Government of **Western Australia**
Child and Adolescent Health Service

Clinical Trial Operations (including Clinic D Research) Standard Operational Procedures

Compassion
Accountability
Excellence
Equity
Collaboration
Respect

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INTRODUCTION

This document provides employees of the Child & Adolescent Health Service (CAHS) and other external research colleagues, including students, the requirements for Clinical Trials and Research involving human participants within CAHS. This document outlines the responsibilities and functions of the various stakeholders involved in these procedures. It is designed to promote good practice, ensuring that CAHS complies with the Australian Code for the Responsible Conduct of Research, 2018 ('the Code') and the National Statement on Ethical Conduct in Human Research 2023 (National Statement).

PURPOSE

The purpose of this document is to provide guidance to those involved in Clinical Trials at CAHS and those accessing Clinic D - Research for the purpose of conducting research with human participants. The creation of a suite of Standard Operating Procedures has been designed to support ongoing as well as new research projects with CAHS.

REFERENCE DOCUMENTS

The documents below are essential for any medical researcher working in Australia, WA and within the WA public health sector. It is also a requirement for researchers at CAHS to complete Good Clinical Practice Training prior to conducting any research activity.

Understand your broad responsibilities as a researcher in Australia:

- National Health and Medical Research Council, Australian Research Council and Universities Australia Australian Code for the Responsible Conduct of Research, 2018

Understand how to design and conduct ethically acceptable research:

- NHMRC National Statement on Ethical Conduct in Human Research 2023
- World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2018)

Understand the fundamentals of conducting clinical trials and all human research:

- Therapeutics Goods Administration Australian Clinical Trial Handbook
- Therapeutics Goods Administration Note for Guidance on Good Clinical Practice
- ICH Guidelines for Good Clinical Practice
- WA Health Translation Network GCP in Australia online training

Understand the National Clinical Trials Governance Framework (NCTGF) requirements when conducting Clinical Trials research at CAHS:

Any clinical trials research conducted at CAHS must be compliant with the NCTGF which outlines the requirements in terms of clinical governance and consumer partnerships.

CAHS is committed to partnering with its consumers to help shape research by the people who will benefit from it the most. Researchers should seek input from the patients/clients, participants, parents, and carers who will be most affected by research advancements. It is suggested community involvement be included at the proposal, protocol design, and participation stages of a research project. All consumer engagement at CAHS, regardless of affiliation, must comply with the CAHS Consumer Representative – Recruitment and Management policy.

All questions regarding NCTGF standards at CAHS can be emailed to CAHS.clinicaltrials@health.gov.au .

Read about how research is governed within WA Health:

- WA Department of Health Research Governance Policy and Procedures

Understand the principles to ensure research is safe, respectful, responsible, high quality and of benefit to Aboriginal and Torres Strait Islander people and communities:

- NHMRC Ethical Guidelines for Research with Aboriginal and Torres Strait Islander Peoples
- AIATSIS Code of Ethics 2020

Follow available guidance on NHMRC requirements on safety reporting and monitoring requirements:

- Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods 2016
    - Risk-based Management and Monitoring of Clinical Trials involving Therapeutic Goods 2018
    - Reporting of Serious Breaches of GCP or Protocol for Trials involving Therapeutic Goods
    - Data Safety Monitoring Boards

ABBREVIATIONS & DEFINITIONS

AI	Associate Investigator
CAHS	Child and Adolescent Health Service
CAPA	Corrective and Preventative Action
CPI	Coordinating Principal Investigator
CoI	Conflict of Interest
CRF	Case Report Form - A paper or electronic questionnaire specifically used in clinical research. The CRF is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.
CRO	Clinical Research Organisation / Contract Research Organisation
CTA	Clinical Trial Application
CTN	Clinical Trials Notification
CTRA	Clinical Trial Research Agreement
DoH	WA Department of Health
DSMB/C	Data Safety Monitoring Board/Committee
GCP	Good Clinical Practice - An international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that involve participation of humans.
HREC	Human Research Ethics Committee
IMP	Investigational Medicinal Product - A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the registered form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.
IRB	Institutional Review Board
Monitor	An individual who acts on behalf of the sponsor to oversee the progress of a clinical trial, and of ensuring that is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Monitoring Report	A written report from the Monitor to the sponsor after each site visit and/or other trial-related communication, according to the sponsor's SOP.
National Statement	National Statement on Ethical Conduct in Human Research, 2023
NHMRC	National Health and Medical Research Council
NTF	Note to File
PCH	Perth Children's Hospital
PD	Protocol Deviation

PI	Principal Investigator
PICF	Participant Information and Consent Form
QA	Quality Assurance
QI	Quality Improvement
REG	Research Ethics and Governance
Regulatory Binder	Method used to organize/store essential study documents and often the first document reviewed during audits and inspections. The Regulatory Binder is referred to synonymously as the Study Files, Investigator Binder or Investigator File.
Researcher	a person who carries out academic or scientific research
Restricted Schedule 4 Substance	Schedule 4 medications subject to additional storage and recording requirements beyond those required for regular Schedule 4 medications. Also known as Schedule 4 Recordable medications, or Schedule 4 Reportable medications. A list of these medications is located in the WA Health Risk based requirements for medicines handling.
RG	Research Governance
RGO	Research Governance Office
Schedule 4 substance	Substances in Schedule 4 of the Poisons Standard
Schedule 8 Substance	Also known as Controlled Drugs. S8 medicines are defined in the Poisons Standard as “substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.”
SIV	Site Initiation Visit - A meeting requested by the sponsor of a newly approved/activated trial for the study team at the clinical site to review the specifics of the protocol in preparation to enrol the first participant (for example: the science, design, procedures, CRF completion, etc.)
SOPs	Standard Operating Procedures
Source Documents	Original documents, data, and records (hospital records, clinic and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).
Sponsor	An individual, company, institution, or organisation that takes responsibility for and initiates a clinical research trial.
TGA	Therapeutic Goods Administration

PROCEDURE 101 – How To Request Support Staff	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To guide study team members on how to request support staff for their research project at Perth Children's Hospital.

Background

- Researchers secure research grant and require a research nurse for their research study.

Key Points

- Researcher should contact Clinical Nurse Manager Research for support with recruiting to their team.

Procedure

- Researcher secures research grant
- Researcher liaises with FBO to create cost centre for research funds
- Researcher contacts CNM Research
- Researcher arranges to meet with CNM Research to discuss project staffing requirements including research department shell position and level depending on duties to be performed, FTE, and start date.
- CNM Research liaises with researcher to create EOI or external advertisement if required to recruit to position
- CNM Research assists researcher to successfully appoint staff member to the position.

Related internal policies, procedures and guidelines
Access to Employment Records (CAHS Policy Manual)
Department of Research - CAHS Research Department Shell Positions
Financial Journal Management
Investigator Responsibilities (CAHS Policy Manual)
Requesting Creation of a New Cost Centre Finance
Research Policy (CAHS Policy Manual)

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf) CAHS Policy Manual

PROCEDURE 102 – Research Data Handling	
Scope (Staff):	Authorised Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To have a reference starting page guiding study team members on all aspects of handling data, for example accessing, handling, sharing and storing their research data or medical records internally at CAHS and externally to Non-CAHS organisation.

Procedures

1. **Accessing** electronic research or medical records is possible and only for authorised users following a strict request and approval processes and must comply with MP 0015/16 – Information Access, Use and Disclosure Policy
   - **DMR Access for CAHS employees**
     - is automatic through employment onboarding process.
   - **DMR Access for Non-CAHS employees**
     - is possible however they must first have an he#number and a WA Health email address.
     - Refer to WI Onboarding for External Collaborators for obtaining HEnumber & WA Health email address.
     - Refer to WI DMR Access for Sponsor Monitors and External Collaborators for request and approval process.
   - **REDCap Access for WA Health database**
     - is available for all CAHS employees. Users must first register by filling out a form WA Department of Health REDCap Registration.
     - For further information refer to REDCap (Research Electronic Data Capture) hub.
     - For any questions, contact REDCap

2. **Storing** a hardcopy or electronic health information must be managed according to
   - WA Health Information Security Policy

3. **Sharing** research data between CAHS and any non-CAHS organisation must be controlled BEFORE sharing the data. For example a data transfer agreement must be in place detailing the custodians.
   - Refer to CAHS Confidentiality, Disclosure and Transmission of Health Information .
   - For any questions, contact CAHS Research Governance Office on CAHS.rgo@health.wa.gov.au .

4. **Handling** or cleaning data must follow the ALCOA++ principles from Good Clinical Practice guidelines.
   - **Attributable:** Who acquired the data or performed an action?
   - **Legible:** Can you read the data and any laboratory notebook entries?
   - **Contemporaneous:** Was the data documented at the time of the activity?
   - **Original:** Is the data an original record or observation, or a certified copy thereof?
   - **Accurate:** Are there any errors or editing without documented amendments?
   - **Complete:** All data, including any repeat or reanalysis performed, is recorded.
   - **Consistent:** All elements are dated or time stamped in expected sequences.
   - **Enduring:** Long term data retention is ensured, allowing for accessibility.
   - **Available:** Data record is available for review, audit, or inspection, over its lifetime.
   - **Traceable:** Data should be traceable throughout the data life cycle, and changes should be recorded as part of the metadata (i.e., audit trails).

Related internal policies, procedures and guidelines
CAHS Health and Medical Record Management (CAHS Policy Manual)

Clinical Documentation (CAHS Policy Manual) Corporate Records Management (CAHS Policy Manual) Information Management Governance Policy – (WA Health Policy) Investigator Responsibilities (CAHS Policy Manual) PCH – CAHS patients Consent to release information (CAHS Policy Manual) Research Policy (CAHS Policy Manual)

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018 Code of Conduct (Code-of-Conduct-Policy.pdf) GUIDELINE FOR GOOD CLINICAL PRACTICE

PROCEDURE 103 – Requesting CAHS Honorary Research Appointment	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To guide research team members on how to request CAHS Honorary Research Appointment at Perth Children's Hospital when they are employed externally (for example: through The Kids Research Institute Australia or University).

Background

- This procedure provides the overarching unremunerated honorary appointment governance process which will enable compliance with legislation, policy and good records management.

Key Points

- The CAHS Research Department is responsible for, and must centrally manage this process.
- The CAHS research department will have oversight of honorary research appointees.
- This procedure will provide a standardised onboarding experience for external researchers.

Procedure

1. Onboarding request:
    - Research Department receives request take on a researcher from The Kids Research Institute or University.

2. Application submission process:
    - Appointee completes and signs Application Form and sends to Research Department with required documentation for review.

3. Approval process:
    - Research Department checks application including all documentation required is present and submits completed application with attachments to the Director of Research Operations for approval.

4. Application approval:
    - Research Department issues Letter of Agreement to appointee including the following requirements:
        - Health screening/immunisation checklist and declaration
        - Working with Children Check
        - Provision of the minimum identity proofing requirements
        - Successful Criminal Record Screening Clearance
        - WA Health Patient Confidentiality Policy
        - CAHS Confidentiality form and Code of Conduct

5. Provide Access:
    - Research Department ensures all clearances are completed and requested documents are signed and returned
    - Research Department manages ongoing credentialling.
    - Complete eHFN-30 to provide HE number, health computer access, DMR access (note: only if required)
    - Arrange ID card access

6. On commencement:

- Book and complete CAHS Induction Emergency procedures walkthrough
- Arrange local clinical area orientation as required
- Complete CAHS MyLearning requirements (BLS/HPLS, Hand Hygiene, Infection prevention and control, Manual tasks, GCP)
- Discuss dress standards
- Role based induction and discuss breach of standards

7. On completion of appointment or termination:
    - Research department completes off-boarding checklist
    - Ensure ID badge/swipe card is returned to PCH Security
    - Terminate ICT access through completion of eHFN-030 form

Related internal policies, procedures and guidelines
Confidentiality, Disclosure and Transmission of Health Information (CAHS Policy Manual)
CAHS.PM.EmergencyManagement.pdf (CAHS Policy Manual)
Employee Orientation and Induction (CAHS Policy Manual)
Pre-Employment Health Assessment (PEHA) (CAHS Policy Manual)
Research Policy (CAHS Policy Manual)
Unremunerated Clinical and Honorary Research Placements (CAHS Policy Manual)
WWC Check Compliance Clinical Researchers (CAHS Policy Manual)

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
Criminal Record Screening Policy
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care

PROCEDURE 104 – Creation, Implementation and Revision of SOPs	
Scope (Staff):	All staff delegated the task of writing, reviewing, approving or distributing a clinical research SOP on behalf of CAHS.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To document the procedure for the development, review, amendment, approval, endorsement and implementation of policy and standard operating procedures (SOPs) documents within CAHS Research.

Background

- SOPs are created/in place to:
    - comply with regulations and institutional policies
    - Standardise practice across CAHS to maintain clinical trial participant safety and rights
    - Standardise practice across CAHS to ensure clinical trial data integrity and credibility
    - Identify and document existing standard practices
    - Mitigate risk identified in clinical trials
    - Improve efficiency
    - Assist in training new staff

Key Points

- Clinical trial SOPs must comply with the trial Protocol and other applicable regulatory requirements.
- Authors of SOPs should have experience in the area covered by the SOP and be authorised to create or modify them.
- Note: It is important to first check whether a similar SOP or guideline is already in place by consulting or reviewing CAHS Research Departments SOPs such as CAHS Research Ethics and Governance and CAHS Research Support and Development.
- Refer to CAHS Policy Management POLICY for CAHS authorisation and delegation schedule listing official approval and endorsement authority for Policies. For example CAHS Policy related to Research must be approved by Tier 3 – Director Research Operations and Endorsement from Research Advisory Committee.

Procedure

1. Establish the need for a new SOP or revision of an existing SOP

- All clinical trials staff involved in the planning, conduct, analysis, governance, education / training, or administration of research may identify the need for a new SOP, or a gap in an existing SOP.
- Development of a new SOP may be triggered:
    - Internally within CAHS (for example resulting from updates to policies, Quality Assurance activities, risk evaluation)
    - Externally (for example resulting from updates to practice guidelines, an audit, legislative requirements).
- Gaps in existing SOPs may include unclear instructions, lack of sufficient detail, or obsolete/inaccurate procedure.
- Ensure that a SOP is the most appropriate and best fit document.

2. Draft the new SOP or modify existing SOP

- The CAHS Sponsor-Investigator (where CAHS is the Sponsor) or CAHS site Principal Investigator (when CAHS is a participating site in an externally led research study) is responsible for developing SOPs where existing SOPs are not already in place.
- The Sponsor-Investigator/Principal Investigator may delegate this responsibility to a suitably qualified member of their research team.

- The SOPs author, reviewer, and approver are responsible for ensuring the content of the SOP:
  - Is compliant with relevant state/National/international requirements and professional regulations
  - Does not conflict with existing institutional policy or SOPs
  - Reflects current 'Best Practice'
- Use the provided template in Appendix B
- The SOP may contain links to or provide tools in the appendix to assist in standardised implementation of procedure, such as:
  - Forms
  - Templates
  - Checklist
  - Timeline
  - Flow chart
  - Quick reference factsheet / table

3. Distribute SOP to relevant stakeholders for review and comment.

- Relevant stakeholders include:
  - all parties who will be affected by introduction of the SOP
  - Parties who may affect changes in the scope of activities covered by the SOP
- Key/high priority stakeholders include:
  - PI
  - head/s of department/s
  - trial staff
  - supporting departments
  - institutional policy makers
- The degree of engagement with stakeholders should be based on the importance of their impact and the degree to which they are impacted.
- Maintain a record of the review process either on a document tracking review log (including at a minimum the SOP ID, version number, reviewer name, review date, changes and comments noted by reviewer, action by owner, date of action, new version) or electronically by using the tracked changes feature with a file naming paradigm and save files on central drive.
- Incorporate relevant comments and if required redistribute to relevant stakeholders for second review.
- If necessary, repeat the above 2 steps until a final version is ready for approval.
- Ensure that the 'SOP effective date' and 'SOP review by date' is in alignment with the timeframe identified in this SOP.

4.Approval and Authorisation of the SOP

- arrange for approval, authorisation and final sign off by the delegated authoriser
- once signed, file/securely store the final approved new/amended SOP electronically as a pdf document

5. Training, Implementation, Distribution of the New or Revised SOP

- All relevant stakeholders must be notified of the new/updated SOP between the authorisation and the effective date.
- distribute to all relevant trial staff/ post on website/s.
- advise relevant trial staff to perform training on new/amended SOP as appropriate

6.Review of the SOP

- The review date is two years after the effective date.
- The time between SOP authorisation and the effective date may be reduced in special circumstances (for example, in urgent situations where procedures must be implemented immediately).
- An earlier review date is permitted where necessary (for example, due to changes in legislation, changes to institutional policy and procedures).
- Actively invite feedback from all relevant stakeholders/users, to inform a regular, formal review of the SOP and to enable a continuous improvement approach.

- A clear mechanism for feedback must be established and advertised widely in advance of the formal review period, to ensure all users and stakeholders have adequate opportunity to contribute to the review process.

7.Superseded SOPs

- All old/outdated SOPs must be marked with SUPERCEDED and filed securely as a record of previously used SOPs.
- notify relevant stakeholders of superseded SOPs.
- remove superseded SOP from relevant websites.

Appendix A: Approval and Endorsement Positions Accountable

Type	Audience	Document Owner	Approval Position	Endorsement Position
Author: Clinical Trials Group at PCH				
SOP	Internal only	Tier 4 Manager	Principal Investigator	Principal Investigator
WI	Internal only	Tier 6 Officer	Tier 6 Officer	Tier 6 Officer
Guidelines	Parent/Patient facing	Principal Investigator	HREC Approval Needed	N/A due to HREC Approval
Guidelines	Internal Only	SME	Principal Investigator	Principal Investigator
Author: CAHS Research Department				
SOP	Clinical Trials Group at PCH	Tier 4 Manager	Research Director Operations	Research Director Operations
WI	Internal only	Tier 6 Officer	Tier 6 Officer	Tier 6 Officer
WI	Cross Departmental at PCH	Tier 6 Officer	Research Director Operations	Tier 3 – Other Department
Guidelines	Clinical Trials Group at PCH	SME	Tier 4 Manager	Research Director Operations

- Refer to CAHS Authorisation Tiers Document for further position examples within Tiers 3, 4 & 6 above.

Related internal policies, procedures and guidelines
CAHS Policy Manual

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 105 – Investigator Responsibilities	
Scope (Staff):	All Investigators involved in clinical trials research at CAHS.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To document Investigator responsibilities associated with undertaking a clinical trial at CAHS in accordance with ICH GCP responsibilities for Investigators in clinical trials and Teletrials.

Background

- The Investigator is primarily responsible for appropriate trial conduct at CAHS, this includes all related activities involved before, during, and after the research project concludes. Investigator refers to Coordinating Principal Investigator (CPI); Principal Investigator (PI); Associate Investigator (AI) and/or Sponsor Investigators (PI Initiated).

Key Points

- This document will act as a reference to standard operating procedures aligned to our CAHS Investigator Responsibilities – Research Policy

Procedure

1.Pre-approval

Before the research/clinical trial commences, the Investigator must:

- Be familiar with the following -
  - CAHS Investigator Responsibility – Research Policy
  - CAHS Standard Operating Procedures for the Approval of Research
- Demonstrate that adequate research participant recruitment is possible.
- Establish appropriate staffing to enable successful trial conduct at the site and any satellite sites.
- Have a thorough understanding of the appropriate use of the Investigational Product (IP) as described in the study Protocol, the Investigational Brochure (IB) for medicines or Product Information for devices, and in any other relevant information sources.
- Ensure appropriate approvals are obtained including HREC approval, Research Governance authorisation, and the registration number of the trial once it is registered on a publicly accessible World Health Organization compliant clinical trials registry before the first participant is recruited to the study.

2. Post-approval

During, and after the research/clinical trial is completed, the Investigator must:

- Ensure strict adherence to the research/clinical trial protocol, including overseeing all staff/team members involved in the trial.
- Ensure all clinical trial/research team members are appropriately qualified, trained and delegated.
- Ensure adequate resourcing to ensure optimal trial conduct.
- Act within their scope of practice.
- Be accountable to their employer within CAHS and the commercial sponsor if applicable.
- Ensure research/trial participant safety and wellbeing at all stages of the trial.
- Ensure necessary clinical care is provided to research participants for care required as a result of any related adverse events experienced during or following the trial.
- Inform the participants' primary physician about their involvement in the trial, if the participant agrees.
- Maintain ongoing informed consent of participants.

- Ensure all trial staff are trained on the Protocol, IB, Adverse Event (AE)/Serious Adverse Event (SAE) reporting to the DSMB or equivalent, and that a system for safety reporting responsibilities is in place for all trial staff.
- Ensure key trial staff are trained on escalation reporting requirements for Serious Breaches, Significant Safety Issues (SSI) or Suspected Unexpected Serious Adverse Reaction (SUSAR). Refer to CAHS Standard Operating Procedures for Approval Research for current reporting timeframes.
- Ensure trial related documentation, files, and procedures are established and maintained.
- Ensure all documentation carried out follow ALCOA+ principles of good documentation practices, which include Attributable, Legible, Contemporaneously, Original, Accurate, Complete, Consistent, Enduring, Available and Traceable.
- Ensure audit/inspection readiness at all times.
- Ensure all trial staff have a thorough understanding of the process for securely and appropriately storing and ensuring accountability for the IMP.
- Follow Sponsor or CAHS Research requirements to ensure that appropriate Corrective and Preventative Actions (CAPA) have been implemented and findings reported to CAHS and the relevant HREC.
- Ensure appropriate ongoing care of participants throughout the trial, if a participant withdraws during the trial and/or if a trial is prematurely terminated.
- Record in the participant's health and medical record at the appropriate Institution (which may be a Satellite Site) the treatment the participant was allocated, if applicable.
- Document and periodically review protocol deviations. If any systemic repeat issues have been identified, put in place corrective actions to mitigate the occurrence.
- Notify the Sponsor, HREC and RGO in writing if staff leave CAHS, with either their new place of employment and contact details or who their proposed replacement is with contact details for recording on all archiving related documentation.

3.Satellite Site – Teletrials

- Perform site evaluation of any Satellite Site deemed to be potentially able to recruit participants to the trial, if applicable.
- Document a detailed Supervision Plan for Teletrials, if applicable.
- Ensure the Site File Index includes an additional column for satellite sites, listing the location of their trial documentation.

4.Project Close

- Sign all trial related documentation at the end of the trial such as documents requiring an end date, indicating the research project is completed including but not limited to: Delegation Log, Training Log, Supervision Plan, agreements, progress reports, eCRF/CRF, SAE reports, etc.
- Ensure all trial related staff and third-party providers have been informed of trial closure, results and publication plan.
- Ensure a lay summary of the trial results (usually provided by the Sponsor) is disseminated to participants in accordance with the HREC application/trial Protocol, and be prepared to respond to queries from participants in relation to the trial results.
- Ensure study related documents are securely archived, including at any Satellite Sites as relevant.

Related internal policies, procedures and guidelines
CAHS Investigator Responsibility – Research Policy CAHS Research Ethics and Governance Standard Operating Procedures Clinic D Research Clerical Officer Manual Clinic D Research Bookings - WI Child and Family Centred Care (CAHS Policy Manual) Clinical Documentation (CAHS Policy Manual)

Health and Medical Record Management (CAHS Policy Manual)

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 106 – Site Staff Qualifications and Training	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To ensure the appropriate documentation of clinical trial site staff qualifications and training records are completed and maintained up to date during the course of clinical trials conducted at CAHS.

Background

In accordance with ICH GCP, the National Statement on Ethical Conduct, and the National Clinical Trials Governance Framework, all CAHS clinical trials staff must:

- be appropriately qualified and trained for the role they are carrying out;
- have qualification, training, and education documented in a way that demonstrates to external reviewers that their training and experience are adequate for their role and responsibilities;
- maintain currency of qualifications, education, and training.

Key Points

The purpose of this SOP is to:

- define the necessary qualifications, education, and training required of CAHS clinical trials team members
- demonstrate how evidence of staff qualification, education and training should be documented
- document the process for clinical trials team members to maintain currency of qualifications, education, and training.

Procedure

1.Site staff qualifications and training

- The PI is responsible for ensuring that they, and the entire clinical trials team including supporting departments and external vendors are qualified by education, experience, and training, and are legally authorised to assume their roles and responsibilities for appropriate trial conduct.
- All staff must have an appropriate level of accredited GCP training
- All staff must have appropriate and documented trial-specific training before performing any clinical trial activities.
- All staff who have been delegated significant duties per the delegation log must have a current CV lodged with the RGO/present in the ISF and be trained appropriately.
- All vendors contracted as third-party suppliers of clinical trial services (such as for IP shipment, laboratory or radiology services) should be assessed as appropriately qualified and credentialed and as having sufficient knowledge and experience to perform their contractual obligations.

2.Site Staff qualification, training, and delegation records

- The PI is responsible for ensuring that:
    - qualifications and training of all clinical trial staff such as CV, AHPRA registration, licenses and GCP certificates are filed in the ISF;
    - training of all clinical trial staff on trial-specific items such as the Protocol, Investigational Product Brochure, and relevant manuals/guildelines is appropriately documented in trial-specific training logs or other trial-specific records;
    - training records are completed and kept up to date and made available for review on request throughout the duration of the trial;

- trial staff duties are appropriately delegated and contemporaneously documented in a trial-specific delegation log including start and stop dates and any changes.

3.Site Staff capability

- The PI must:
  - Carry out the roles and responsibilities of the PI in accordance with ICH GCP, the National Statement on Ethical Conduct, and the National Clinical Trials Governance Framework;
  - Demonstrate the potential for meeting recruitment targets;
  - Have adequate time to conduct and complete trial related activities within the specified timeframe;
  - Show evidence of adequate resources such as appropriate number of qualified staff and relevant facilities and equipment for the duration of the trial;
  - Provide appropriate supervision and oversight of all personnel and parties with trial-related duties;
  - Be responsible for all trial participant safety, trial-related duties and all data generated.

Related internal policies, procedures and guidelines
CAHS Policy Manual

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 107 – Site Initiation	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To document the procedures involved in initiation of a clinical trial at CAHS.

Background

A clinical trial site initiation visit (SIV) is an essential meeting held before a clinical trial begins to ensure the site can fulfil the study specific and regulatory requirements for trial conduct.

Key Points

- There are multiple responsibilities for the Investigator prior to, during, and at the end of the SIV.

Procedure

1. Prior to the SIV, the Investigator must:

- mutually agree with the Sponsor a scheduled date, time, and location for the SIV to ensure the site is prepared
- In case of a Teletrial, SIV may be at the Primary Site only, or could include the Satellite Site/s remotely depending on the study complexity, and as depending on the Sponsor/PI.
- review all trial related documentation and have an understanding of the Investigational Product, Investigator Brochure, Case Report Forms (CRF), and Protocol.
- Ensure all relevant staff involved with the trial are informed about the meeting and are available to attend (eg: AI, Pharmacist, Clinical Research Coordinator and others as appropriate including those at Satellite Site/s).
- Request an agenda from the Monitor or create one for the SIV, if needed.
- Ensure any study-specific initiation visit checklists are completed in advance of the visit.
- Ensure Institutional Review Board (IRB) approval has been obtained, or review is in process.
- Ensure the finalised budget and contract are in process, if not fully executed.
- If required, schedule separate educational/training sessions with involved clinical staff (eg: pharmacist, nurse, study coordinator, physicians).
- Complete the regulatory binder checklist to ensure that it contains all of the necessary documents.

2. During the SIV, the Investigator must ensure the following are available or addressed:

- Ensure that the PI is present
- Review details of the protocol, including study operations with the Monitor.
- Discuss with the Monitor which key personnel are authorised to perform what study-related functions or procedures.
- Document operational questions not covered in the Protocol and the answers provided by the Sponsor.
- List of all trial personnel attending on an attendance log/training log
- Original, signed, dated curriculum vitae of all trial personnel involved
- Other documents including financial disclosures, training logs, medical licenses and other essential documents per Sponsor requirements
- Study master file containing all required essential documents
- Trial related manuals and documents, including timeline for receipt by site
- Timeline for shipment, delivery, and receipt of Investigational Product and other trial related supplies by site
- Specialised equipment/resources/personnel required for trial conduct (eg: centrifuge, freezers etc).
- Discuss Investigational Product administration and accountability (if applicable)
- Review directions for source documentation and/or CRF completion.

- Discuss applicable study-specific training involving protocol execution (eg: training for PI, research nurse, pharmacy, imaging staff)
- Archiving of trial documents at close-out

3. At the end of the SIV, the Investigator must:

- File the SIV report/letter in the Site Master File
- Ensure staff at Satellite Site/s document and file all communication in the Satellite Site Files.
- Document SIV in Site Visit Log if not provided by sponsor and file in regulatory binder.
- Assemble screening/enrolment materials.
- Activate recruitment plan once IRB approval is obtained.
- File all training certificates in the regulatory binder. If the sponsor does not provide a record of training, record the timing and details of any training sessions and file in the regulatory binder.

Related internal policies, procedures and guidelines
CAHS Policy Manual

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 108 – The Study Master File / Investigator Site File	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To document the procedures related to maintenance of the Study Master File (SMF) / Investigator Site File (ISF) for a clinical trial being conducted at CAHS in accordance with Good Clinical Practice (GCP).

Background

The purpose of the SMF/ISF is to organise the Essential Documents for a trial in a way that will ensure appropriate conduct of the trial, and facilitate auditing and inspections that enable evaluation of the quality of trial conduct and the data produced by the trial. The contents of the SMF/ISF must enable adequate reconstruction of trial conduct at CAHS along with any key trial decisions.

Key Points

- The SMF/ISF must be current at all times during the trial.

Procedure

1. <u>About the SMF/ISF:</u>

- the PI is responsible for establishing the SMF/ISF prior to clinical trial commencement;
- should be prefaced with an index of contents and location of Essential Documents;
- contains identifiable data and must be stored securely with restricted access to authorised trial staff only;
- must be actively maintained as the trial progresses;
- direct access to all trial related records stored in the SMF/ISF should be provided when requested by monitors, auditors, ethics committees or regulatory authorities;
- the storage system used during the study and for archiving (regardless of paper or electronic) should provide for document identification and location, version history, ability to search and retrieve appropriately for the length of the archiving retention time.

2. <u>Essential Documents within the SMF/ISF:</u>

- must be complete, accurate, and legible;
- must be filed contemporaneously ensuring version control;
- documents stored in the SMF/ISF should be originals or certified copies of original documents;
- if documents are stored separately from the SMF/ISF (for example: calibration records for equipment used in the trial), a file note in the SMF/ISF must indicate their location;
- superseded documents should be retained but scored through to indicate that the document is no longer in use;
- include the correspondence generated during a trial. These documents (for example: emails, telephone call reports, meeting minutes) are an important component in reconstructing the trial as they contain key decisions and discussions relating to the care of participants and the management of the trial.

3. <u>Contents of the SMF/ISF:</u>

- Trial related Essential and Source Documents generated for/by the Primary Site will be filed in the SMF/ISF as per the below at a minimum:

1. Site Staff Contact List
2. Trial Documents
   2.1 Investigational Brochure
   2.2 Safety Updates (reports, expedited safety letters/notifications, etc.)
   2.3 Clinical Trial Protocol
   2.4 CRF (blank)
   2.5 CRF Completion Guidelines
   2.6 IP Shipping Records (refer to Pharmacy Folder/Records)

- IP handling documentation e.g. shipping, receipt, Interactive Web Response System (IWRS), codes, randomisation list and accountability and destruction documents etc. may be kept in a separate file e.g. at the site pharmacy. In this case the location is to be recorded on the SMF index. However, the records must be made available to Sponsors, monitors, auditors and regulatory agencies at any time. The Investigational Product documentation will be archived with the SMF after completion of the study.

2.7 IP Accountability Records (refer to Pharmacy Folder/Records)

3. Contracts
   3.1 Site Agreements (CTRA, Indemnities, Confidentiality Agreements, staff personal information consent, etc.)
   - Where financial documentation, such as the Clinical Trial Agreement and Sub-Contract, invoicing and remittances etc. may be filed in a separate location to the SMF, the location is to be recorded on the SMF index. A copy may be filed in the SMF if requested by the Sponsor.

4. Regulatory Authority Documents
   4.1 Regulatory Agreements
   4.2 Financial Disclosure Forms (FDFs)
   4.3 Other Regulatory Documents (CTA, CTN, etc.)

5. Human Research Ethics Committee (HREC)
   5.1 Initial Submissions/Approval
   5.2 Other Submissions/Approval
   5.3 Clinical Study Report
   5.4 HREC Correspondence

6. Site Staff Qualification
   6.1 Curriculum Vitae and Medical Licences
   6.2 Training (GCP, study specific, vendor specific)
   6.3 Delegation of Authority Log

7. Supervision Plan

8. Participant related Documents
   8.1 Blank Informed Consent Forms (signed Forms in participant files)
   8.2 Screening Log
   8.3 Enrolment Log
   8.4 Subject Identification Log
   8.5 Other participant facing materials/documents (for example: blank subject diaries, emergency card, recruitment material, etc.)

9. Safety Related Documents
   9.1 Safety Monitoring Plan
   9.2 Risk Management Plan
   9.3 Serious Adverse Events Log
   9.4 Serious Adverse Events Form(s) - blank
   9.5 SUSARs
   9.6 Other Safety Reports eg Breaches, Annual Safety Reports

10. Laboratory
    10.1 Central and Local Lab Accreditation/Certification (NATA, CLIA) (print or website reference)
    10.2 Central and Local Lab Normal Ranges
    10.3 Central Lab Manual/Instructions
    10.4 Biospecimen Shipment Logs Records
    10.5 Other (equipment calibration certificate, temperature logs)
    - Sample handling procedures are to be clearly documented if performed e.g. in a laboratory manual. Sample management records at both Primary and Satellite Site/s including the storage, processing and transportation of samples between Satellite and Primary Sites are filed in the SMF as agreed.

11. Monitoring Reports

11.1 Site Visits (incl. initial) / Monitoring Visits / Sponsor Visits
11.2 Protocol Deviation Log
11.3 Audit (correspondence, reports, follow up letters, etc.)
11.4 Monitoring Plan

12. Correspondence
12.1 General with Sponsor, Teleconference, Meeting Notes

13. CRF
13.1 Blank CRF if Paper Available
13.2 CRF Completion Guidelines
13.3 Data Query Documentation

Related internal policies, procedures and guidelines
CAHS Policy Manual

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 109 – Case Report Forms	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To document the procedures related to the completion of Case Report Forms (CRFs) and the maintenance of Source Documents for all clinical trials conducted at CAHS.

Background

- In accordance with GCP, the CRF is a paper or electronic document designed to record all of the Protocol required information to be reported to the Sponsor on each clinical trial participant.
- The PI has ultimate responsibility for the content of and access to the CRF but may delegate the task to suitably qualified individuals.

Key Points

- As the source data collected in the CRF contributes to the data for regulatory approval of unapproved therapeutic goods and is the basis for trial reports and any publications; it is of utmost importance.

Procedure

1. Contents of the CRF:

- The CRF is a paper or electronic collection of all source data (transcribed from within source documents).
- Source data is original information such as clinical findings, observations, or other records from a clinical trial that are necessary for the reconstruction and evaluation of the trial.
- Source data must therefore be collected accurately and in accordance with GCP.
- Source data should be attributable, legible, contemporaneous, original and accurate (ALCOA).
- Changes to source data should be traceable (signed and dated), should not obscure the original entry, and should be explained if necessary (via audit trail to maintain data integrity).
- Source Data in electronic format should be complete, consistent, enduring, and available (ALCOA +).

2. Completion of the CRF:

- Source data from within source documents is transcribed into the CRF.
- Electronic data capture systems must contain an inbuilt correction and audit trail feature, if not, printed records of changes/corrections (such as due to data queries) must be retained.
- The PI must ensure that any personnel delegated to perform data entry or signing for data completeness is recorded on the trial-specific Delegation Log and trained to perform these trial related duties in accordance with GCP.
- The PI is responsible for accuracy, completeness, legibility (including changes/corrections) and timeliness of source data and entry into the CRF in accordance with GCP, trial protocol, and monitoring plan requirements.

3. Access to the CRF:

- CRF contains identifiable data and must be stored securely with restricted access to authorised trial staff only;
- Access must be limited to authorised users (for example: active trial staff, trial monitors, auditors, and inspectors) for the purposes of source data entry, source data verification, sponsor audits, or regulatory inspections;
- Access to source data is stipulated in the clinical trial research agreement and outlined to the participant via the participant informed consent form.
- If paper copies of electronic CRF are made these should be certified and only made available to authorised users.

Related internal policies, procedures and guidelines
CAHS Policy Manual

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
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National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 110 – Note to File Use	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To guide research team members on when and how to use Note to File in clinical trials conducted at CAHS.

Background

- This procedure provides guidance on how to use Note to File in clinical trials following idenfication of common issues/occurrences.

Key Points

- A Note to File (NTF) is a documented explanation created to clarify or provide context for a deviation, discrepancy, or unusual occurrence in the conduct of a clinical trial.

Procedure

1. Any clinical trial team member may identify an issue or protocol deviation (PD) that is considered to be ‘important’ by the PI
2. All PDs should be documented in a Protocol Deviation Log and those classified as ‘important’ should be captured in a Note to File.
3. The NTF:
    - Explains why something occurred that was not in accordance with the protocol, SOPs, or regulations.
    - Describes what was done to correct or address the issue.
    - Is signed and dated by the person responsible for the documentation.
4. The NTF helps to:
    - Maintain transparency in the trial documentation.
    - Provide a rationale for decisions or actions taken.
    - Ensure the regulatory inspectors or monitors can understand the context of an issue.
    - Demonstrate that the integrity of the data and the rights and safety of participants were preserved.
5. Use NTF sparingly and only when necessary.
6. What to include:
    - Clinical trial title
    - Protocol number
    - Site number/name
    - Principal Investigator
    - Date of NTF
    - Participant number/ID if applicable
    - Description of issue
    - Reason for issue
    - Impact assessment
    - Corrective and preventative action (CAPA)
    - Signed and dated by who prepared the NTF

Related internal policies, procedures and guidelines
CAHS Policy Manual

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 111 – Participant Informed Consent Process	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To describe procedures and documentation management relevant to the initial and ongoing informed consent process for clinical trials at CAHS, including consenting via telehealth.

The objective is to seek and retain voluntary informed consent through ongoing communication and information exchange between a patient/participant and a clinician about the best interests of each participant. The provision of sufficient information to make an informed decision is understood as "informed consent" and this term will be applied in this context in this SOP.

Background

The participant Informed consent process involves information exchange that results in a potential trial participant (or their legally acceptable representative) confirming their willingness to participate, and to continue to participate, in a trial.

Key Points

- A person's decision to take part in a trial must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation, including the risks and potential benefits of (and alternatives to) taking part.
- In obtaining and documenting Informed Consent, all persons involved in the research must comply with the National Statement Chapter 2.2, the National Clinical Trials Governance Framework (including the Roles and Functions of Identified Positions) and applicable regulatory requirements, and adhere to ICH GCP R2 and to the ethical principles that have their origin in the Declaration of Helsinki.

Procedure

1. Participant informed consent process responsibilities:

- The PI is responsible for ensuring that consent has been obtained the correct manner, including at satellite sites.
- PI may delegate this responsibility to suitably qualified Associate Investigator (AI).
- The PI remains responsible for any delegated activity.
- The Investigator must ensure that they have the relevant Research Governance approval, inclusive of approval by an appropriate HREC, for all written information and any other media used to provide information to potential participants, before these forms, information or other materials may be used to obtain consent from any participant.
- If changes are made to approved Participant Information resources the Investigator must have the relevant HREC's written approval (and if needed the written authorisation from the local RGO) before these may be used to obtain consent or continued consent (re-consent) from any participant.
- For clinical trials, consent is documented using a written, signed and dated Participant Information and Consent Form (PICF).
- Consent must be obtained before the first study-specific procedure or intervention is undertaken.

2. Participant informed consent process

2.1 Providing Information

- If a participant expresses interest in participating in a clinical trial, the PI or delegate must provide the correct version of the HREC approved Participant Information and any other approved media. This can be provided in person, by telehealth or by telephone and email or weblink.
- Potential participants, or their legally acceptable representative, should be given adequate time to read any information or to watch any approved media and to discuss with any family and friends and/or their family doctor, prior to agreeing to participate.

- delegated personnel such as Study Coordinators/Research Nurses or other appropriately qualified person may initiate the process of recruitment, and provide guidance around the written information and media
- all medical questions must only be answered only by Medically qualified persons working within their scope of practice and appropriate to oversee the use of an unregistered medicine.
- The PI or delegate must assess the potential participant's understanding of what they are agreeing to, that they are aware of the purpose of the study, what will be involved and any risks that may exist.
- The participants must demonstrate that they fully understand the implications of decisions that may be made within the course of the trial.

2.2 Informed consent signature process

- After all questions are satisfactorily answered, potential participants who wish to participate in the trial will provide a record of their agreement either through physically signing a paper copy of the consent form or electronically signing a consent form using an approved format that accurately documents the time, date and authenticity of their signature.
- The PI/delegate will countersign and date that the consent process has occurred. Ideally this will be done contemporaneously; however, under special circumstances related to the nature of the study the HREC may approve this signature to occur at a later time with appropriate documentation.
- Witnesses are not a requirement in Australia unless they are providing a signature on behalf of a person who cannot sign themselves or are attesting to a translation of the Participant Information provided. If a witness is required, the witness should sign and personally date the witness section of the consent forms.
- Once the PICF is signed and dated by both participant and the Investigator, the original PICF is kept in the ISF
- A copy of the PICF must be placed in the participant's health and medical record to indicate that they are participating in research as part of their medical care.
- the participant must be provided a copy of the signed consent form and all other written information and media provided to the participant that were used as part of the consent process.
- If Informed Consent is obtained by telephone, this must be recorded on the Informed Consent form and in the participant's health and medical record, and/or Source Document, stating (as an example):
  "The protocol was discussed with [participant's name] via telephone on [DD/MMM/YYYY]."
- The Informed consent process that was followed must be documented in the participant's site file
- Participants may withdraw their consent at any time without giving a reason.

3. Process when new information arises

- Changes/amendments can be made to the Protocol after the trial has started.
- The PI or delegate must contact the HREC to obtain ethical approval for these changes
- The PI must ensure that all currently enrolled participants are re-contacted in a timely manner with the relevant new information as approved by a HREC.
- Where there is an amendment to the PICF, this should be signed by the participant as confirmation of their willingness to continue in the trial (re-consent). This must be recorded and kept in the medical records and the ISF, and a copy must be provided to the participant.
- If approved by the HREC, continued consent may be obtained verbally and recorded in the participant's medical records and Source Documents.

4. Participants who are unable to provide consent

- Children/minors, patients/participants with severe dementia:
  - consent must be provided by legally acceptable representative (ie: parent) or guardian
- Person giving consent unable to read, physically unable to sign or mark the document, or where a translator is being used for non-English speaking participants:
  - consent may be given orally in the presence of an impartial witness (i.e. someone not involved in the conduct of the trial)
  - witness signs and personally dates the consent form to attest that the information in the PICF was read and explained to the participant or legal representative and that consent was freely given.

  - if translation is required, a professional interpreter should be accessed to facilitate the process.
- The Investigator must ensure that the National Statement, Chapter 2.2 and ICH GCP E6 (R2) 4.8.15 are complied with, and the following is taken into consideration:
  - the Declaration of Helsinki states that research involving participants who are physically or mentally incapable of giving consent, for example, unconscious patients/participants, may be done only if the physical or mental condition that prevents giving Informed Consent is a necessary characteristic of the research group
  - in these cases, the trial must be relevant to the physical or mental condition of the participant that prevents them from being able to consent to participate in the study.

5. Waiver of consent

- For some trials consent is not possible due to age of records, a characteristic of the cohort or for some other reason.
- In these cases, PI may request a HREC to consider waiving the requirement to seek consent.
- HREC must review and approve the waiver when using personal information in medical research or personal health information (2.3.9 National Statement).
- This only applies to Low Risk Research projects. For example, may include some types of clinical trials in which the only foreseeable risk is no greater than discomfort (2.3.10 National Statement).

6. Electronic consent - Teletrials

- E-consent is preferred for teletrials as consent signatures may be obtained at both primary and satellite sites contemporaneously.
- Before Informed Consent is obtained by telehealth consultation, all persons who are not known to each other must produce identification to the other person to ensure verification of each person's identity and to confirm the identity of the participant who is giving valid consent.
- A description of how study procedures, visits, assessments, collection of data and medical consultations will be undertaken (as they may be conducted in person or via telehealth or a combination of both) must be clearly detailed in the HREC application and the PICF and clearly described to the participant during the consent process.
- All measures must be taken to ensure privacy and confidentiality of the participant's identity.
- If Informed Consent is obtained by telephone, this must be recorded on the Informed Consent Form and in the participant's health and medical record, and/or Source Document. The Investigator must then sign the Consent Form on the date they received the Consent Form, NOT the date they obtained consent from the participant.

Related internal policies, procedures and guidelines
Child and Family Centred Care (CAHS Policy Manual)
Clinical Documentation (CAHS Policy Manual)
Consent to Treatment (CAHS Policy Manual)

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 112 – Adult Participants in Research	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Please refer to CAHS Research Ethics and Governance SOP 211 – Adult Research Participants.

PROCEDURE 113 – Handling and Shipping of Biological Substances	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To document procedures for the safe handling, processing, storage and transport of biospecimens category B collected from research participants (such as blood, urine, tissue, sputum, faeces).

Background

- This SOP has been developed to assist research staff to comply with GCP and regulations that guide the safe handling of biospecimens including:
    - The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines
    - National Pathology Accreditation Advisory Council (NPAAC) Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition 2013)
    - International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) and Packing Instructions 602, 650 and 904
    - Australian Civil Aviation Amendment Regulations 2003 (Part 92).
- When references to biospecimens/biological samples/substances are made, category B is implied.

Key Points

- Procedures for the safe handling, processing, storage and transport of biospecimens must be followed to ensure:
    - integrity of the specimens
    - safety of all staff involved in these activities; and
    - compliance with the study protocol, associated procedures, ICH-GCP and local/national requirements.

- The Principal Investigator is responsible for ensuring that any deviation from this SOP that results in a potential risk to the integrity of biospecimens or the safety of staff is investigated.

Procedure

1. Delegation of responsibility

- The PI must delegate responsibility only to trained and qualified research team members.
- Delegation of staff should be documented on the Delegation log and signed on/off by the PI.
- The PI remains responsible for any delegated activity.
- All research team members must operate within their scope of practice.

2. Training

Research team members must complete the following training to be delegated biospecimen processing and shipping activities. Training must be completed before conducting any related activities.

2.1 Training on Study Protocol and study specific Laboratory Manual, and in accordance with individual department training methods.

- Training should be documented on the study Training log and certificates of training must be filed in Study Master File

2.2 Training on Biological Safety.

- Biological Safety – Online self enrolment via MyLearning
- Phlebotomy training

2.3 Training on use of the Clinic D space, and any other space used for biospecimen handling activities.

- For Clinic D Research, this is done by completing the Clinic D Induction training with the CNM Research.
- For all other CAHS/The Kids Research Institute Laboratory space, the research team should consult the relevant laboratory manager to establish the laboratory training requirements.

2.4 Training on preparing biospecimens for shipment by air.

- by completing the IATA/CASA approved Certified Dangerous Goods Packaging Course.
- Staff must be re-certified every two years.
- If trial staff do not hold current IATA/CASA certification and it is not practical for them to do so, arrangements for biospecimen/dry ice shipments must be made with certified staff.

2.5. Pathwest research reception compliance

- abide by Pathwest requirements/procedures for delivery and transport of specimens when applicable to trial

3. Documentation

- All documentation (e.g. receipts, shipping records, order forms, proformas) related to the collection, handling and transport/shipment of biospecimens must be maintained and filed in the respective Investigator Site File.
- In order to ensure that the integrity of biospecimens has been maintained, there should be evidence of the chain of custody from their point of collection through processing, storage, transport, through to disposal, with evidence of appropriate storage and transit conditions.
- If requested by the Sponsor, maintain a biospecimen tracking log and file in the Investigator Site File.

4. Specimen handling and processing

- Specimens must be handled and processed according to Sponsor requirements including the study Protocol and study specific Laboratory Manual and local requirements.
- Ensure correct sample collection tubes are used as per study protocol/Laboratory Manual and that these are in date.
- Laboratory kits provided by Sponsors must be stored in an appropriate environment and reviewed periodically to ensure they are sufficient for the purpose of the study and they remain in date.

5. Equipment

- Ensure that the equipment used for processing and storage of biospecimens entail evidence that they are appropriately calibrated and maintained (eg: centrifuge/fridge/freezer).
- Research team members must know how to access the maintenance/calibration records and provide access to Monitors/Auditors/Inspectors upon request.

6. Specimen transport

- The courier service for shipment of biospecimens will be organised by the Sponsor and details will be provided to the study team. This will include but is not limited to shipping instructions, documentation, and packaging material.
- The Sponsor should be notified if there is a delay in biospecimen collection by the allocated courier service.

Related internal policies, procedures and guidelines
CAHS Policy Manual Specimen Collection and Transport (PCH Operational Manual)

Related external policies, procedures and guidelines
• Code of Conduct (Code-of-Conduct-Policy.pdf) • Civil aviation amendment regulations 2003 (part 92) Available from: https://www.casa.gov.au/search-centre/rules/part-92-casr-consignment-and-carriage-dangerous-goods-air • GUIDELINE FOR GOOD CLINICAL PRACTICE • Handling and Shipping of Biological Substances, Category B and/or Dangerous Good for Clinical Trials Standard Operating Procedure Office of Health and Medical Research Queensland Health. Available from: https://www.health.qld.gov.au/__data/assets/pdf_file/0020/151067/gcp_sop12.pdf • IATA - Training • National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care • National Pathology Accreditation Advisory Council (NPAAC) Requirements for the packaging and transport of pathology specimens and associated materials (Fourth Edition 2013 and all updates). • Available from: https://www.health.gov.au/internet/main/publishing.nsf/content/health-npaac-publication.htm • National Statement on Ethical Conduct in Human Research | NHMRC Chapter 3.2 • National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia

PROCEDURE 114 – Management of Investigational Product	
Scope (Staff):	All researcher team members involved in clinical trials using Investigational Medicinal Products.
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To outline the principles, responsibilities, and procedures research team members must follow when managing Investigational Medicinal Products (IMP) at CAHS in settings outside the direct control of pharmacy services.

Background

- This document has been developed to support investigators managing IMP in clinical trials conducted at CAHS. Procedures specific to pharmacy operations are outside the scope of this document.

Key Points

- This SOP is intended to complement existing institutional policies, including the PCH Medication Management Manual and CAHS Policy Manual, by clarifying how IMPs should be managed by investigators outside of pharmacy-controlled environments, and aligning investigator responsibilities with established medication governance frameworks.

Procedure

1. Principles of IMP Management

To help safeguard the rights, safety, and wellbeing of CAHS research participants and produce scientifically valid research, all IMP activities at CAHS should adhere to the following guiding principles:

- **Quality** through the appropriate use of clinical trial pharmacists and other relevant experts qualified by education, training, and experience for the design and conduct of protocol specific IMP and clinical activities.
- **Documentation** that is consistent with ALCOA+ principles (attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available).
- **Proportionality** of procedures tailored to the risk and complexity of the IMP and trial design.
- **Compliance** with the protocol, essential documents, sponsor requirements, state and institutional policy, and applicable legislation, standards, and regulatory requirements.
- **Auditability** of records sufficient to demonstrate the principle of compliance and IMP management activities, and pass audits and inspections from sponsors and regulators, such as the TGA GCP Inspection Program and NSQHS accreditation including the National Clinical Trials Governance Framework.

2. Responsibilities for IMP Management

- Division of responsibilities between investigator and sponsor with regards to IMP are outlined in International Conference on Harmonization Good Clinical Practice (ICH GCP) E6(R3) sections 2.10 and 3.15 respectively. Under GCP guidelines the investigator retains overall responsibility for IMP management at site but may delegate IMP management tasks to suitably qualified staff within their scope of practice.
- As Perth Children's Hospital (PCH) is a tertiary hospital with expert research and clinical staff, IMP management tasks must be delegated to appropriate staff within their usual scope of practice.
- The PCH Pharmacy Department has a dedicated clinical trial satellite pharmacy located in clinic D. Investigators must consult pharmacy for all trials that involves IMP management, and pharmacy site authorisation will be required for the project in the Research Governance Service (RGS) system. The pharmacy can also assist with expert advice on protocol development as it relates to IMP management

and IMP sourcing. Investigators are advised to consult pharmacy early in the study planning phase, preferably before submitting grant applications, to ensure accurate scoping of IMP, services, and associated costs. Pharmacy is partially self-funded and IMP costs may also be significant, particularly for double-blind clinical trials. The pharmacy can be contacted at: PCH.PharmacyClinicalTrials@health.wa.gov.au

3. Governance of IMP

- The legal exemption permitting the supply of an unapproved therapeutic good for a clinical trial is not applicable until lodgement of the Clinical Trial Notification (CTN) or approval of the Clinical Trial Approval (CTA) by the Therapeutic Goods Administration (TGA). IMP must not be shipped to PCH or another CAHS site prior to this.

- IMP cannot be supplied or administered to a patient prior to approval of the project by the Research Governance Office (RGO).

- Investigators must ensure that the supply and administration of IMP occurs in accordance with the Human Research Ethics Committee (HREC) approved consent process.

4. Handling and Administration of IMP

- In accordance with the CAHS Procurement, Distribution, Storage and Disposal of Medication Policy, IMP which is not registered in the Australian Register of Therapeutic Goods (ARTG) must be handled as for a similar substance that is currently included in the Poisons Standard, or else as for a Schedule 4 substance.

- Storage of IMP must comply with the CAHS Access to Medication Storage Areas Policy. For PCH trials IMP is typically stored in clinical trial pharmacy unless alternative suitable arrangements have been made with pharmacy such as ward storage.

- All handling and administration of IMP must comply with CAHS policies and procedures in the PCH Medication Management Manual and CAHS Policy Manual including the CAHS Medication Safety Policy, CAHS Medication Preparation, Checking and Administration Procedure, and CAHS Medication Administration Policy.

- Appropriately delegated staff acting as the patients delegate, such as study coordinators, may collect Schedule 4 IMP from pharmacy on behalf of patients in accordance with the PCH Patient's Own Medication: Use, Storage and Transfer Guideline. These staff may also receive returned Schedule 4 IMP from patients and assess accountability for recording in the Case Report Form (CRF) or other source documentation in accordance with protocol and sponsor requirements. Returned IMP should be returned to pharmacy as soon as practicable for secure storage.

- Restricted Schedule 4 and Schedule 8 IMP must be handled in accordance with the CAHS Schedule 8 and Restricted Schedule 4 Medication Policy and WA Health Monitored Medicines Prescribing Code.

- Staff must be aware of guidelines and policies that affect specific IMP management requirements such as the CAHS High Risk Medicines Policy, CAHS Antineoplastic (Cytotoxic) Agents Safe Handling and Administration Guideline, and CAHS In Vivo Gene Therapy Policy.

- Where clinical trial participants/carers/guardians are expected to administer IMP, they must be trained to administer the IMP as per trial protocol by delegated clinical trial staff. This training must be documented in the source documentation.

- Patient facing resources illustrating/documenting administration instructions must be approved by HREC and the RGO prior to distribution and must be provided to the carer/guardian and/or participant if relevant to the protocol.

- Storage and temperature excursions, transport, and chain of custody must be considered with pharmacy input for the specific requirements of each trial.

- Where Direct to Patient (DTP) shipment of IMP is included in the protocol, procedures must align with applicable institutional oversight.

5. Deviations and Incidents

- Clinical trials that may require emergency unblinding of participants should have a documented procedure to approve, manage, and disclose the blinded status of participants in a clinically appropriate timeframe in accordance with the protocol.

- Investigators must comply with all reporting obligations relating to IMP safety and trial conduct including Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Events (SUSARs), Significant Safety Issues (SSI), Annual Safety Reports, Urgent Safety Measures, protocol deviations, and any other incidents impacting IMP safety or management without delay within the appropriate timeframes to any applicable parties.

6. Essential Records and Source Documents

- Sites must maintain accurate, accessible records to support IMP management throughout the clinical trial. Essential records in the Investigator Site File (ISF) and/or Trial Master File (TMF) should align with the principles and requirements in ICH GCP E6(R3) Section 2.12 and Appendix C.

- ICH GCP E6(R3) Section 2.10.4 outlines the specific IMP accountability source records required. These records are generally managed by pharmacy in the site pharmacy file.

- Investigators must ensure all IMP is reconciled and accounted for prior to trial close-out, with pharmacy oversight as applicable.

- If applicable, the site pharmacy file, containing essential IMP management records, should ideally be archived with the ISF. If maintained separately there should be a documented cross-reference in the ISF.

Related internal policies, procedures and guidelines
Access to Medication Storage Areas (PCH Medication Management Manual)
Antineoplastic (Cytotoxic) Agents Safe Handling and Administration (PCH Medication Management Manual)
High Risk Medicines (CAHS Policy Manual)
In Vivo Gene Therapy (PCH Medication Management Manual)
Medication Administration (PCH Medication Management Manual)
Medication Preparation, Checking and Administration (PCH Medication Management Manual)
Medication Safety (CAHS Policy Manual)
Patients Own Medication Use Storage And Transfer (PCH Medication Management Manual)
PCH Medication Management Manual and CAHS Policy Manual
Procurement, Distribution Storage and Disposal of Medications (CAHS Policy Manual)
Schedule 8 And Restricted Schedule 4 Medication (PCH Medication Management Manual)

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
GUIDELINE FOR GOOD CLINICAL PRACTICE
Medicines and Poisons Act 2014 (Western Australian Legislation)
Medicine and Poisons Regulations 2016 (Western Australian Legislation)

Medicines Handling Policy (WA Health)
Monitored Medicines Prescribing Code (WA Health)
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC
Poisons Standard
WA Health Risk based requirements for medicines handling (WA Health)

PROCEDURE 115 – Safety Data Monitoring and Reporting Requirements	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Please refer to CAHS Research Ethics and Governance SOP 306- Data and Safety Monitoring Requirements

PROCEDURE 116 – Site Close-Out	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To describe the processes related to close-out of a clinical trial at CAHS to ensure all required actions are completed.

Background

Site close-out is the process of ensuring that:

- all trial-related activities have been appropriately reconciled, recorded, and reported in accordance with GCP, trial protocol, and applicable regulatory requirements;
- all relevant parties (for example: review bodies, oversight committees) have been notified;
- all essential documents are within the SMF/ISF and are ready for archiving.

Key Points

- Site close-out is integral to the quality assurance of a clinical trial and GCP compliance of the study according to sponsor requirements.

Procedure

1.Reasons for Site Close-Out

- Trial end point as defined in trial protocol is reached;
- Early closure due to safety issues;
- Early closure due to new information which makes further participant recruitment unnecessary;
- Early closure for other reasons (for example: recruitment targets unmet or Sponsor decision).

2.Site close-out due to early termination or suspension of trial

- The PI must promptly:
  - inform the relevant parties of the Sponsor, the TGA, HREC, RGO, and the AI by providing a detailed written explanation;
  - inform the trial participants and their primary care physician (if consented by participant) and if applicable, of the IP and dose they were being administered;
  - assure appropriate therapy and follow-up for all participants' continued care.

3.Final Site Close-Out

- final close-out of a trial must only occur when the sponsor has reviewed SMF/ISF and confirmed that all necessary documents are in the appropriate files;
- the Sponsor must notify the PI that Site Close-Out can occur;
- the PI must:
  - ensure all close-out activities are in accordance with Sponsor requirements and the Delegation Log;
  - provide a summary report of the trial's outcome to the HREC and RGO.
  - file documentation and correspondence in the SMF;
  - arrange for archiving of SMF/ISF;
  - ensure final disposition of any IP/other trial related materials. This may entail return to Sponsor or destruction of any remaining materials.

4.Close-Out Monitoring Visit

- occurs once the trial recruitment target has been reached or adequate positive/negative data results have been obtained;
- consists of multiple activities to confirm that the site's trial obligations have been met and that any post-trial obligations are understood and followed through.

5. Site close-out activities

- The SMF/ISF is complete and up to date and all necessary original documents are located in the appropriate files prior to archiving;
- All end of trial notifications have been completed and lodged;
- All data has been cleaned, all data queries corrected and resolved, all trial data signed-off by PI, and the trial database can be locked for final analysis;
- All safety events have been reconciled as per trial protocol;
- All biological samples have been received by the Central Laboratory, if applicable, and none remain at the site;
- All IP has been reconciled, if applicable;
- All site payments are fulfilled.

Related internal policies, procedures and guidelines
CAHS Policy Manual

Related external policies, procedures and guidelines
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC

PROCEDURE 117 – Archiving	
Scope (Staff):	Approved Research Staff Member
Scope (Area):	CAHS and external institutes utilising CAHS patients, patient information, and/or CAHS facilities.

Aim

To describe the processes related to archiving of all trial related documentation at CAHS.

Background

All essential documents relating to a clinical trial ISF at CAHS must be archived in accordance with:

- GCP
- The Therapeutic Goods Administration (TGA)
- The Health Services Act 2016
- The Australian Code for the Responsible Conduct of Research.

Key Points

Processes related to archiving of all trial related documentation must be followed to ensure:

- the documents and data contained within documents are preserved and remain legible for the duration of the retention period;
- participant information is protected and secure.

Procedure

1. Access to archived records

- Archived records must be secure.
- Access to archives should be restricted to authorised personnel.
- Changes to ownership and location of archived materials should be tracked.
- The PI is responsible for ensuring that the sponsor is aware of storage arrangements for the Essential Documents.
- If storage arrangements can no longer be maintained at any stage, the sponsor must be notified in writing so that alternative storage arrangements can be agreed upon.

2. Period of archiving

- Where the specified archiving period is conflicting, documentation is to be archived for whichever period is the longest.
- Archiving can be changed to longer periods or indefinitely for legal reasons.
- Jurisdictional and Institutional requirements for clinical trial records where the participants are children/adolescents must be adhered to.
- Jurisdictional and Institutional requirements for clinical trial records where the participants are adults must be adhered to.

3. Archiving paper records

- Archived material must be enduring (for example: fax thermal paper copied to standard paper to prevent fading) and protected from damage or destruction in a secure, environmentally controlled location (for example: with protection from fire, water damage, pest infestation, and theft).
- Original documents or certified copies are to be retained.
- Evident identification (for example: a document retention sticker) that the health and medical record forms part of a clinical trial is to be placed on all volumes of the participant's health and medical record in an

appropriate position, without obscuring any information, as per health information management services policy.

- For commercially sponsored clinical trials, archiving arrangements are negotiated with the study Sponsor (in conjunction with health information management services) prior to study commencement. These details are to be noted in the study specific CTRA.
- Identifiable information (for example: Participant Identification Log and signed Participant Information Sheet and Consent Forms) must be archived separately from the main study documents. This information is to remain with the PI/at CAHS, in case identification of participants is required later. A reference to the type and location of these documents is to be filed with the SMF.
- If the study documentation is to be filed by the Sponsor, the identifiable information (for example: Participant Identification Log and signed Participant Information Sheet and Consent Forms) site records must not be filed with the Sponsor study records.

4. Archiving electronic records

- Electronic documents must be suitably protected from unauthorised changes.
- Electronic Medical Records may be archived indefinitely.

5. Transfer of paper records into an electronic format

- If original records are transferred to other media for the purpose of archiving, the system of transfer should be validated to ensure that information will not be lost or altered.
- Filing systems should allow review (for example: by an auditor) in an efficient manner, analogous to that possible with paper study files.
- Paper records must be scanned in a logical order (for example: in accordance with the Study Master File index) to ensure that trial reconstruction is possible.
- There should be a quality control process to certify that the scanned image has been captured without error and so is a suitable record of the original document.

Related internal policies, procedures and guidelines
Health and Medical Record Management (CAHS Policy Manual)

Related external policies, procedures and guidelines
Australian Code for the Responsible Conduct of Research, 2018
Code of Conduct (Code-of-Conduct-Policy.pdf)
GUIDELINE FOR GOOD CLINICAL PRACTICE
Freedom of Information Act 1982 - Federal Register of Legislation
WALW - Health Services Act 2016 - Home Page
National Clinical Trials Governance Framework | Clinical Trials in Australia | Australian Commission on Safety and Quality in Health Care
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia
National Statement on Ethical Conduct in Human Research | NHMRC
WALW - Public Health Act 2016 - Home Page
State Records Act 2000 - [01-g0-01].pdf
Therapeutic Goods Administration (TGA) | Australian Government Department of Health, Disability and Ageing

This document can be made available in alternative formats on request for a person with a disability.

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