Australia is included.
- The cover per claim must be at least $20 million (Australian dollar).
- The certificate must include Clinical Trials cover.
- The expiry dates and trial period dates should be stated.
- An excess/deductible or self-insured retention amount not greater than $25,000 for each and every claim.

For more information, see NSW Health PD2011_006 Clinical Trials - Insurance and Indemnity, section 2.2.

A current insurance certificate must be kept on file and supplied via a REGIS milestone throughout the duration of an approved project.

17.2. Collaborative Research Group

Under the CRG CTRA, each party is liable for its acts and omissions in relation to the conduct of the Clinical Trial and must maintain insurance to provide cover in relation to any liability which it may incur. This insurance should cover a minimum amount of $10 million (Australian dollar).

The nature of the CRG must be clear in any application to conduct research at a NSW Health Organisation.

Please refer to *NSW Health Research Agreement SOP* for further information.

17.3. Investigator Initiated Clinical Trial

NSW Health, through the Treasury Managed Fund (TMF), provides cover for the Sponsor-related liabilities of Clinical Trials initiated by NSW Health Staff and conducted at a site under the control of a public health organisation (PHO), as specified in this section. (Note that “NSW Health Staff” is a defined term. Visiting Medical Officers who sponsor a Clinical Trial at a PHO are covered by TMF for

Sponsor-related liabilities provided they have a current, signed Services Contract and Contract of Liability Coverage.)

TMF provides products liability cover for trials initiated by NSW Health Staff for: a) products still in development by a party that is not a NSW Health Staff investigator-initiator; b) products still in development by a NSW Health Staff investigator initiator; or c) an off label use of a registered product. This cover excludes product warranty liabilities because these liabilities ordinarily attach to the manufacturer or supplier of the product.

17.4. Treasury Managed Funds (TMF)

The TMF is a self-insurance scheme created by the NSW government to insure NSW government agency risk. It delivers on the government's responsibility to keep the people and property of the state safe.

As members of the TMF, agencies and government related businesses are indemnified for all insurable risks.

To be indemnified by TMF for Sponsor-related liabilities for trials conducted under the control of a PHO, NSW Health Staff investigator initiator or PHO which takes on the role of sponsor on their behalf, must comply 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).

18. Safety Monitoring and Reporting Responsibilities of Research

Institutions are responsible for ensuring that any human research they conduct is run in accordance with *the Code* and ethically approved and monitored in accordance with the guidance of the *National Statement* and HREC approved protocol.

Under section 5.5 of the *National Statement*, monitoring refers to the process of verifying that the research is being conducted in accordance with the approved proposal. Mechanisms for monitoring can include:

- Reports from researchers.
- Reports from independent agencies (such as data and safety monitoring boards).
- Review of safety reports.
- Random inspection of research sites, data or consent documentation.
- Interview with research participants or other forms of feedback.

The frequency and type of monitoring will depend on the degree of risk to the research participants, the researcher and the institution (also see NHMRC Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018).

All research is monitored for compliance with policy, legislation and procedures to ensure systems are in place for the management of complaints, including research misconduct and fraud.

For all projects granted authorisation to conduct research at a NSW Health Organisation the Research Development Office must be notified of any new information that might warrant further review of authorisation of the project. In addition, the Research Development Office must be provided with annual progress reports, as well as a final report at the completion of the project via REGIS

See *NSW Health Research Governance SOP* for further information.

18.1. Reporting Safety Events

NSW aligns its reporting requirements with the NSW Health PD2017_039 Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations and the NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) which sets out the requirements for the monitoring, collection and reporting of adverse events and adverse reactions that occur in regulated Clinical Trials (i.e. involving unapproved therapeutic goods). The guidance is also broadly applicable to all Clinical Trials involving therapeutic goods.

This NHMRC publication defines the roles and responsibilities of the Sponsor, researchers, institution and HREC in terms of reporting and managing of the below safety events.

- Serious adverse events (SAEs)
- Serious adverse reactions (SARs)
- Suspected unexpected serious adverse reactions (SUSARs)
- Unanticipated serious adverse device effects (USADEs)
- Significant safety issues (SSIs)
- Urgent safety measures (USMs)

It should be noted that safety data collection and reporting responsibilities attributable to NSW as a Clinical Trial investigator site may be different for a Clinical Trial depending on the recipient, i.e., the Sponsor, HREC, RGO, TGA. For example the Sponsor but not the HREC or RGO may require the investigator site to collect and report all adverse events.

The information provided in the NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) publication should be considered best practice for all research projects and applied to non-Clinical Trials where applicable.

18.2. Data Safety Monitoring

The NHMRC publication Guidance on Data Safety Monitoring Boards (DSMB) 2018 outlines the role, function and composition of an independent DSMB where required. DSMBs are established by the Sponsor or relevant responsible body to review at regular intervals, accumulating trial data, in order to monitor the progress of a Clinical Trial. DSMBs are an important component of monitoring plans, but not required for all trials. A DSMB is one of a range of mechanisms available to sponsors to mitigate trial risks and every trial must identify the most appropriate mix of monitoring activities according to a risk based model (also see NHMRC publication Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018).

Where appropriate alternative non-DSMB safety monitoring structures may be put in place (i.e. for low-risk trials) which may include oversight by a Trial Management Committee, Trial Steering Committee and/or use of an independent Medical Monitor.

Risk-based monitoring and oversight activities should be considered as early as possible in the trial design phase. For IITs it is important that funding is sourced which covers the cost of this activity where required (i.e. considered in grant applications or funding agreements).

<if applicable insert: Where a NSW Health Organisation is intended to be the Sponsor of a Clinical Trial conducted under the CTN scheme researchers should contact the Research Development Office as early as possible to discuss requirements and options for monitoring arrangements>. See *NSW Health Clinical Trial Sponsorship SOP*.

18.3. Reporting Serious Breaches (of GCP)

The NHMRC Reporting of serious breaches of Good Clinical Practice or the protocol for trials involving therapeutic goods (2018) sets out the requirements for reporting serious breaches that occur in Clinical Trials.

A protocol deviation is any breach, divergence or departure from the requirements of GCP or the Clinical Trial protocol. GCP requires all deviations to be reported to, and collated by the Sponsor. The term serious breach describes the subset of deviations that are likely to affect to a significant degree:

a) The safety or rights of a trial participant, or

b) The reliability and robustness of the data generated in the Clinical Trial.

See *NSW Health Investigation of Potential Breaches of the Australian Code SOP.*

19. Research Misconduct & Complaints Management

The Code describes research misconduct as "a serious breach of *the Code* which is also intentional or negligent".

Research misconduct includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and the failure to declare or manage a serious conflict of interest. It includes avoidable failure to follow research proposals as approved by a HREC, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. It also includes the wilful concealment or facilitation of research misconduct by others.

Research misconduct does not include differences in judgement in management of the research project and may not include honest errors that are minor or unintentional.

It is the responsibility of all staff to notify the NSW Health Organisation in a timely manner if they become aware of any potential breaches to *the Code* and/or any type of research misconduct either resulting from their own actions or of any NSW Health staff. Research related complaints and potential breaches of *the Code* will be managed in accordance with the *NSW Health Investigation of Potential Breaches of the Australian Code SOP* which is aligned with the NHMRC Guide to Managing and Investigating Potential Breaches of the Code.

20. Authorship, Research Output & Communications

NSW Health Organisations have a responsibility to ensure that findings and advances in knowledge from publicly funded research are disseminated to other researchers and the wider community, subject to relevant restrictions on the publication of results (see also Section 11: Intellectual Property).

In accordance with t*he Code*, researchers are responsible for:

- Disseminating their research findings responsibly, accurately and as broadly as possible (R23),
- Ensuring appropriate and fair attribution of authorship to those who have made a significant contribution to the research and its output, and that all authors have agreed to be listed as authors in publications (R25), and
- Acknowledging contributions other than authorship (R26).

The following principles apply to publication of research findings:

- Researchers must ensure that their research findings are accurate and are reported in a complete, correct and unambiguous manner.
- It is just as important to report negative results as well as positive results.
- Potential conflicts of interest must be disclosed in accordance with the NSW Conflict of Interest Policy.
- The same set or subset of data may not be published more than once, except where due reference is made.

Many professional journals require evidence of ethical review before results will be published. Intending authors should always check and follow the specific journal requirements.

NSW Health Organisation staff should also be aware of any institution specific requirements regarding the presentation of research findings in publications or at conferences including:

<insert institution specific details to be aware of i.e. institution Communication Team contact, institution publication archives, publication policies, conference attendance requirements etc>.

The *NSW Health Managing Authorship of Research Outputs SOP* provides further guidance in accordance with *the Code* and the supporting the NHMRC Publication and Dissemination of Research Guide (2020) and the NHMRC Authorship Guide (2019).

The roles allocated on ethics and governance application forms do not automatically determine authorship order, this is done through the research team. Any in-kind support provided to the research which does not meet the criteria for authorship should be listed as acknowledgements, including support provided by other NSW Health Organisations, research partners, sponsors and/or organisations. As a general rule, researchers are recommended to obtain permission from named contributors before acknowledging them in research outputs.

Researchers should list all affiliations relevant to the research project and report the publication to these affiliations in a timely manner. NSW Health Organisation staff should also check to ensure there are no other contractual obligations in place relating to the publication of research findings.

APPENDIX A: Version History

Version	Date Approved	Summary of Changes
1.0	<xx/mm/yyyy>	First Edition

APPENDIX B: Glossary of Definitions

Term	Definition
Australian Code (*the Code*)	Means Australian Code for the Responsible Conduct of Research 2018.
ARPANSA Code	The Code of Practice – Exposure of Humans to Ionizing Radiation for Research Purposes Radiation Protection Series Publication No. 8.
Certification	Certification by the Regulator of a facility to a particular containment level under the Act.
Chief Executive	The Chief Executive of a NSW Health Organisation or a person delegated to perform certain functions of the Chief Executive.
Clinical Trial	*A Clinical Trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical Trials include but are not limited to:* - *Surgical and medical treatments and procedures* - *Experimental drugs* - *Biological products* - *Medical devices* - *Health-related service changes* - *Health-related preventative strategies* - *Health-related educational interventions.*
Collaborative Research Group (CRG)	An academic and/or not-for-profit legal entity responsible for sponsoring, initiating, managing, developing, and coordinating a non-commercial trial.
Coordinating Principal Investigator (CPI)	The person who takes overall responsibility for the design, conduct and reporting of a study. Where the research is conducted at a single centre this is the PI.
CTN/CTA Trial	A Clinical Trial conducted under the TGA Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes (i.e. involving an unapproved investigational product).
Data Breach	Where any data held by NSW are accessed, or disclosed, without authorisation, or are lost.
Dealing	As defined by the GT Act to deal with in relation to a GMO, means the following: (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; (h) transport the GMO; (i) dispose of the GMO; and includes the possession, supply or use of the GMO.
Early Phase Clinical Trial (EPCT)	Early Phase Clinical Trial (EPCT) includes all Clinical Trial phases up to but not including Phase II, including studies with any Phase I component.
External research contractor	Is a person who wishes to conduct research at NSW (either as an investigator or supporting role) without having an affiliation or appointment at NSW. This may include but is not limited to: academic; external institution researchers or research support staff; volunteer/work experience.

External research student	Is a person who intends to conduct a higher degree research project without having an affiliation or appointment at NSW.
Good Clinical Practice (GCP)	Is defined as an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of humans. The term "GCP" within this document is with reference to two internationally accepted standards: (1) ICH GCP and (2) ISO 14155.
Genetically Modified Organism (GMO)	As defined by the Gene Technology Act 2000 is: *(a) an organism that has been modified by gene technology; or* *b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or* *I anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms.*
Good Manufacturing Practice	A system for ensuring that investigational products are consistently produced and controlled according to quality standards.
Head of Department	As per NSW Health PD2010_056: *Heads of departments (or divisional directors or other authority) responsible for the site where human research is to be conducted, are required to:* • *Discuss each research project with the PI* • *Assess whether the project meets appropriate governance requirements; and* • *Provide a declaration of support for the project.*
Head of Supporting Department	As per NSW Health PD2010_056: *Heads of supporting departments responsible for providing additional support of services to the human research project conducted at the NSW Health Organisation must provide a declaration of support for the project.* *Examples of support departments include pharmacy, pathology, medical imaging, medical records and treatment units providing care.*
Investigator	An investigator is defined as a member of the research team who has the qualifications, training and delegated authority to conduct integral study procedures. This may include but is not limited to: Provision of an intervention; Interpretation of results/outcomes; Decision making authority with regards to treatment/intervention; Conduct of Interviews/focus groups; Protocol design and development.
Investigational Brochure	The Investigator's Brochure is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human participants. Its purpose is to provide the investigators and others involved in the research project with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration and safety monitoring procedures.

Intellectual Property (IP)	As per NSW Health PD2023_007: *Intellectual Property is the legally recognised outcome of creative effort and economic investment in creative effort. Intellectual Property includes:* • *inventions, and patents granted in respect of such* • *inventions and applications for such patents* • *unpatented know-how, which comprise an invention or a* • *way of doing something which is not public knowledge* • *confidential information and trade secrets* • *registered and unregistered designs and applications for* • *registered designs* • *copyright* • *circuit layout rights* • *registered and unregistered trademarks and applications for registration of trademarks* • *get-up and trade dress associated with products and services* • *plant variety rights* • *all other rights resulting from intellectual activity in the* • *scientific, industrial, literary, or artistic fields, and* • *any contractual rights to use or exploit any of these rights.*
Investigational product	Any therapeutic good (including placebos) being tested in a Clinical Trial.
ICH GCP	The International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use (ICH), Harmonised Guideline for Good Clinical Practice.
International Organisation for Standardisation (ISO)	An independent non-governmental international organisation for standardisation with worldwide membership of national standards bodies including Australia.
ISO 14155	An internationally recognised standard addressing Good Clinical Practice for the design, conduct, recording and reporting of clinical investigations carried out in human participants to assess the clinical performance or effectiveness and safety of medical devices.
National Statement	Means the National Statement on Ethical Conduct in Human Research (2007) updated 2023.
Negligible Risk Research	Is defined as research in which the only foreseeable risk is no more than inconvenience. This term was replaced by minimal research in the National Statement on Ethical Conduct in Human Research (2023).
National Mutual Acceptance (NMA)	National Mutual Acceptance is a scheme enabling mutual acceptance of scientific and ethical review of multi-centre human research projects undertaken in Public Health Organisations within six Australian jurisdictions (Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia).
NHMRC Licencing Committee	NHMRC Embryo Research Licensing Committee.

Notifiable Low Risk Dealing (NLRD)	Notifiable Low Risk Dealing is an activity with a GMO that is - undertaken in containment in a facility certified by the Gene Technology Regulatory or approved in writing by the Regulator - assessed as posing low risk to the health and safety of people provided certain risk management conditions are met.
Non-identifiable data	As adopted by the NHMRC: *Data which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.*
Principal Investigator (PI)	Principal Investigator (PI) is the person responsible, individually or as a leader of the research team at a site, for the conduct of a Clinical Trial at that site. As such, the PI is responsible for adequately supervising his or her research team. N.B. In a single centre investigator-initiated study, the PI is also often the person who takes overall responsibility for the design, conduct and reporting of a study.
Protocol	A document that describes the rationale, objective(s), design and proposed analysis, methodology, monitoring, conduct and record-keeping of a Clinical Trial. The sponsor of a Clinical Trial is responsible for the protocol.
Research	Means Human Research which is research conducted with or about people, or their data or tissue as described in the current version of the *National Statement* and t*he Code*.
Research Governance	Refers to the processes used by an organisation to ensure that it is accountable for the health and medical research conducted under its auspices.
Research Governance Framework	Sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards. It includes the structure and roles and responsibilities for managing research in an organisation. A robust RGF is comprised of research policies, procedures, training and a quality assurance program.
Research Development Office	The Research Development Office is the entity that oversees research governance at a NSW Health Organisation. As part of its business services it can include the provision of strategic and procedural guidance to researchers and is responsible for the development and publication of relevant local procedures and guidelines.
Research Project	A research project is a scientific endeavour to answer a research question. Research projects may include: • Cohort study • Clinical Trial • Survey • Secondary data analysis such as decision analysis, cost effectiveness analysis or meta-analysis.

Site	A facility, location or institution (or group of institutions) that conducts a Clinical Trial/Study and comes under research authorisation sign off.
Site Authorisation	Means the authorisation granted by the Chief Executive or delegate of NSW for the commencement of a research project at that site.
Sponsor	An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance (or arranging the finance) for a study. The Sponsor carries the medico-legal responsibility associated with the conduct of a Clinical Trial. The sponsor takes overall responsibility for the conduct of a Clinical Trial, including responsibility for the protocol.
Under the auspices of NSW Health Organisation	Research under the auspices of NSW Health Organisation has a broad scope. It includes funded and unfunded research, and research conducted by NSW Health research and professional staff, honorary and visiting researchers. If any of the questions below are answered 'yes', a researcher should be considered to be conducting work under the auspices of a NSW Health Organisation, so is subject to the standards and responsibilities described in this document: - Will the research activity or output be claimed for internal or external purposes through NSW Health Organisation? - Will the work be identified (for example, to potential participants, sites and in any output) as being NSW Health research? - Are there any contracts or agreements associated with the work that will describe it as being under the auspices of a NSW Health Organisation? - Are there any invoices or other payments associated with the work that will describe it as being under the auspices of a NSW Health Organisation? - Is the work covered by NSW's insurance or indemnity?
The GT Act	The Gene Technology Act 2000.
Therapeutic Goods Administration (TGA)	The Australian regulatory authority for therapeutic goods. The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods in Australia.

NSW Health Research Handbook

APPENDIX C: References and Resources

All NSW policies and documents can be found here.

Below is a list of external references and resources.

Theme	Reference	Category
Responsible Conduct of Research / Good Clinical Practice	The Australian Code for the Responsible Conduct of Research, 2018 (The Code)	Code
	Supervision – A guide supporting the Australian Code for the Responsible Conduct of Research	Guidance
	Investigator-Initiated Trials Toolkit	Resource
	GCP providers – TransCelerate recognised.	Resource
	ICH Guideline for Good Clinical Practice – Annotated with TGA comments	Standard
	ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice	Standard
	The National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials	Guidance
NSW Ministry of Health Policy Directive and Guidelines	NSW Health PD2015_049 - Code of Conduct	Policy
	NSW Health PD2010_056 - Research - Authorisation to Commence Human Research in NSW Public Health Organisations - (under review)	Policy
	NSW Health PD2011_006 Clinical Trials - Insurance and Indemnity	Policy
	NSW Health PD2023_017 Research Agreements in NSW Health Organisations	Policy
	NSW Health PD2023_007 Intellectual Property Arising from Health Research	Policy
	NSW Health PD2015_045 Conflicts of Interest and Gifts and Benefits	Policy
	NSW Health PD2017_034 Aboriginal Health Impact Statement	Policy
	NSW Health PD2015_037 Data Collections – Disclosure of Unit Record Data for Research or Management of Health Services	Policy

	NSW Health PD2018_001 Disclosure of unit record data by Local Health Districts for research or contractor services - (under review)	Policy
	NSW Health PD2017_039 Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations	Policy
	NSW Health PD2023_015 Fee Schedule for Research Ethics and Governance Review of Clinical Trial Research	Policy
	NSW Health GL2023_008 Use of Human Tissue for Research	Guidance
Project Design	SPIRIT Statement	Guidance
	The James Lind Alliance	Guidance
	Statement on consumer and community involvement in health and medical research	Guidance
	Consumer and community engagement (includes links to additional references/toolkits)	Guidance
	Consumer Involvement and Engagement Toolkit	Templates
	Peer Review	Guidance
Funding	NHMRC Funding research	Guidance
	Australian Research Council	Guidance
Human Research Ethics	National Statement on Ethical Conduct in Human Research (2023)	Guidance
	AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (AIATSIS code), 2020	Code
	Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018	Guidance
	A Guide to applying The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research	Guidance
	Keeping research on track II. A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders	Guidance
Data and Primary Materials Management	Privacy Act 1988	Legislation (Cth)
	Privacy Regulation 2013	Regulation (Cth)
	NSW Privacy Manual for Health Information	Guidance

	Office of the Australian Information Commissioner (OAIC)	Authority
	Australian Privacy Principles quick reference	Guidance
	List of State and Territory Privacy Laws	Guidance
	Guidelines under Section 95 of the Privacy Act 1988	Guidance
	Guidelines approved under Section 95A of the Privacy Act 1988	Guidance
	Health records and information Privacy Act 2002	Legislation (NSW)
	Privacy and Personal Information Protection Act 1998	Legislation (NSW)
	Statutory Guidelines on Research. Section 27B.	Guidance (NSW)
	Statutory Guidelines on Research. Information and Privacy Commission NSW.	Guidance (NSW)
	Guardianship Act 1987 (NSW)	Legislation (NSW)
	Guide to the legislation relating to the provision of consent for an adult with impaired capacity to provide informed consent to participate in the conduct of human research	Guidance
	NHMRC Management of data and information in research	Guidance
	Ethical and Legal Issues in Relation to the Use of Human Tissue in Australia and New Zealand	Guidance
	International Air Transport Association Dangerous Goods Regulations (IATA DGRs)	Guidance
	Civil Aviation Act 1988	Legislation (Cth)
	Civil Aviation Safety Regulations 1998 Statutory Rules No. 237	Regulation (Cth)
	CASR part 92 – Consignment and carriage of dangerous goods by air (including part 92 advisory documents)	Authority - Guidance
Therapeutic Goods Administration	Therapeutic Goods Act 1989	Legislation (Cth)
	Therapeutics Goods Regulations 1990	Regulation (Cth)
	Therapeutic Goods (Medical Devices) regulation 2002	Regulation (Cth)

	Therapeutic Goods Administration (TGA) – Clinical Trials	Authority
	TGA Clinical Trials Handbook	Guidance
	TGA – legislation & Legislative instruments	Guidance
Biobank	NSW Health Statewide Biobank Certification Program	Guidance
	NSW Health Statewide Biobank Standard Operating Procedures	Templates
Medicines and poisons Controlled Substances	Poisons and Therapeutic Goods Act 1966	Legislation (NSW)
	NSW Ministry of Health	Authority (NSW)
	Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)	Guidance (Cth)
Gene Technology	Gene Technology Act 2000	Legislation (Cth)
	Gene Technology Regulations 2001 (current compilation)	Regulation (Cth)
	Office of the Gene Technology Regulator	Authority
	Guidelines and checklists for certification of PC2 facilities	Guidance
	Risk Analysis Framework	Guidance
	Requirements under the Gene Technology Act 2000 for Clinical Trials in humans involving GMOs – Guidance for Clinical Trial sponsors	Guidance
	Risk Groups and Safety Levels of GMOs	Guidance
Embryo Research	Research Involving Human Embryos Act 2002 (RIHE Act)	Legislation (Cth)
	Prohibition of Human Cloning for Reproduction Act 2002 (PHCR)	Legislation (Cth)
	Assisted Reproductive Technology Act (2007)	Legislation (NSW)
	Research Involving Human Embryos Act 2003	Legislation (NSW)
	Human Cloning for Reproduction and Other Prohibited Practices Act 2003	Legislation (NSW)
	Research Involving Human Embryos Regulations 2017	Regulation (Cth)
	Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017 (the ART Guidelines)	Guidance – Ethics

	NHMRC Embryo Research Licensing Committee	Authority
	Information for applicants webpage	Guidance
	Embryo Research Licensing Committee information kit	Guidance
	Objective criteria on embryos that are unsuitable for implantation	Guidance
	Instructions for completing the embryo research licence application form	Guidance
	Consent Checklist for licensed activities using excess ART embryos	Guidance
	Additional Information on obtaining consent	Guidance
	Research Involving Human Embryos Act 2002 Embryo Research Licensing Committee of the NHMRC – Standard Conditions of Licence	Guidance
Ionising Radiation	Radiation Control Act 1990 No 13	Legislation (NSW)
	NSW Radiation Control Regulation 2013	Regulation (NSW)
	Environment Protection Authority (EPA)	Authority (NSW)
	ARPANSA Code of Practice – Exposure of Humans to Ionizing Radiation for Research Purposes RPS 8	Guidance
Research Agreements, Insurance and Indemnity	Medicines Australia Clinical Trial Research Agreements	Templates
	Medicines Australia Indemnity & Compensation Guidelines	Templates
	Medical Technology Association of Australia - Clinical Investigation Research Agreements	Templates
	Collaborative Research – A guide supporting the Australian Code for the Responsible Conduct of Research	Guidance
	Indemnity and insurance arrangements for Clinical Trials	Guidance
Safety Monitoring and Reporting of Research	NHMRC Guidance: Safety monitoring and reporting in Clinical Trials involving therapeutic goods November 2016	Guidance
	Risk-based management and monitoring of Clinical Trials involving therapeutic Goods 2018	Guidance

	Data Safety Monitoring Boards	Guidance
	Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving therapeutic Goods 2018	Guidance
Research Complaints and Misconduct	Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research 2018	Guidance
	Research Integrity Advisors	Guidance
Research Outputs, Authorship & Communications	Publication and dissemination of research - A guide supporting the Australian Code for the Responsible Conduct of Research 2020	Guidance
	Authorship: A guide supporting the Australian Code for the Responsible Conduct of Research 2019	Guidance

APPENDIX D: List of NSW Health Research Governance SOPs

These SOPs are generic and are intended to be adopted by NSW Health Organisations as required. Use of the below SOPs is not a policy directive.

SOP Theme	SOP Reference	Title
Research Governance	NSW_RG01_SOP	Research Governance
	NSW_RG02_SOP	Operations Manual: Human Research Ethics Committees for NSW Public Health Organisations
	NSW_RG03_SOP	Operations Manual: Human Research Ethics Committee Executive Officers
	NSW_RG04_SOP	Operations Manual: Research Governance Officers
	NSW_RG05_SOP	Clinical Trial Sponsorship
	NSW_RG06_SOP	Research Credentialing
	NSW_RG07_SOP	Research Agreements
	NSW_RG08_SOP	Conducting Research with Ionising Radiation
	NSW_RG09_SOP	Investigation of Potential Breaches of the Australian Code
	NSW_RG010_SOP	Research Related Complaints Management
	NSW_RG11_SOP	Research Data Management
	NSW_RG12_SOP	Managing Authorship of Research Outputs
	NSW_RG13_SOP	Supervision of Research Students
Administration	NSW_AD01_SOP	Creation, Implementation and Maintenance of SOPs and Policies
Quality Assurance	NSW_QA01_SOP	Documentation of Qualifications and Training Records
	NSW_QA02_SOP	Management of Serious Breaches and Corrective and Preventative Actions (CAPA) Process
	NSW_QA03_SOP	Hosting an External Audit or Inspection

APPENDIX E: Competencies For the Research Support Team

These competencies are designed to highlight what a research support team needs to know, understand and be able to do, in order to provide an effective service for health research in their institution.

How to use the competencies
These competencies recognise the diversity of roles of the research office within and between institutions, and can be adapted to suit individual requirements. Each competency has three levels to reflect a range of abilities from a new or inexperienced team member to a proactive leader of activity. The skills under each level are cumulative. The expectation is that Columns A, B and C would represent the competencies that will enable staff within an institution to effectively support the successful delivery of both externally and internally sponsored trials.

The competencies are an aid to identifying and developing skills, but do not dictate specific roles. It is for managers and team members to decide how they are used and to what level. This document provides a foundation for:

- Clarifying those activities for which an institution is accountable to provide a more consistent approach to managing research studies
- Developing common job descriptions
- Assessing current skill levels
- Working towards new skills and objectives
- Determining who should focus on specific competencies within the organisation
- Staff appraisal, performance review and personal development

The ultimate goal is to inform the development of an organisation's governance structure, which may extend beyond the traditional role of a Research Governance Officer.

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NSW Health Research Handbook

A. Supporting the Growth and Delivery of Research within Own Organisation

A1. Supporting the Growth and Delivery of Clinical Research within Own Institution			
	A	**B**	**C**
A1.1 National objectives and priorities.	Is aware of national objectives and priorities for research.	Advises and promotes to stakeholders the national objectives and priorities for research.	Develops local strategy for research in line with national objectives and priorities.
A1.2 Local strategic direction.	Is aware of the local strategy for research in their institution.	Advises and promotes to stakeholders the local strategy for research through presentations and training and champions research within the institution.	Sets the local strategy for research in line with national objectives and priorities and ensures its implementation. Champions research at an executive level.
A1.3 Promotion of research.	Actively promotes research. Helps develop materials for promotional or educational forums for research.	Promotes the use of research in evidence based practice to all relevant stakeholders and the importance of research to the community, patients and the institution. Develops and updates the research office's website to ensure appropriate web-based information is available to all stakeholders.	Develops a research management culture that understands and promotes the benefits of research to the community, patients and the institution.
A1.4 Chief executive (CE)/Board engagement to support research activity.	Understands the need and benefits of CE/Board level engagement in research.	Acts as the conduit for any communication requiring Board consideration/sign off. Understands the importance of keeping the Board aware of the institution's research performance metrics through the appropriate communication lines.	Maintains board engagement to continually strengthen the culture of research-led clinical practice. Identifies and presents opportunities and risks at executive level.
Possible implementation strategies: Provide induction training; create online resources; support conference attendance; establish lines of communication and regular exchange of information between Research Office and CE/Board and NSW Ministry of Health; develop relations internally across specific departments such as the health promotion unit and the clinical governance team; facilitate consumer engagement; ensure research is included as an agenda item in high level management committee meetings, e.g. Clinical Council; ensure that regular briefings and meeting minutes are provided to committees			

that report to the LHD/ Institution Board; develop and implement working groups or committees that are responsible for reviewing and ensuring that local strategy and the promotion of research is aligned with the National Objectives; use the Institution Enterprise Risk Management System to assist with the above.

A2. Working with External Partners			
	A	**B**	**C**
A2. 1 Stakeholders & Partnerships.	Is aware of the institution's immediate stakeholders and partnerships.	Works effectively with all immediate stakeholders (e.g. Human Resources for honorary appointments/Letter of Access). Understands how his or her own role fits within and complements the range of stakeholders and partnerships involved in delivering research.	Works strategically with the range of stakeholders and partnerships to deliver the institution's objectives. Recognises and promotes the importance of consumer involvement in the research process.
A2.2 Industry.	Understands the importance of facilitating prompt study start-up and the objectives of the site selection process.	Facilitates the start-up process and maintains oversight of studies to ensure projects are recruiting to time and target.	Applies proactive commercial insight to the delivery of research in the institution and takes a strategic view on the importance of working with industry.

Possible implementation strategies:

Provide induction training; provide related on-the-job experience opportunities; develop overarching research agreements/MOUs with key partners; consider establishing a first point of contact for external partners who wish to engage with institution to conduct research.

Promote consumer involvement by: ensuring information is readily available to consumers; promoting opportunities for consumers to participate in research; promoting and facilitating opportunities for consumer involvement in research including setting research priorities, developing strategy, and advising on study design, protocol requirements, study documentation, dissemination of findings etc.

A3 Working as a Team to Deliver Successful Research Projects			
	A	**B**	**C**
A3.1 Team work.	Understands the role of individuals in the team and takes care to understand the roles and workloads of others.	Actively manages team work and delegates responsibilities where appropriate.	Ensures roles and responsibilities for research are clear within the team working environment and facilitates wider collaborative team work between the Research Office and other departments within own institution.
A3.2 Good customer service.	Delivers a culture of good customer service across the institution.	Promotes good customer service and manages situations when expectations are not met.	Creates, establishes and monitors a good customer service culture in the department and with wider stakeholders and partners.
A3.3 Standard Operating Procedures (SOPs).	Understands the policies/SOPs that are relevant to his or her role and proactively identifies any changes required.	Develops and updates the guidelines/policies/ SOPs relating to ongoing best practice in research governance, trial management and conduct and trains others in their use.	Reviews and challenges SOPs on local and national merit and discerns best practice for local use.
A3.4 Role of service support departments.	Understands the role of service departments and can advise investigators during the study set-up process.	Works with investigators and service support departments from an early stage to ensure research is delivered effectively. Facilitates and enables the process by managing any issues that may arise.	Engages with support departments to ensure research is appropriately supported and delivered at a strategic level.
Possible implementation strategies: Provide induction training; provide 'good customer service' training; promote to all internal stakeholders the importance of 'research delivery' to contract requirements; Provide rotational on-the-job training; attend and participate in interdepartmental and multidisciplinary team meetings; implement common position descriptions; proactively engage with support service departments; engage with colleagues/ peers at other institutions at a state level and nationally to inform and develop best practice; encourage a collaborative and positive research support team environment and process improvement–driven Initiatives.			

B. Supporting Research Projects throughout their Lifecycle and Managing Research Delivery

B1. Supporting Development of New Studies – Early Stages			
	A	B	C
B1.1 Protocol advice.	Signposts researchers to relevant support or guidance for protocol development.	Promotes the importance of a robust protocol. Is aware of the contents of a GCP compliant protocol and advises researchers accordingly.	Liaises with sources of advice and researchers to help ensure a robust protocol is developed. Ensures researchers have access to relevant support and guidance for the development of key study documentation.
B1.2 Sponsorship/ authorisation decisions.	Advises and explains to researchers or student research supervisors, the information required for the decision to sponsor and authorise a study.	Makes recommendations relating to the sponsorship decision for locally led studies and the authorisation/non-authorisation of both locally and externally sponsored studies.	Determines whether the institution will act as the sponsor for a study and ensures that a mechanism for oversight of the project is in place.
B1.3 Intellectual property (IP).	Has a good understanding of IP.	Advises researchers on the institution's IP policy.	Refers to, and works with the relevant hospital departments to ensure research IP is negotiated on behalf of the institution.
B1.4 Scientific peer review.	Understands the role of peer review.	Advises others on how to obtain peer review.	Enables researchers to access scientific peer review for locally sponsored trials.
Possible implementation strategies: Provide GCP, risk management and IP training; support attendance at external courses and relevant on-the-job training; source guidance material; develop a comprehensive website; develop a clear pathway for escalation of complicated projects/risk issues with timelines; develop related internal business operation guidelines.			

B2. Supporting Good Financial and Contractual Management			
	A	**B**	**C**
B2.1 Funding for research.	Is aware of the different funding avenues for commercial and non-commercial studies.	Understands the role of funding bodies, their requirements and the importance of appropriate research funding being available. Signposts researchers to relevant help and advice on grant applications.	Fosters a local environment and strategy that creates opportunities for research funding.
B2.2 Contracts and agreements for research.	Has a good understanding of contracting with commercial companies and non-commercial institutions. Understands how contracts affect the management of a study and can signpost people to the relevant member of staff/source of information.	Works with commercial companies and non-commercial institutions. Is aware of when a contract is needed and how PHOs and academic partners interact with regard to IP, insurance and finance to administer non-commercial agreements. Advises researchers on non-commercial contracts/agreements.	Forms effective working relationships with companies and negotiates commercial contracts, informed by an understanding of the cost of study elements and clinical study budgeting principles. Ensures that appropriate agreements are in place with academic/collaborative partners (e.g. Memoranda of Understanding).
B2.3 Invoicing requirements.	Understands the importance of appropriate invoicing to the institution and her or his role in the invoicing process.	Proactively manages the invoicing process with colleagues.	Oversees systems for invoicing. Effectively manages and reinvests research income through agreed policies and arrangements.
Possible implementation strategies: Develop an interactive online Clinical Trial budgeting tool; create referral pathways to the finance department; provide training on role of funding bodies and their operations; develop a relationship with research support offices within the University Sector; encourage professional networking opportunities.			

B3. Supporting Feasibility and Risk Assessments of Proposed Research			
	A	**B**	**C**
B3.1 Feasibility process.	Understands the importance of a robust feasibility assessment and gives basic advice to investigators.	Actively engages with researchers on the importance of feasibility and facilitates the process.	Creates an environment of transparency so that stakeholders know if undertaking a research study is likely to be feasible (e.g. by making public, information on the institution's capabilities, research priorities and resources and identifying the types of research study it can undertake). Ensures researchers are fully aware of their responsibilities around project delivery.
B3.2 Proportionate risk management.	Understands what proportionate risk management is for all governance activities and his or her own role in assessing acceptable risk.	Leads risk assessments, taking pragmatic actions and escalating concerns based upon findings.	Advises on legislation and risk and manages study and institutional risks proportionately.
B3.3 Project recruitment strategy.	Understands what can prevent or improve recruitment.	Advises researchers on recruitment strategy.	Promotes and actively assists in the development of an environment that facilitates recruitment (e.g. marshalling public demand for opportunities to participate in research by increasing patient awareness).
Possible implementation strategies: Develop an Institution research capability report; dedicate staff to the area of feasibility and capability; become familiar with the institution Enterprise Risk Management system; develop relationships with other institution departments that can provide data for feasibility assessments; provide GCP training; provide risk management training.			

B4. Supporting Research Study Management and Delivery			
	A	B	C
B4.1 Research study set-up.	Advises researchers on what needs to be in place before recruitment can start.	Works with researchers to ensure that set up processes are completed in a timely way and allow a prompt start to recruitment.	Establishes a system which ensures prompt study set up and research team readiness to start recruitment.
B4.2 Conflicts of Interest	Maintains records of how conflicts of interest are managed.	Develops/maintains a policy on managing conflicts of interest and advises researchers on its contents.	Supports a research culture where actual or apparent conflicts of interest are actively disclosed.
B4.3 Using internal KPIs to monitor performance.	Is aware of key performance indicators(KPIs)/metrics and uses them at team level to monitor performance.	Monitors KPIs/metrics to report to senior managers on performance. Ensures KPIs meet NSW Ministry of Health benchmarks.	Promotes openness and accountability with research process. Oversees KPIs and local strategy to ensure performance is monitored and reported to the CE/Board.
B4.4 Supporting research delivery.	Understands the importance of supporting research to meet study visit and retention goals. Escalates concerns when identified.	Manages the resources required for study delivery. Acts on escalated concerns about delivery and performance and is able to support research teams to develop solutions /action plans.	Encourages a proactive and pragmatic approach to research that is fully supported at CE/board level. Ensures the availability of the appropriate resources required for successful study delivery. Ensures the development of systems that support proactive management of all research activities that reduce timelines and embed good practice. Manages research infrastructure.

	A	B	C
B4.5 Research management.	Provides signposting advice to research teams on good research practice and Coordinating Principal/ Principal Investigator responsibilities, referring to study protocols, regulations/guidelines, and contractual agreements when necessary.	Manages the overall delivery of research by supporting investigators to put in place the necessary practical arrangements to manage their study, including all safety monitoring arrangements.	Ensures the team has the skills and abilities to support research management. Maintains clear lines of communication for the escalation of research issues relating to risk, continued trial acceptability and breaches of good practice.
B4.6 Study amendments and reports.	Advises investigators and sponsors on the process for submitting amendments and study reports.	Reviews amendments and other post approval reports and assesses their impact on continued site authorisation.	Actively encourages compliance with all requirements for ongoing study amendment and reporting.
B4.7 Internal and external auditing/monitoring requirements.	Understands the reasons and information required for audit and monitoring, and advises others on the principles of audit practices.	Establishes a post-approval auditing system for internally- and externally-sponsored trials using a risk-based approach to determine priority. Ensures arrangements are in place for the monitoring of internally sponsored trials.	Tracks and trends audit findings across studies, and translates findings into quality assurance improvements. Reports on the system outputs to assure key stakeholders of robust governance.
B4.8 Research misconduct.	Is aware of and follows policies/ guidance on research misconduct and seeks guidance on potential research misconduct issues.	Advises staff on the types of situations which may lead to research misconduct.	Manages/instigates the appropriate actions in cases of research misconduct and helps researchers develop and follow up on corrective and

			preventative action plans.
B4.9 Research study closure and archive.	Monitors the closure of research studies on internal systems.	Ensures that appropriate final reporting and close out measures are collected on a study, and ensures that documents and materials are appropriately archived.	Ensures research studies are appropriately closed and accurate activity reports are made available to the Board. Ensures the organisation has appropriate facilities for archiving of research documentation and materials.
B4.10 Publication, communication and translation of research findings.	Discusses and advises researchers on the publication of research findings (to both scientific and lay communities) and signposts researchers to resources.	Monitors whether research findings are disseminated (in accordance with the funder's publication policy) through the final reporting mechanism.	Through local and national channels actively promotes the publication and dissemination of research findings and the importance of adoption of research findings into practice, in light of strategic direction.
Possible implementation strategies: Create relevant induction training material; provide relevant training courses/workshops; contract with an external auditor; provide a website for linking outputs and publications; develop a comprehensive internal data management and tracking system for report generation; develop procedures for declaring and managing conflicts of interests; develop SOPs for study conduct; develop manuals and Standard Operating Procedures for clinical quality assurance/compliance audits.			

C. Understanding Governance and Good Practice for Research

C1. Understanding and Assessing the Regulatory and Legislative Compliance of a Study			
	A	B	C

C1.1 TGA Requirements.	Advises and assists researchers with the TGA notification and reporting requirements for CTX/CTN trials.	Develops guidance and support for researchers on TGA requirements for CTX/CTN trials and other schemes to access unapproved medicines and other therapeutic goods, and, where relevant, provides advice on any other regulatory submissions to support the development of niche technologies.	Ensures the team supports researchers in all aspects of regulatory compliance and the regulatory submission process.
C1.2 Regulation and legislation.	Is aware of the need for legal and regulatory compliance and describes in broad terms what is required.	Applies the appropriate regulations and legislation pragmatically and proportionately to their work.	Advises others on the appropriate legislation and regulations applicable to their research and confidently challenges the inappropriate or unnecessary application of legislation.
C1.3 Electronic research management and governance systems.	Maintains electronic research management and governance systems and runs reports from the systems.	Understands electronic research management and governance systems, efficiently appraises reports and trains others on the use of those systems.	Understands and actively promotes the use of electronic research management and governance systems and explores their strategic use in supporting the management of research activity and reporting metrics.
Possible implementation strategies: Provide on-the-job training; develop SOPs for study conduct; support attendance at external training courses; remain abreast of national and state key initiatives; provide training on topics such as regulatory frameworks, biosafety, accreditation standards (GLP; NATA), requirements for Phase 1 studies, privacy issues, and research involving GMOs, stem cell therapies, human tissue, etc.			

C2. Understanding the Principles of Good Clinical Practice and Good Research Practice within Research			
	A	**B**	**C**
C2.1 Good Clinical Practice (GCP) and good research practice.	Understands the principles and requirements of GCP and good research practice and how they apply to different studies i.e. GCP is a legal requirement for regulated Clinical Trials.	Understands the nuanced application of the principles and requirements of GCP and good research practice and promotes training and adherence as applicable.	Challenges poor practice according to GCP and good research practice principles and requirements and recommends and secures the necessary improvement/corrective and preventative actions.
C2.2 Adverse event reporting.	Is aware of adverse event reporting and handles basic queries about the reporting of adverse events.	Handles queries about the reporting of adverse events and administers the process for reporting adverse events.	Acts and advises on the process and requirements for adverse event reporting.
C2.3 Breaches of Good Clinical Practice (GCP).	Is aware of GCP and handles queries about the reporting of GCP breaches.	Handles queries about the reporting of GCP breaches and facilitates the necessary improvement.	Acts and advises on the requirements for reporting GCP breaches. Develops a culture where breaches are freely reported for continuous process and quality improvement. Tracks and analyses institutional trends and develops and implements process improvements and training.
C2.4 Training for researchers.	Identifies different training requirements for different types of research studies and can recommend options.	Promotes appropriate training and ensure its delivery for appropriate staff. Delivers relevant training on research governance topics.	Provides advice on, sources and/or delivers training on good research practice.
Possible implementation strategies: Create relevant induction GCP training material; provide relevant GCP training courses/workshops; source guidance material; develop SOPs for study conduct.			

C3. Understanding Research Roles and Responsibilities			
	A	**B**	**C**
C3.1 Roles & responsibilities of sponsors and sites (the institution participating in externally sponsored trials).	Understands the roles and responsibilities of the institution as a sponsor and/or site and applies them to her or his role.	Advises others on the roles and responsibilities of sponsors and sites, in particular, with respect to study-specific agreements.	Manages inappropriate delegation of roles and responsibilities and any breaches of sponsor and site roles and responsibilities.
Possible implementation strategies: Develop related internal business operation guidelines; provide training on research agreements.			

Access Request Decision Tree

Access Request or SSA

Is participant recruitment at the site achieved through a passive approach only (posters, leaflets, handouts, or letter of invitation) and there is no direct contact with potential participants or enrolment occurring at the site?

- **N/A** - There is no participant recruitment.
- **Yes** - Where the participant recruitment is passive only an Access Request is suitable.
- **No** - Where any research activity such as direct participant recruitment is occurring on the site, a site specific assessment will need to be submitted.

OR

Is the study a distribution of a survey or questionnaire through staff of the of the site OR will be distributed directly to NSW Health staff as the participants at the site and there is no need for a local staff member to collate, collect or analyse the responses?

- **N/A** - This study is not a distribution of a survey or questionnaire.
- **Yes** - where a survey is to be distributed by local staff only OR distributed directly to staff as the participant but there is no local activity beyond this an Access Request is suitable.
- **No** - where any research activity such as collation or analysis of surveys is occurring at the site, a site specific assessment will need to be submitted.

OR

Is the only activity of the site access to data or tissue held at the Public Health Organisation but not processing or analysis at that Public Health Organisation.

- **N/A** - This study is not for site access to data or tissue.
- **Yes** - Where the activity is access only to data or tissue with no processing or analysis on site an Access Request is suitable.
- **No** - Where any research activity such as processing or analysis of data or tissue is occurring at the site, a site specific assessment will need to be submitted.

**Where a study involves more than one of the above activities then Yes must be met for each activity for an Access Request to be suitable.*