Office for Health and Medical Research

NSW Health Research Handbook

NSW GOVERNMENT

We acknowledge the traditional owners of the land we work on.

We honour the ancestors of yesterday, the custodians of today and those of tomorrow.

We recognise the continuing connection to land and waters and how culture is held, nurtured and shared.

We pay our respects to Elders past and present and extend that respect to other Aboriginal peoples here today.

NSW GOVERNMENT

House keeping

This webinar is being recorded

The webinar is for 30 mins

30 mins Q & A time after the webinar

Type questions in Q & A window during the webinar

Email us at MOH-ResearchEthics@health.nsw.gov.au

All hyperlinks in blue

Scan the QR code for the NSW Health Research Handbook & associated documents

Agenda

- NSW Research Handbook Overview
- Implementation strategy
- Feedback Form
- Q&A session – 30 min

Introduction

Purpose

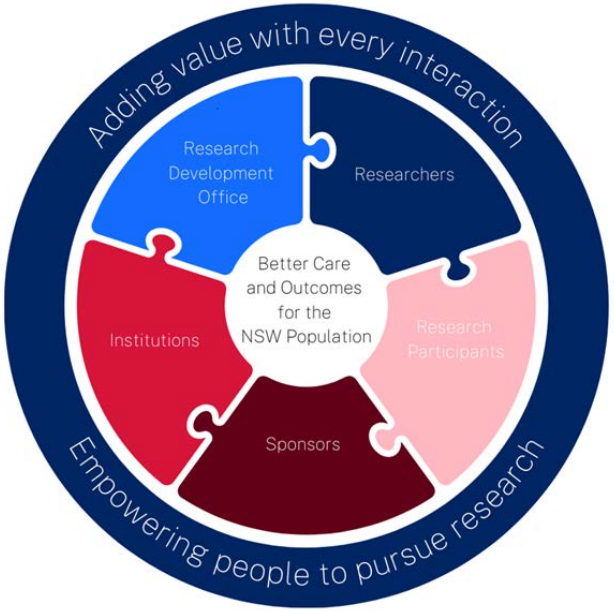
- Guide researchers and Development Offices - Ensure safe, valid, high-quality research.
- Excludes - designing a research project, conducting literature reviews, developing research protocols, data cleaning, statistical analysis, writing up results

Scope & Applicability

- Covers all human research at NSW Health.
- Applies to all NSW Health employees (NSW Health staff, participants and/or resources) and partners engaged in the research activity at NSW Health.

Scan the QR code for the NSW Health Research Handbook & associated documents

Embedding a Research Enabling Culture in NSW Health Organisations

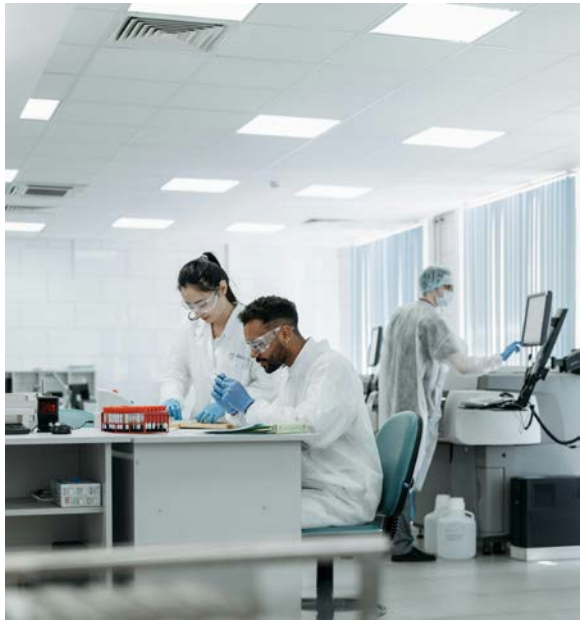


Researchers

1.Training Compliance

Good clinical practice

Transcelerate Biopharma Inc



2.Researcher Credentialing

3.Principal Investigator Requirements

For further information regarding PhD students, see NSW Health PD2022_049 Student Placements in NSW Health

4.Student Access to Medical Records

Appendix 3 of the NSW Health Privacy Manual for Health Information

New Research Proposals

- Research Governance
- Organisation
- Aligning with NSW Health Strategy
- Consultation Requirements
- Risk Assessment and Mitigation
- Engage Research Development Office

Protocol Design

High-Quality Protocol

Team Composition

Consumer Engagement

(NHMRC Consumer and Community Engagement)

Aboriginal and Torres Strait Islander Engagement

Panel of Aboriginal and Torres Strait Islander Representatives NHMRC

Resources

(ACTA) Consumer Involvement and Engagement Toolkit (2022)

Protocol Templates

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement

Support Resources

James Lind Alliance and Core Outcome Measures in Effectiveness Trials (COMET) methodology

Ethical Review

Guiding Principles	Ensure participant rights and safety	The National Statement on Ethical Conduct in Human Research (2023) AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (AIATSIS code), 2020 Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017 (the ART Guidelines)
	Adhere to ethical guidelines:	Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders, 2018
Risk Assessment	Evaluate risks comprehensively	
	Determine appropriate review level:	HREC vs. exemption pathways
NHMRC Risk Continuum	Facilitates nuanced risk assessment	NHMRC National Statement on Ethical Conduct in Human Research (2023)
Review Pathways	**Lower Risk Research:**	GL2023_007 Low and Negligible Risk Research
	Higher Risk Research:	Requires full HREC review; TGA approval (CTN/CTA)
Exemption from Review	Criteria under National Statement (5.1.17)	
Quality Improvement	QA projects generally exempt from ethical review	NSW Health GL2007_020: Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW https://www.medicalresearch.nsw.gov.au/ethical-scientific-review-2/

Ethical Review

Biobanks	Require HREC approval (The NSW Health Statewide Biobank)	National Statement Chapter 3.2: Human Biospecimens in laboratory-based research. Office of the Gene Technology Regulator & TGA
Specialist HREC Review	Justice Health	www.nsw.gov.au/health/justicehealth
	Aboriginal Health & Medical Research Council (AH&MRC)	www.ahmrc.org.au/ethics-at-ahmrc/
	NSW Population & Health Service Research Ethics Committee (PHSREC)	www.cancer.nsw.gov.au/research-and-data/nsw-population-health-services-research-ethics-com
	Early Phase Clinical Trials EPCT HRECs	www.medicalresearch.nsw.gov.au/hrec-scheme/
	Clinical Trials with Persons Unable to Provide Consent	https://ncat.nsw.gov.au/case-types/guardianship/clinical-trials.html
Research Ethics and Governance Information System (REGIS) System	Mandatory for ethics and governance submissions Facilitates streamlined approval processes	https://regis.health.nsw.gov.au/how-to/ Instructional videos: https://www.youtube.com/channel/UCYYI8wUSjJacGMF7pPAsIlA

Site Authorisation in NSW Health Organisations

Purpose of Site Authorisation

- Ensures compliance with ethical, scientific, regulatory, and professional standards
- Determines suitability of conducting research at the organisation
- Provides oversight of all research activities

Pathways to Site Authorisation

- **Site Specific Assessment (SSA)**
- **Access Requests**
- Download SSA roles and responsibilities using the QR code

Process and Requirements

- Conducted according to NSW Health PD2010_056: Research – Authorisation to Commence Human Research in NSW Public Health Organisations.
- SSA and HREC reviews may occur concurrently
- Applications submitted via REGIS SSA Form to Research Governance Officer (RGO) Quick Reference Guide: Completing a Site-Specific Assessment.

Role of Research Governance Officer (RGO)

- Assesses site-specific aspects of research applications
- Recommends authorisation to Chief Executive or delegate
- Manages post-authorisation activities and project oversight

Resources and Support

- Utilise NSW Health Operations Manual and OHMR resources
- Access decision tree for guidance on SSA vs. Access Requests (download the document using the QR code)

Conflicts of Interest and Data Management

Conflicts of Interest

NHMRC Disclosure of interests and management of conflicts of interest Guide (2019)

Adhere to NSW Health Conflicts of Interest and Gifts and Benefits Policy

Data and Primary Material Management & retention

National Statement, Chapter 3.1 The Elements of Research, Element 4: Collection, Use and Management of Data and Information

Develop data management plan: NHMRC Management of Data and Information in Research: A guide to supporting the Australian Code for the Responsible Conduct of Research)

Electronic Documents and Data

NSW Health PD2020_046 Electronic Information Security Policy

Utilise Research Electronic Data Capture (REDCap) for secure data collection and management within NSW Health infrastructure

Clinical Trial Management System (CTMS)

Mandatory use for all new Clinical Trials in NSW Health from September 1st, 2023

https://nswhealth.sharepoint.com/sites/NSWH-CTMS

Confidentiality, Privacy, and Data Sharing

Must abide by:

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

Use secure methods like Kiteworks (Accellion) Secure File Transfer for file sharing; avoid email or portable devices

Retention

For Clinical Trials - minimum of 15 years for adult studies or 25 years for paediatric studies Gene therapy research - data must be retained permanently

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

Biospecimen

NSW Health Pathology - Requests can be submitted via eResearchWithUs

Intellectual Property and Regulatory Requirements

Intellectual Property (IP)

- National Principles of Intellectual Property Management for Publicly Funded Research
- NSW Health Policy Directive for Intellectual Property Arising from Health

Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) Schemes

- TGA regulates therapeutic goods used in Clinical Trials
- TGA Clinical Trials Handbook
- NSW organisation as a sponsor: TGA Clinical Trials Handbook, ICH GCP Section 5 and ISO 14155

Authority to Prescribe Drugs of Addiction in Research

- Poisons and Therapeutic Goods Act 1966 (NSW)
- Researchers must obtain NSW Health authority for prescribing Schedule 8, 9, or 1 drugs
- NSW legal requirements for an authority to prescribe drugs of addiction

Gene Technology

- Gene Technology Act 2000 Gene Technology Regulations 2001 and Australia New Zealand Standards Safety in laboratories standard AS/NZS 2243.3
- GMO licence for dealings involving gene modification OGTR; GMO dealings; GMO Register

Regulatory Requirements

Research Involving Human Embryos

- Regulated under 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)
- NHMRC licenses required for activities involving human embryos. NHMRC – Information for applicants
- Requires HREC approval and adherence to legislative frameworks

Research Involving Ionising Radiation

- Conduct according to 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).
- Compliance with NSW Radiation Control Regulation 2013 standards essential
- Requires understanding of roles and responsibilities outlined in the ARPANSA code

NSW Civil and Administrative Tribunal (NCAT) Approval for Clinical Trials

- Approval required for participants unable to provide informed consent. https://ncat.nsw.gov.au/
- NSW Research Development Offices require NCAT approval, prior to governance authorisation

Clinical Trials Registration

Clinical Trials Registration

Requirement: Trials must be registered on WHO International Clinical Trials Registry Platform before first participant recruitment.

Benefits: Enhances transparency, promotes collaboration, and avoids duplication.

Responsibility: CPI/PI ensures accurate, updated registration.

Publication Requirement

International Committee of Medical Journals Editors (**ICMJE) m**andates public registration before participant enrolment.

Non-Clinical Trials

Funding Condition: Some studies require registration.

National Clinical Trials Governance Framework (NCTGF)

National Clinical Trials Governance Framework (NCTGF)

Objective: Enhance trial quality and patient outcomes nationwide.

Components: Governance, safety, performance, environment, consumer engagement.

Accreditation: Assesses adherence to framework standards.

Resource Availability: Guides, tutorials, and case studies.

Implementation

Flexibility: Allows adaptation to local health service needs.

Support: To become part of the working group please contact: clinicaltrialsnsw@health.nsw.gov.au

Resources

https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework.

Resources 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

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Resource management

Budgeting Requirements

Definition: Includes all costs essential for research (labor, equipment, fees, materials)

Ensuring Adequacy: Essential for project feasibility and outcome delivery

PI Confirms whether the budget is in place, or has been applied for, to cover all third party activities

Clinical Trials Management

NSW Health CTMS: Requires funding source and details details as part of mandatory dataset

Include study budget as a part of the Research Agreement Payments schedule

NSW Health Fee Policy

Responsibility: Research Development Office verifies agreements (third party contracts and site agreements) are in place

Funding Sources

Types: Monetary payments, in-kind support, donated products, grant funding

Transparency: Clear financial management processes required.

Resource Support & Service Provision

Approval Process: Head of department's endorsement necessary for external resource allocation

Documentation: Confirmation of support in REGIS (Part C) for Governance Authorisation

External Service Provider Agreements

Requirement: Service agreements for external providers (e.g., PRP Diagnostic Imaging)

Responsibility: PI ensures qualifications, approvals, and ongoing oversight per ICH GCP (TGA).

Principal Investigator Responsibilities

Third Party Oversight: Ensures compliance with protocols, approvals, and timely communications

Obtain approval from the study Sponsor prior to engaging any third parties

Research Agreements

Overview of Research Agreements

- Essential for projects involving NSW Health and external entities (e.g., commercial sponsors, CROs, institutes)
- Approval required from Chief Executive or their Delegate before project commencement.

Types of Research Agreements

- Determined by research activity and collaborating parties' relationship
- For investigator-initiated trials (IIT) and collaborative group research use standard agreements aligned with PD2023_017
- Medicines Australia Clinical Trial Research Agreement (CTRA) for medicinal products
- Medical Technologies Association of Australia (MTAA) Standard Clinical Investigation Research Agreement (CIRA) for medical devices
- Custom agreements if no suitable standard template exists

Electronic Signatures

- Encouraged for research agreement execution
- Follow institution-specific guidelines on platforms and processes

National Clinical Trial Agreement (NaCTA) Panel

- Aims to standardise terms of Medicines Australia CTRAs across states
- Changes to the existing clauses in the body of the CTRA or CIRA should be submitted to the NaCTA panel for review
- Submit changes to NaCTA for streamlined review and approval.
- Application details available at NaCTA Website

Insurance and Indemnity in Research

Overview of Insurance and Indemnity

Essential for all Clinical Trials conducted at NSW Health Organisations

Sponsors must provide indemnity and insurance per regulatory requirements

Review conducted as part of site-specific assessment via REGIS

2. Commercially Sponsored Trials

Must be indemnified and insured by an Australian sponsor

Medicines Australia Standard Form of Indemnity for drug trials

MTAA Standard form of Indemnity for projects involving a device

3. Collaborative Research Group (CRG)

Each party liable for acts and omissions

Insurance cover minimum $10 million (AUD)

Clearly define CRG nature in research applications

4. Investigator Initiated Clinical Trial

Treasury Managed Funds provides cover for NSW Health Staff-initiated trials

Covers Sponsor-related liabilities under specified conditions

Excludes product warranty liabilities

5. Treasury Managed Funds (TMF)

NSW government self-insurance scheme

Insures NSW government agencies for all insurable risks

6. Compliance and Further Information

NSW Health PD2011_006 Clinical Trials - Insurance and Indemnity

Maintain current insurance certificates via REGIS milestones

Safety monitoring and Reporting responsibilities

1. Mechanisms

- Reports from researchers and independent agencies.
- Safety report reviews and site inspections.
- Participant interviews and feedback.
- Frequency and type of monitoring depend on risk level (NHMRC guidelines).

2. Reporting Safety Events

- Aligns with 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)
- Best practice for all research projects, including non-Clinical Trials.

3. Data Safety Monitoring

- NHMRC Guidance on Data Safety Monitoring Boards (DSMB) 2018
- NHMRC Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018
- Alternative monitoring structures for low-risk trials (e.g., Trial Management Committee).

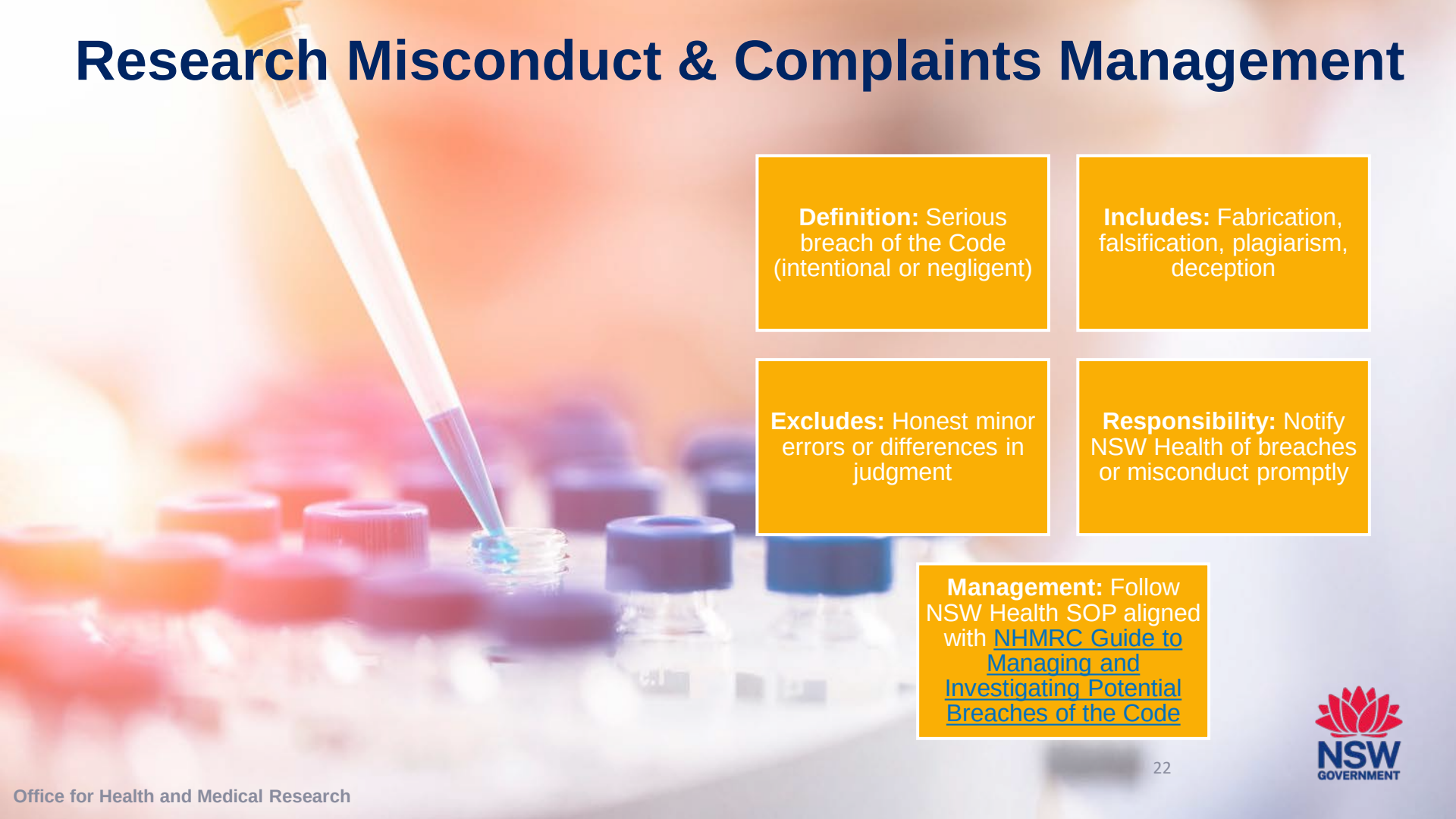
4. Reporting Serious Breaches

- NHMRC Reporting of serious breaches of Good Clinical Practice or the protocol for trials involving therapeutic goods (2018)
- Serious breaches affect participant safety or data reliability.

5. NSW Health Specific Requirements

- Notification of new information to Research Development Office via REGIS.
- Annual progress reports and final report submission requirements.

Research Misconduct & Complaints Management



Definition: Serious breach of the Code (intentional or negligent)

Includes: Fabrication, falsification, plagiarism, deception

Excludes: Honest minor errors or differences in judgment

Responsibility: Notify NSW Health of breaches or misconduct promptly

Management: Follow NSW Health SOP aligned with NHMRC Guide to Managing and Investigating Potential Breaches of the Code

Authorship, Research Output & Communications

Responsibilities: Disseminate findings responsibly and accurately.

Authorship: Fair attribution and agreement among authors.

Principles: Accuracy, complete reporting, disclosure of conflicts.

Publication: No duplicate publication of the same data.

Ethical Review: Verify ethical review for journal submissions.

Institution-Specific Requirements:

- Contact Institution Communication Team for details.
- Follow institution-specific publication policies and conference requirements.
- Refer to Managing Authorship of Research Outputs SOP, NHMRC Publication and Dissemination of Research Guide (2020) and the NHMRC Authorship Guide (2019)

Additional Considerations:

- Authorship order not determined by ethics/governance roles.
- Acknowledge in-kind support appropriately.
- Report findings to relevant affiliations promptly.
- Check for contractual publication obligations

The Handbook Implementation strategy

July-Sep 2024	July-Sep 2024	July-Dec 2024	By Dec 20 2024	Jan 2025	Jan-June 2025
					
Communication	**Education**	**Use extensively and disseminate widely**	**Provide feedback**	**Release of version “1.2”**	**Feedback for the next version**

Feedback Form

1. Your Name *

Enter your answer

2. Role *

Enter your answer

3. LHD or Organisation *

Enter your answer

4. Email *

Enter your answer

NSW Research Handbook - Section Review and Comments

A question has been added to this form for each section of the document. Where a subheading exists, please add this into the beginning of your comment, this will allow us to keep track of the comments. e.g. in the comment section for Section 4. Researchers note the subheading "4.3 Principal Investigator Requirements" then add your comment.

5. Section 1. Introduction

Enter your answer

6. Section 2. Embedding a research enabling culture in NSW Health Organisations

Enter your answer

7. Section 3. Research governance

Enter your answer

Q & A session