Australian Government
Department of Health, Disability and Ageing

Draft National Standard Operating Procedures for Clinical Trials in Australia (National SOPs)

Contents

SOP 01: Creation, Implementation and Review of Standard Operating Procedures

Purpose

To ensure that Standard Operating Procedures (SOPs) for clinical trials are developed, reviewed, approved, implemented, and maintained in a consistent, transparent, and risk-proportionate manner, supporting ethical conduct, regulatory compliance, and high-quality clinical trial delivery.

To ensure the SOPs are revised in accordance with guidelines/expectations to ensure they remain contemporaneous.

Scope

This SOP applies to all individuals and groups involved in the development, review, approval, implementation, and maintenance of National Standard Operating Procedures for Clinical Trials which will include the Teletrial Principles moving forward.

Whilst the coordination of this suite of resources is within the remit of the Inter-Governmental Policy Reform Group and as such engagement with the Jurisdictional representations, the key groups required in the revisions are:

- Clinical trial personnel
- IGPRG Sub-committees
- Subject matter experts and contributors through ACTA and ARCS (or their equivalent)
- Commonwealth agencies: NHMRC, TGA and OGTR

As such, this SOP applies to:

- Creation of new SOPs
- Revision of existing SOPs
- National consultation and endorsement processes
- Implementation and lifecycle management of SOPs

Principles

The following principles underpin the lifecycle management of SOPs:

- Governance and accountability
    - SOPs must be developed and maintained under defined governance structures, with clear accountability for authorship, review, approval, and version control
- Quality by design and risk-proportionate approach
    - SOP development and review must adopt a quality-by-design approach, ensuring that:
        - SOPs are fit for purpose
        - Requirements are proportionate to trial complexity and risk

        - Unnecessary administrative burden is minimised
- Transparency and stakeholder engagement
    - To ensure applicability, usability and national consistency, SOP development and review must include appropriate consultation with:
        - Jurisdictions
        - Clinical trial sites
        - Subject matter experts
        - Relevant stakeholders
- Consistency and standardisation
    - SOPs must be developed using a standardised format and language to support:
        - Consistent interpretation
        - Ease of implementation
        - Audit and inspection readiness
- Lifecycle management and continuous improvement
    - SOPs must be subject to regular review and continuous improvement to ensure alignment with key documents and regulations:
        - NHMRC National Statement latest version 2025
        - ICH GCP - most recent update to E6(R3) in 2025 and the TGA comments to GCP
        - ISO 14155 – most recent update 2026
        - TGA - Australian Clinical Trial Handbook
        - Any other regulatory, ethical, and operational changes in Australia
- Documentation and traceability
    - All stages of SOP development, review, approval, and implementation must be documented to enable reconstruction of decisions and demonstrate governance.

Procedure

The IGPRG leads national reforms to strengthen and streamline the health and medical research regulatory and operating environment, providing national oversight and coordinating the development and maintenance of SOPs. SOPs development and updates align with the relevant guidance and regulatory document updates.

Together and with consensus of the IGPRG members, the IGPRG will endorse priority areas for:

- New SOP development
- Revision of existing SOPs
- Facilitating coordination across jurisdictions to ensure national consistency
- Acting as the central escalation and decision-making body where:
    - Cross-jurisdictional issues arise
    - Variability in interpretation or implementation is identified

1.1 Initiating the creation of a new SOP or revision of existing SOPs

Any individual involved in clinical trials may identify the need for a new SOP to address an emerging issue or suggest updates to the existing SOPs where there are omissions or areas requiring strengthening.

National SOPs:

Developing or revising the suite of National SOPs, individuals/organisations are advised to escalate the proposed need through established governance channels to the Inter-Governmental Policy Reform Group (IGPRG) as the national coordinating body.

In process, notify the relevant jurisdictional health department (or equivalent), including:

- SOP title and number (if existing)
- Description of the issue or proposed improvement

The need for a new or revised SOP must be assessed and verified prior to initiation. This includes allocation of resources and support for this work, aligned to the National Reforms and avoids unnecessary duplication.

Consultation on the development or revision of SOPs is essential and includes the following steps:

- Circulate draft/revised SOPs to relevant stakeholders for review and comment
- Ensure representation across:
    - Jurisdictions
    - Clinical trial sites
    - Subject matter experts
- Where appropriate, provide updates to IGPRG on:
    - Progress
    - Key issues arising
    - Areas requiring national agreement

This process may be iterative until a final version is ready.

1.2 Approval, Authorisation and Distribution

Following consultation and input from all relevant stakeholders, the final SOP(s) must be reviewed and endorsed by IGPRG.

A communication plan endorsed by IGPRG must be implemented which includes:

- Sector wide communication through jurisdictions and stakeholders
- Training and public awareness as required

Evaluation of adoption or uptake of the SOPs nationally should also be considered.

1.3 Review and Continuous Improvement

These National SOPs must undergo a scheduled review at least every three years as agreed by the IGPRG. Earlier review may be triggered by:

- regulatory or legislative changes,
- updates to the National Statement, GCP or ISO

- feedback from implementation or audits.

The current SOPs must be available in word and PDF format on the Australian Clinical Trials website, and superseded version archived and may be retrieved in accordance with Commonwealth guidelines.

SOP 02: Investigator Responsibilities

Purpose

To define the responsibilities of Investigators in the conduct of clinical trials to ensure participant safety, data integrity, and compliance with ethical, regulatory, and governance requirements.

This SOP applies to both commercially sponsored trials and investigator-initiated or collaborative group trials and aligns with ICH GCP E6(R3) and TGA Comments, the 2025 National Statement, the National Clinical Trials Governance Framework and in accordance with applicable regulatory requirements.

Scope

This Standard Operating Procedure (SOP) applies to all personnel undertaking Investigator roles, including Coordinating Principal Investigators (CPI), Principal Investigators (PI), Sub-Investigators (SI), and Associate Investigators.

This applies to:

- Commercially sponsored trials
- Investigator-initiated trials (IITs)
- Collaborative group trials
- Trials conducted across Primary and Satellite Sites
- Trials incorporating decentralised, teletrials, pragmatic, or real-world elements

All Investigators must operate within their scope of practice based on education, training, and experience.

Principles

Paramount to the conduct and delivery of trials are the following key principles:

- Protection of participants and integrity of research
    - Investigators are responsible for protecting the rights, safety, wellbeing, dignity, and confidentiality of participants. The reliability of trial outcomes depends on the quality of trial design, conduct, and oversight.
- Risk-proportionate and quality-by-design approach
    - Clinical trials must be conducted using a risk-proportionate approach. Investigators must:
        - identify critical-to-quality (CtQ) factors, including critical data and processes

        - apply oversight strategies proportionate to trial complexity, design, and operational model
        - ensure quality is built into trial design and conduct.
- Governance and accountability
    - The Investigator is responsible for the conduct of the trial and oversight of all delegated activities.
    - Delegation of tasks does not remove accountability.
    - Where the CPI acts as Sponsor-Investigator (e.g. IITs), they assume both Sponsor and Investigator responsibilities.
- Equity, inclusion and participant access
    - Investigators must promote equitable access for participation and must ensure that any exclusion is appropriately justified.
    - Recruitment strategies should reflect population diversity and consider participants who may experience increased risk, with appropriate safeguards in place.
    - Achieving equitable access may require additional resources and should be appropriately considered.
- Data integrity, privacy and digital systems
    - Clinical trial data must be accurate, complete, and reliable.
    - Investigators must ensure data integrity, privacy and confidentiality are maintained.

For trials conducted under decentralised or teletrial models:

- Responsibilities between Primary and Satellite Sites must be clearly defined
- Supervision Plans, Delegation Logs, and communication pathways must be established
- Escalation pathways for clinical and trial-related issues must be documented
- Participant care must be equivalent regardless of location

Procedure

2.1 Investigator Responsibilities (CPI/PI/SI)

Coordinating Principal Investigator/Principal Investigator

- Responsible for the conduct of a trial at a site in accordance with the protocol, ICH GCP and ISO 14155 (medical devices) and applicable regulations.
- Responsible for oversight of all activities delegated to staff, contractors and third-party providers, and satellite sites as described in the Supervision Plan/s.
- Overall responsibility for the safe conduct of the trial at site and any satellite site.
- Participating in training and ensuring staff are appropriately qualified and trained.
- Overall responsibility for safety event reporting to Sponsor and organisation (if an accredited health service organisation, in accordance with National Clinical Trials Governance Framework requirements).
- Overall responsibility to ensure all administrative requirements for the trial conduct are completed in accordance with HREC and RGO requirements - e.g. Annual Progress Reporting.

Sub-Investigator

- Step in for PI as required (cover leave, sabbatical).
- Responsible for the safe conduct of the trial at their site.
- Leadership support to site teams, with delegated role and responsibility for clinical trial activities.
- Support the PI to ensure all administrative requirements for trial conduct are completed in accordance with applicable guidelines.

2.2 Responsibilities Before the Research Project/Trial Commences

The Principal Investigator must ensure:

- Conflicts of interest are declared
- Adequate resources, staffing, and infrastructure are available
- Feasibility of recruitment, including diverse and representative populations
- Understanding of the investigational product and protocol
- Ethics and governance approvals are in place -
    - Including organisational specific governance requirements such as Infection Prevention, Digital Health (cybersecurity/data governance), WHS, Biomedical Engineering and any credentialling requirements (where applicable such as new devices or introduction of new ways of operating)
- Trial registration has occurred on a publicly accessible WHO-compliant registry
- Systems (including digital and remote technologies) are fit-for-purpose and secure

For trials conducted under decentralised or teletrial models:

- Satellite Sites are appropriately assessed
- Supervision Plans and Delegation Logs are developed
- Roles, responsibilities, and escalation pathways are clearly defined

2.3 Responsibilities During the Course of the Research Project/Trial

The Principal Investigator must ensure:

- Staff are trained, competent and are delegated tasks in accordance with their scope of practice
- Protocol adherence is maintained
- Safety events are identified, classified, managed, and reported appropriately
- Data is entered accurately and in a timely manner
- Digital systems support traceability, auditability, and security
- Investigational product accountability is maintained

For trials conducted under decentralised or teletrial models:

- Communication pathways between sites are maintained
- Safety escalation processes operate effectively across all sites
- Oversight extends to Satellite Sites and third-party providers
- Oversight of delegated activities must be proportionate to risk. Trials must be maintained in a state of continuous inspection readiness.

2.4 Responsibilities at Completion of the Research Project/Trial

The Principal Investigator must ensure:

- Trial close-out activities are completed
- Ongoing participant care is arranged where required
- Trial documentation is complete and archived appropriately
- Participants are informed of trial outcomes, including provision of lay summaries
- Data is retained in accordance with regulatory and institutional requirements

2.5 Additional Responsibilities by Trial Type

2.5.1 Commercially Sponsored Trials

In industry/commercially sponsored trials, the sponsor/CRO retains overall responsibility for the trial. Site investigators must:

- Comply with sponsor requirements and contractual obligations
- Review and confirm accuracy of CTN/CTA submissions where applicable
- Ensure organisational governance processes are not compromised
- Ensure timely reporting of safety events and deviations to the Sponsor
- Maintain communication with the Sponsor regarding trial conduct

Noting for international trials conducted in Australia, there has to be a local sponsor, which must be an Australian entity.

2.5.2 Investigator-Initiated and Collaborative Group Trials

In Investigator-initiated and collaborative group trials, the Coordinating Principal Investigator has overall responsibility for trial oversight, however tasks may be delegated to the Coordinating Centre/Project Office.

The CPI responsibilities include:

- Trial oversight and governance
    - Overall responsibility for trial design, conduct, and reporting
    - Implementation of a risk-based quality management approach
- Regulatory and ethics compliance
    - Submission to HREC and regulatory authorities
    - Ongoing reporting, including amendments and progress reports
- Safety oversight
    - Establishment of safety monitoring processes
    - Oversight of safety reporting across all sites
- Monitoring
    - Ensuring the trial is appropriately monitored
    - Implementing risk-based monitoring strategies
- Data management and integrity
    - Ensuring systems are fit-for-purpose (refer to SOP 14)
    - Oversight of data quality and integrity
- Vendor and third-party oversight
    - Selection and oversight of service providers

    - Ensuring delegated activities are appropriately managed
- Trial registration and transparency
    - Registration and maintenance of trial information
- Financial and resource management
    - Ensuring adequate funding and resourcing
- Insurance and indemnity
    - Ensuring appropriate arrangements are in place

Investigators must notify the Sponsor, HREC, and institution of any change in role or departure and ensure continuity of trial oversight.

Related SOPs

- SOP 07: Study Master File
- SOP 13: Site Close-Out and Archiving
- SOP 14: Database Development and Data Management

SOP 03: Site Staff Qualifications, Training Records and Capability

Purpose

To ensure that all clinical trial personnel are appropriately qualified, trained, and supported to perform delegated responsibilities in a manner that protects participant safety, ensures data integrity, and complies with ethical, regulatory, and governance requirements.

This SOP ensures:

- Staff qualifications, training, and experience are appropriate and documented.
- Training is proportionate to roles, responsibilities, and trial risk.
- Workforce capability supports the safe and effective conduct of all clinical trial types, including decentralised and teletrial models.

This SOP aligns with ICH GCP E6(R3), the 2025 National Statement, the National Clinical Trials Governance Framework, and applicable regulatory requirements.

Scope

This SOP applies to all personnel involved in clinical trials, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

All personnel must operate within their scope of practice based on education, training, and experience.

Principles

The following principles underpin a risk-proportionate, quality-by-design approach to workforce capability across the clinical trial lifecycle.

- Qualified and competent workforce
  - Clinical trial activities must be conducted by personnel who are qualified by education, training, and experience to perform their roles.
  - Roles and responsibilities must be clearly defined, and staff must only undertake tasks for which they are appropriately trained and authorised.
- Risk-proportionate training and competency
  - Training requirements must be proportionate to the trial's complexity and design, the level of risk to participant safety and data integrity and the nature of delegated responsibilities.
  - A risk-based approach should be used to determine the level, type, and frequency of training and re-training as required.
- Quality by design and supervision
  - Workforce capability must be established proactively through:
    - appropriate resourcing and workforce planning
    - structured and role-specific training
    - ongoing supervision and oversight.
  - Where staff undertake activities outside their usual scope of practice, additional training and supervision must be provided and documented.
- Cultural safety, inclusion and consumer engagement
  - Trial staff must be trained to support culturally safe, inclusive, and participant-centred research.
  - This includes
    - awareness of consumer engagement principles
    - inclusion of culturally and linguistically diverse populations
    - respectful engagement with First Nations people and communities.
- Documentation and accountability
  - Qualifications, training, and delegation must be documented and maintained throughout the trial lifecycle.
  - The Principal Investigator is responsible for ensuring that all staff are appropriately qualified and trained.
  - Delegation of duties does not remove accountability.

For trials conducted under decentralised or teletrial models:

- Capability of Primary and Satellite Sites must be assessed.
- Training, delegation, and supervision arrangements must be clearly defined.
- Personnel must be competent to perform activities across distributed care settings.

Procedure

3.1 Site Staff Qualifications

The Principal Investigator must ensure:

- All staff are qualified by education, training, and experience to perform delegated duties
- Evidence of qualifications and credentials is current and maintained (e.g. CV, professional registration where applicable)
    - A current CV must be maintained in the Study Master File
    - Evidence of relevant training (e.g. GCP) must be documented
- Staff meet competency expectations aligned with the National Clinical Trials Governance Framework

For trials/studies involving third party providers and vendors, the Sponsor or CPI must ensure they are:

- appropriately qualified and experienced
- assessed prior to engagement
- subject to oversight proportionate to the risk and complexity of their role
- included in the risk-based monitoring plan and audit program.

For trials conducted under decentralised or teletrial models:

- Qualification and capability of Satellite Site staff must be verified prior to delegation of responsibilities

3.2 Training Requirements and Records

The Principal Investigator must ensure that all staff:

- Are trained in the protocol, investigational product (if applicable), and trial procedures prior to undertaking trial activities
- Receive training relevant to their roles, including safety reporting, data recording, and protocol compliance
- Complete training on applicable SOPs and trial systems

The trial specific training must also:

- Be documented (e.g. training logs)
- Include details of content, provider, and date
- Be maintained and kept current throughout the trial
- Always be available for review

For decentralised and teletrial models, it is essential that staff at primary and satellite sites understand their roles and responsibilities and have training specific to that function. Training and competency must be documented in the Delegation Logs and Supervision Plans.

3.3 Capability and Feasibility

To support the safe end affective conduct of the trial, the Principal Investigator must ensure:

- Adequate staffing, time, and facilities are available for the duration of the trial
- Recruitment capability is sufficient and appropriate to meet study requirements
- Workforce capability supports safe and effective trial delivery

In assessing feasibility of the trial, the Principal Investigator must consider the following:

- Availability and suitability of participant populations
- Avoidance of over-research in specific populations
- Inclusion of diverse populations reflective of the community and their organisation
- Alignment with organisational priorities and clinical services

For trials conducted under decentralised or teletrial models:

- Capability of each Satellite Site must be assessed
- Delegation of activities must align with site capability
- A staged approach to capability development may be used where appropriate

3.4 Delegation and Supervision

The Principal Investigator is responsible for the trial team and must:

- Maintain a Delegation Log documenting assigned responsibilities
- Ensure delegation is completed prior to staff undertaking trial-related activities
- Ensure delegated staff are appropriately trained and competent to perform their assigned responsibilities

For trials conducted under decentralised or teletrial models, a Supervision Plan must be developed and include:

- Supervision arrangements across Primary and Satellite Site
- Communication and escalation pathways
- Training and competency assessment processes
- Coverage for planned absences

The Satellite Sites must maintain appropriate delegation documentation, with oversight by the Primary Site.

3.5 GCP and Other Regulatory Training

It is essential that clinical trial Investigators and clinical trial staff with significant delegated trial related responsibilities are trained in the principles of GCP and ISO 14155 (if applicable) and the National Statement as a minimum requirement.

Staff with significant trial responsibilities/core trial staff must:

- Undertake GCP training appropriate to their role
- Maintain awareness of applicable ethical and regulatory requirements, including the National Statement
- Undertake trial specific training by the Sponsor which should include ISO14155 for device trials
- Ongoing refresher training at appropriate levels

Ancillary staff involved in trials with novel/non-routine interventions must have:

- Targeted training relevant to their role
- Awareness of key requirements (e.g. safety reporting, documentation, escalation)

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 07: Study Master File
- SOP 13: Site Close-Out and Archiving
- SOP 14: Database Development and Data Management

Appendices

- Training Record Template
- Delegation Log Template
- Supervision Plan Template

SOP 04: Protocol, Investigator Brochure, Clinical Investigation Plan, and Product information

Purpose

To ensure that clinical trial protocols, Investigator Brochures (IB), Clinical Investigation Plans (CIP), and product information are scientifically robust, ethically sound, and developed in accordance with applicable regulatory, ethical, and governance requirements.

This SOP supports the design of clinical trials that are feasible, participant-centred, and capable of generating reliable and meaningful data.

This SOP aligns with ICH GCP E6(R3), ISO 14155, the 2025 National Statement, and applicable regulatory requirements.

Scope

This SOP applies to all staff involved in the development, review, or amendment of trial protocols, IBs, CIPs, and related product documentation.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- intervention types (medicines, devices, behavioural, digital health)
- trial models, including decentralised and teletrial models

Principles

The following principles underpin a risk-proportionate, quality-by-design approach to protocol and trial document development:

- Scientific validity and research merit

    - Clinical trials must be based on sound scientific principles and designed to generate reliable, valid, and clinically meaningful data.
    - Trial design must also be feasible and fit-for-purpose, minimise bias and avoid research waste.
- Quality by design and critical-to-quality factors
    - Quality must be built into trial design with the identification and management of critical-to-quality (CtQ) factors.
    - Protocols should focus on data and processes critical to participant safety and decision making, avoid unnecessary complexity and data collection burden and include risk management strategies.
- Participant safety, rights and wellbeing
    - The rights, safety and wellbeing of participants are paramount.
    - Protocols must
        - minimise risks and burdens,
        - clearly describe benefits and risks in an open and transparent manner
        - include provisions for ongoing safety monitoring and post-trial care.
- Inclusion, equity and participant-centred design
    - Trials should be designed to support inclusion of diverse populations reflective of those who will benefit from the intervention.
    - Protocols should consider culturally appropriate approaches and inclusive practice.
    - Protocols and trials design should also reduce participation burden where possible and consider appropriateness of technology or tools reflecting on needs of the target population.
- Ethical and regulatory compliance
    - Protocols and supporting documents must comply with:
        - Ethical principles (including the National Statement and Declaration of Helsinki).
        - Applicable regulatory requirements (APP and Privacy legislations).
        - Institutional governance requirements (including Digital Health – Cybersecurity, Data Governance, Infection Prevention, use of clinical resources).

For trials conducted under decentralised or teletrial models:

- Trial processes must be clearly defined across Primary and Satellite Sites.
- Roles, responsibilities, and supervision arrangements must be documented.
- Delivery models (e.g. telehealth, hybrid visits) must be clearly described.

Procedure

4.1 Protocol/Clinical Investigation Plan Development

Specific content of a Protocol/CIP will vary depending on the subject of the research, the level of risk to participants, the phase of the research and study design, and whether a medicinal product or a device or a therapeutic intervention is being researched. Consequently, the terminology will be different and should be adapted appropriately.

A range of guidance material may inform and be referred to in development of the Protocol/CIP, including but not limited to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and the Consolidated Standards of Reporting Trials (CONSORT) and Consort-Outcomes 2022 Extension.

Where the Investigator is responsible for protocol development, they must ensure that:

- The protocol aligns with ICH GCP E6(R3) (Appendix B where applicable)
- The design is scientifically valid and operationally feasible
- Risks are identified and mitigated

The protocol should include:

- Objectives and endpoints
- Study design and methodology
- Safety monitoring and reporting
- Statistical considerations
- Participant population and inclusion strategy
- Data collection requirements (proportionate to CtQ factors)

For trials conducted under decentralised or teletrial models, the protocol or supporting documents must address:

- Visit schedules (face-to-face vs remote)
- Consent processes
- Data collection and monitoring approaches
- Roles across Primary and Satellite Sites

4.2 Investigator Brochure (IB) and Product Information Content Development

In the circumstances where the Investigator contributes to IB or product documentation:

- Content must align with ICH GCP requirements
- Information must be current, accurate, and relevant to the study

The IB (or equivalent) must:

- Be reviewed regularly and updated as new information emerges
- Provide sufficient information for safe and appropriate use of the investigational product

Where appropriate, approved product information may be used in place of an IB.

4.3 Amendments and Ongoing Review

Protocols and supporting documents such as the IB must be reviewed regularly throughout the trial and updated when new scientific or safety information becomes available to the researchers and community.

- Amendments must be justified, documented and endorsed by the Steering/Management Committee.

- Should safety updates require notification to regulatory bodies eg. TGA, OGTR, the CPI PI/Sponsor should notify them accordingly.
- Any amendments must be submitted to the HREC and approved, with RGO acknowledgment obtained, prior to implementation.

4.4 Integration with Supporting Documents

To ensure the consistent and effective operationalisation of the protocol requirements, the following supporting documents should be provided:

- Supervision Plans
- Monitoring Plans
- Laboratory and pharmacy manuals
- Data management plans

The inclusion of these documents, consistent and aligned, will aid with role clarity, specifically for trials conducted under decentralised or teletrial models.

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 07: Study Master File
- SOP 12: Safety Monitoring and Reporting

SOP 05: Communication with HREC, RGO, Sponsor and Insurer

Purpose

To ensure that communication with Human Research Ethics Committees (HREC), Research Governance Offices (RGO), Sponsors, and insurers is timely, accurate, proportionate to risk, and appropriately documented to support ethical oversight, regulatory compliance, and the safe conduct of clinical trials.

Scope

This SOP applies to all staff involved in clinical trials, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

Principles

The following principles underpin communication across the clinical trial lifecycle:

- Timely and risk-proportionate communication
    - Communication must be proportionate to the significance of the information and support prompt decision-making and risk management.
- Documentation as evidence
    - All communication must be documented to enable reconstruction of trial oversight and decision-making.
    - Verbal communication relating to key decisions must be followed by written confirmation (e.g. email or file note).
- Transparency and accountability
    - Information must be shared with relevant stakeholders to support ongoing ethical acceptability, governance compliance, and protection of participant safety and rights.
- Alignment with review pathways
    - Communication pathways must align with ethical review requirements, institutional governance processes and sponsor and regulatory expectations.

Procedure

5.1 General Communication

The PI and study/trial team must ensure that:

- All communication is accurate, complete and timely
- Key communications are to be well documented and filed in the Study Master File
- Communication pathways and escalation processes are clearly understood by the study team

The procedure for communication with the HREC and RGO is illustrated in a tabular form in the Single Ethical Review of Multi-centre Human Research Projects - Monitoring and Reporting Tables.

5.2 Communication with Reviewing HREC

Prior to study commencement, the Investigator (CPI/PI/SI) must:

- Select a reviewing HREC acceptable to participating institutions
- Submit all required documentation in accordance with HREC requirements
- Clearly describe any decentralised or teletrial elements (e.g. remote consent, telehealth visits)

in the ethics application

During the study, the Investigator (CPI/PI/SI) must:

- Comply with all reporting requirements and timelines specified by the HREC
- Submit:
    - Protocol amendments
    - Annual progress reports

    - Significant safety issues and serious breaches
    - Any new information affecting ethical acceptability
- Report only deviations that:
    - Impact participant safety or rights, or
    - Affect the reliability and robustness of trial data
- Immediately notify the HREC of:
    - Serious breaches
    - Urgent safety measures
    - Participant claims or intended claims

At study completion, the Investigator (CPI/PI/SubI) must:

- Submit a final report or close-out notification as required
- Ensure all documentation is filed in the Study Master File

5.3 Communication with the Research Governance Office (RGO)

Governance Submissions

The Investigator must ensure submission of a complete governance application, including:

- Clinical Trial Research Agreement (CTRA)/Clinical Investigation Research Agreement (CIRA)
- Site Specific Assessment (SSA)
- Indemnity and insurance documentation
- HREC approval

Note: Parallel submission with HREC may be undertaken where appropriate.

During the study trial, the Investigator (CPI/PI/SI) must:

- Notify the Research Governance Office of:
    - Changes to contracts, budgets, or agreements
    - Changes affecting institutional risk or liability
    - Serious breaches and significant deviations
- Report any issues that may impact:
    - Medico-legal risk
    - Institutional/organisational reputation
    - Compliance with contractual obligations
- Immediately notify the RGO of participant claims or intended claims

At the end of the trial, the Investigator (CPI/PI/SI) must:

- Notify the RGO the trial has closed or terminated (with reason for early termination).
- Ensure all documentation is appropriately filed and archived in accordance with the institutional requirements.

5.4 Communication with the Sponsor

The Investigator (CPI/PI/SI) must:

- Comply with the reporting requirements outlined in SOP 12: Safety Data Monitoring and Reporting and should consult and adhere to existing guidance for safety monitoring and reporting published by NHMRC and the TGA.

- Report to the Sponsor:
  - Serious Adverse Events (SAEs) within required timelines
  - Protocol deviations and breaches
  - Any issue significantly impacting trial conduct or participant safety
- Provide the Sponsor with:
  - Relevant correspondence from HREC, RGO, and insurer
  - Updates on trial progress
- Participate in monitoring activities (on-site or remote)
- Immediately notify the Sponsor of:
  - Serious breaches
  - Participant claims or intended claims

5.5 Communication with Institution's Insurer

The Investigator and/or Institution must:

- Promptly notify the insurer of any actual or potential claim arising from trial participation
- Ensure indemnity and insurance arrangements are understood and maintained throughout the trial

5.6 Non-Compliance, Deviations and Serious Breaches

The Investigator and study team is responsible for clear, accurate and timely communication to all stakeholders at all times.

As such, all non-compliance events must be identified, documented, assessed and reported to the Sponsor and regulatory bodies in accordance with protocol requirements.

A Serious Breach is defined as a breach likely to significantly affect:

- The safety or rights of participants, and/or
- The reliability and robustness of trial data

Examples may include:

- Loss of blinding
- Failure to control investigational product
- Significant eligibility violations
- Missing critical source data
- Persistent non-compliance
- Fraud or data falsification

Serious breaches must be:

- Reported to the Sponsor immediately
- Reported to the HREC and RGO in accordance with regulatory requirements

Corrective and Preventive Actions (CAPA) must be implemented as required.

Related SOPs

- SOP 02: Investigator Responsibilities

- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 07: Study Master File
- SOP 12: Safety Monitoring and Reporting

Appendices

- Protocol Deviation Log Template
- Communication Log Template

SOP 06: Site Initiation

Purpose

To ensure that clinical trial sites are appropriately prepared, resourced, trained, and authorised prior to commencement of trial activities, such that participant safety, data integrity, and protocol compliance are maintained from the outset of the trial.

Scope

This SOP applies to all staff involved in clinical trials, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

All staff must operate within their scope of practice based on education, training, and experience.

Principles

The following principles underpin a risk-proportionate, quality-by-design approach to site initiation:

- Participant safety and trial integrity
    - No clinical trial activities may commence until the site is appropriately prepared to ensure participant safety, protection of rights, and integrity of trial data.
- Trial readiness and quality by design
    - Site initiation must confirm that all critical-to-quality (CtQ) factors have been addressed, including:
        - staff capability
        - systems and processes
        - investigational product management
        - safety reporting processes
        - escalation pathways.

- Training, competency and supervision
    - All staff must be trained, competent, and appropriately supervised prior to undertaking trial-related activities.
    - For decentralised or teletrial models, supervision arrangements must be clearly defined and documented.
- Risk-proportionate and efficient processes
    - Initiation activities should be proportionate to the complexity and risk of the trial and avoid unnecessary administrative burden while ensuring compliance.
- Documentation and accountability
    - Site readiness, training, and initiation activities must be documented to enable reconstruction of trial start-up and demonstrate compliance with regulatory and ethical requirements.

Procedure

6.1 Pre-Initiation Requirements

Prior to initiation of the study, the Investigator must ensure that:

- All required approvals and authorisations are in place, including:
    - HREC approval
    - Research Governance authorisation
    - Contractual agreements (e.g. CTRA or equivalent)
- The Investigator and study team are:
    - Familiar with the protocol/CIP
    - Familiar with the investigational product, devices, and trial procedures
    - Aware of safety reporting requirements
- Adequate resources are available, including:
    - Qualified and trained staff
    - Facilities and equipment
    - Systems for data capture and safety reporting
- All staff (including Satellite Site staff and third-party providers where applicable):
    - Are identified and delegated appropriately
    - Have completed required training prior to performing trial activities
- For decentralised or teletrial models:
    - A Supervision Plan is in place and approved
    - Roles and responsibilities across Primary and Satellite Sites are clearly defined
    - Communication and escalation pathways are established
- A Site Initiation Visit (SIV) is scheduled with the Sponsor, which may be conducted:
    - Face-to-face, or
    - Remotely (e.g. videoconference), depending on trial complexity

For further guidance refer to Appendix 7 Initiation Checklist Example.

6.2 Site Initiation Visit

During the Initiation Visit the Investigator must ensure the following are available and addressed and that the Site Initiation Visit confirms site readiness, including:

- Trial documentation and systems
    - Study Master File (SMF) is established and organised
    - Satellite Site Study File (SSSF) is established where applicable
    - Essential documents are available and current
    - Data capture systems (e.g. CRFs/eCRFs) are accessible and understood
- Training and Delegation
    - All relevant personnel attend the initiation visit (or receive equivalent training)
    - Training is conducted on:
        - Protocol/CIP
        - Safety reporting requirements
        - Investigational product handling
        - Data collection and documentation requirements
    - Training is documented in Training Logs
    - Delegation of responsibilities is documented and aligned with staff competency
- Investigational product and trial materials
    - Arrangements for supply, storage, and accountability of investigational product are confirmed
    - Pharmacy and laboratory manuals (where applicable) are available and understood
    - Equipment required for trial conduct is available, calibrated, and functional
- Communication and oversight
    - Contact lists for all stakeholders (site staff, Sponsor, third parties, Satellite Sites) are established
    - Communication pathways and escalation processes are confirmed
    - Monitoring arrangements (including remote monitoring where applicable) are understood

For decentralised and teletrial models, it is essential that the capability of satellite site teams is confirmed, supervision plan is reviewed and operationalised, training across all sites is completed and documented and processes for data flow, safety reporting and oversight across sites are clearly defined.

6.3 Post Site Initiation Visit Activities

Following the Site Initiation Visit, the Investigator must ensure that:

- Any outstanding actions identified during initiation are completed prior to recruitment
- The Sponsor's initiation report/letter is reviewed and filed in the SMF
- Satellite Sites file relevant documentation in the SSSF
- Staff unable to attend the initiation visit must:
    - Receive appropriate training prior to undertaking any trial activities
    - Have all training documented

6.4 Authorisation to Commence Recruitment

Recruitment must not commence until:

- All HREC/Governance/Sponsor approvals are in place

- All initiation requirements have been met
- Staff are trained and delegated
- The site is confirmed as ready by the Investigator (and Sponsor where applicable)

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 05: Communication
- SOP 07: Study Master File
- SOP 11: Investigational Product

Appendices

- Site Initiation Checklist Template
- Training Record Template
- Supervision Plan Template

SOP 07: The Study Master File and Essential Documents

Purpose

To ensure that essential clinical trial documents are appropriately created, maintained, and controlled to support the safe conduct of the trial, protection of participants, and integrity and reliability of trial data.

The Study Master File (SMF) provides evidence that the trial is conducted in accordance with the protocol, Good Clinical Practice (GCP), and applicable regulatory and ethical requirements.

This SOP aligns with ICH GCP E6(R3), the National Statement (2025), the National Clinical Trials Governance Framework, and applicable regulatory requirements.

Scope

This SOP applies to all clinical trials and all personnel responsible for the creation, maintenance, oversight, or use of essential documents.

It applies to all:

- trial types (commercial, investigator-initiated, collaborative
- formats (paper and electronic Trial Master Files [TMF/eTMF])
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

Principles

The following principles guide the creation, maintenance, and oversight of essential documents and the Study Master File (SMF) to ensure compliance with ethical, regulatory, and governance requirements.

- Documentation as evidence of quality and compliance
    - The SMF must enable reconstruction of the trial and provide evidence that:
        - participant safety was adequately protected
        - the trial was conducted in accordance with the approved protocol and regulatory requirements
        - trial data are credible, accurate, and complete.
- Risk-proportionate documentation
    - Documentation requirements should be proportionate to:
        - the complexity and risk of the trial
        - critical-to-quality (CtQ) factors, including critical data and processes.
    - Essential documents must focus on those necessary to ensure participant safety and data integrity.
- Contemporaneous, accurate, and complete records
    - All documents must be:
        - accurate, complete, and legible
        - created and maintained contemporaneously
        - attributable, traceable, and verifiable.
    - Documentation must comply with ALCOA+ principles
- Digital systems and data integrity
    - Where electronic systems are used:
        - systems must be fit-for-purpose and secure
        - access controls, audit trails, and version control must be implemented maintained
        - data integrity, traceability, and long-term accessibility must be ensured.
- Governance and accountability
    - The Principal Investigator is responsible for the SMF at their site.
    - For investigator-initiated trials, the Coordinating Principal Investigator (CPI) is responsible for oversight of the TMF across all sites.
    - Delegation of document management tasks does not remove accountability.

For trials conducted under decentralised or teletrial models:

- Documentation must clearly reflect roles and responsibilities across Primary and Satellite Sites.
- Site-specific documentation must be maintained at each site.
- Oversight and communication processes must be documented.

Procedure

7.1 Creation of the Study Master File

A Study Master File (SMF) must be established prior to trial commencement.

The SMF must:

- Be organised in a logical and consistent structure
- Include all essential documents relevant to the trial
- Be accessible to authorised personnel

For multicentre trials:

- A central TMF may be maintained by the Sponsor or CPI
- Each site must maintain a Site Master File containing site-specific documents

7.2 Contents of the Study Master File

- The SMF must include essential documents that enable evaluation of trial conduct and data quality, including:
    - Protocol and amendments
    - Investigator Brochure or equivalent
    - Ethics and governance approvals
    - Participant Information and Consent Forms
    - Delegation Logs and Training Records
    - Safety reporting documentation
    - Monitoring and audit documentation
    - Correspondence relevant to trial conduct
    - Data management documentation
    - Documentation should be aligned to trial-specific risks and CtQ factors.

- In addition, the SMF must be appropriately indexed and clearly document the location of all Essential and Source Records.
- Where financial documentation (e.g. Clinical Trial Agreement, Satellite Site Agreement, invoices, and remittances) is stored separately from the SMF, the location must be recorded in the SMF index.
- Investigational Product (IP) handling documentation (e.g. shipping, receipt, Interactive Voice Response System (IVRS)/Interactive Web Response System (IWRS) records, codes, randomisation lists, accountability and destruction records) may be maintained in a separate file (e.g. at the site pharmacy). Where this occurs, it must be recorded on the SMF index. All IP documentation must be readily available to Sponsors, monitors, auditors and regulatory agencies upon request, and archived with the SMF following study completion.
- Sample handling procedures are to be clearly recorded if performed (e.g. in a laboratory manual). Sample management records for 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.

7.3 Maintenance of the Study Master File

The SMF must be maintained throughout the lifecycle of the trial, updated in a timely manner as documents are generated or amended and organised to allow efficient review and retrieval of information.

The Principal Investigator or delegate ensures:

- Documents are filed promptly
- Version control is maintained
- Superseded documents are retained appropriately

For trials conducted under decentralised or teletrial models:

- Documentation from both primary and satellite sites must be maintained and be accessible
- Oversight of document completeness across sites must be ensured

7.4 Oversight, Access and Quality Control

The Principal Investigator must ensure:

- Regular review of the SMF for completeness and accuracy
- Any deficiencies are identified and addressed
- Oversight is proportionate to the risk and complexity of the trial

For Investigator-Initiated/Collaborative Group trials:

- The CPI/Coordinating Centre/Project Office must ensure consistency and completeness of documentation across all sites

Access to the SMF must be:

- Restricted to authorised personnel
- Controlled through defined access permissions
- Must be available for
    - monitoring
    - audit
    - regulatory inspection.

Confidentiality of participant information and proprietary information must be always maintained.

7.5 Close-out and Archiving

At the time of study/trial completion:

- The SMF must be reviewed for completeness
- Documents must be archived in accordance with regulatory and institutional requirements

Some contents of the SMF may be archived in accordance with regulatory and institutional requirements. They therefore must:

- Be secure and protected from loss or damage
- Remain accessible for the required retention period
- Maintain data integrity and confidentiality

For multicentre trials:

- Site-specific documentation must be archived at each site

- Central TMF records must be retained by the Sponsor or CPI

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 13: Site Close-Out and Archiving
- SOP 14: Database Development and Data Management

Appendices

- SMF Index Template
- Essential Documents Checklist

SOP 08: Case Report Forms and Source Records

Purpose

To ensure that clinical trial data are accurately recorded, verified, and maintained in a manner that supports participant safety, data integrity, and compliance with ethical, regulatory, and governance requirements.

Scope

This SOP applies to all personnel involved in the creation, handling, review, or management of clinical trial data, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- data formats (paper and electronic)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

All personnel must operate within their scope of practice and delegated responsibilities.

Principles

The following principles underpin a risk-proportionate, quality-by-design approach to clinical trial data management.

- Data integrity and reliability
    - All clinical trial data must be complete, accurate, and reliable, and must support reconstruction of trial conduct and participant care.
    - Data must comply with ALCOA+ principles:
        - attributable
        - legible

        - contemporaneous
        - original
        - accurate
        - complete, consistent, enduring, and available.
- Source data as the foundation of evidence
    - Source data must reflect the original clinical observations, assessments, and care provided to participants and must be sufficient to verify the accuracy of reported trial data.
- Risk-proportionate data collection
    - Data collection should focus on information critical to:
        - participant safety
        - trial endpoints
        - regulatory decision-making.
    - Unnecessary or duplicative data collection should be avoided.
- Traceability and auditability
    - All data entries and changes must be traceable, with a clear audit trail documenting:
        - who made the change
        - when the change was made
        - why the change was made.
- Confidentiality and access control
    - Access to participant data must be restricted to authorised personnel and managed in accordance with privacy and confidentiality requirements.

For trials conducted under the decentralised or teletrial models, where trials involve multiple sites or remote interactions consider the following:

- Data must remain accessible, traceable, and attributable across sites.
- Responsibilities for data entry, verification, and oversight must be clearly defined.
- Data flow between Primary and Satellite Sites must be documented.

Procedure

8.1 Source Records

The Investigator and team must ensure:

- Adequate and accurate source records are maintained for each participant
- Source records enable reconstruction of:
    - clinical care provided
    - trial-related decisions and events.
- Source data are recorded:
    - contemporaneously
    - clearly and legibly
    - in accordance with the protocol/CIP and clinical practice.
- For telehealth or remote visits:
    - A record of the interaction is documented in the participant's health record
    - The method of consultation (e.g. telehealth) is recorded

- Key clinical information and follow-up actions are documented

8.2 Case Report Forms (CRFs)

The Investigator must ensure:

- CRFs (paper or electronic) are completed accurately and in a timely manner
- Data entered into the CRFs are consistent with source records
- Data entry is performed only by appropriately trained and delegated personnel

The Principal Investigator retains overall responsibility for the accuracy and completeness of data reported to the Sponsor.

8.3 Data Corrections and Audit Trail

The Investigator must ensure:

- Corrections to paper records:
  - do not obscure the original entry
  - are signed, dated, and explained where required.
- Electronic systems:
  - Maintain a secure, validated audit trail
  - Capture all changes to data entries
- Where electronic systems do not provide adequate audit trails:
  - Alternative documentation of changes is maintained

8.4 Electronic Systems and Data Governance

Where electronic systems (e.g. EMR, eCRF) are used, the Investigator must ensure:

- Systems are fit-for-purpose and secure
- Access is restricted to authorised users
- Users are provided training in the use of the systems, including procedures for reporting security or data breaches
- Data integrity, traceability, and auditability are maintained
- Systems are approved by the organisational cybersecurity and data governance teams

8.5 Data Access and Verification

The Investigator must ensure:

- Direct access to trial-related records is provided to authorised personnel (e.g. monitors, auditors, regulatory authorities), as permitted by participant consent and regulatory requirements
- Access is managed in accordance with privacy and confidentiality obligations

8.6 Storage and Retention

The Investigator must ensure:

- Source records and CRFs are securely stored
- Records are maintained in the Study Master File (SMF) and Satellite Site Study File (SSSF), where applicable

- Records are protected from unauthorised access, loss, or premature destruction

8.7 Data Management in Decentralised and Teletrial Models

For trials conducted under decentralised or teletrial models, the Investigator must ensure:

- Data generated at Satellite Sites are:
  - Accessible to the Primary Site for oversight
  - Available for monitoring and verification
- Where shared electronic medical record (EMR) access is available:
  - Appropriate access is enabled for oversight and monitoring
- Where shared access is not available:
  - Certified copies of source records are transferred securely
  - The method of transfer (e.g. secure email, post) is defined and documented
- The Supervision Plan defines:
  - Location of original and copied records
  - Responsibilities for data entry and verification
  - Data flow between sites

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 06: Site Initiation
- SOP 07: Study Master File
- SOP 14: Database Development and Data Management

Appendices

- Source Data Guidance Template
- Case Report Form (CRF) Completion Guidelines

SOP 09: Participant Informed Consent Process and Documentation

Purpose

To ensure that informed consent is obtained, documented, and maintained in a manner that respects participant autonomy, supports understanding, and complies with ethical, regulatory, and governance requirements.

In this SOP, the term informed consent means the provision of sufficient information to enable a person to make a **free** and informed decision. Where relevant, the term consent also includes assent.

A reference to participant includes their legally acceptable representative (LAR) where relevant.

Scope

This SOP applies to all personnel involved in the informed consent process for clinical trials, including Investigators (CPI/PI/SI), study coordinators, and delegated clinical trial staff.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- participant populations
- consent formats (written, electronic, verbal where approved)
- trial models, including decentralised and teletrial models.

All personnel must operate within their scope of practice and delegated responsibilities.

Principles

The following principles underpin a participant-centred, ethically robust, and risk-proportionate approach to informed consent.

- Consent as an ongoing process
    - Informed consent is a continuous process of communication between the research team and the participant, not a single event.
    - Participants must be provided with ongoing opportunities to ask questions, receive new information, and confirm their willingness to continue participation.
- Respect for autonomy and voluntariness
    - Participation in research must be voluntary and free from coercion or undue influence.
    - Participants must be given sufficient time and opportunity to consider participation and make an informed decision.
- Understanding and meaningful engagement
    - Information must be presented in a way that supports participant understanding, considering:
        - language
        - literacy
        - cultural context
        - individual needs.
    - The consent process must confirm that the participant understands:
        - The purpose of the research
        - Risks and benefits
        - What participation involves
        - Their right to withdraw
- Inclusion, equity and cultural safety
    - Consent processes must support equitable participation and be inclusive of diverse populations, including:
        - Culturally and linguistically diverse communities
        - Aboriginal and Torres Strait Islander peoples.
    - Appropriate supports (e.g. interpreters, culturally appropriate materials) must be provided where required.

- Proportionate and flexible consent approaches
    - Consent processes should be proportionate to the:
        - Level of risk
        - Complexity of the trial
    - Flexible approaches (e.g. electronic consent, remote consent) may be used where ethically approved and appropriate.
- Documentation and accountability
    - The consent process must be appropriately documented to demonstrate:
        - valid consent was obtained
        - consent was informed and voluntary
        - ongoing consent was maintained.
    - The Principal Investigator retains overall responsibility for the consent process.

Procedure

9.1 Preparation for Consent

The Investigator must ensure:

- The Participant Information and Consent Form (PICF) has been approved by the reviewing HREC and is the correct version
- Staff obtaining consent are:
    - Appropriately trained
    - Listed on the Delegation Log
- The consent process is:
    - Appropriate to the participant population
    - Supported by required resources (e.g. interpreters, translated materials)

9.2 Obtaining Informed Consent

The Investigator (or delegated staff) must ensure:

- Consent is obtained prior to any trial-specific procedures
- The participant:
    - Is provided adequate time to consider participation
    - Is given the opportunity to ask questions
    - Receives clear, understandable information
- The discussion includes:
    - Purpose of the study
    - Procedures involved
    - Risks and potential benefits
    - Alternatives to participation
    - Privacy and confidentiality
    - Compensation and insurance (if applicable)
    - Right to withdraw at any time
- The person obtaining consent:
    - Confirms participant understanding
    - Answers questions appropriately

9.3 Documentation of Consent

The Investigator must ensure:

- Consent is documented using the HREC-approved PICF
- The PICF is:
  - Signed and dated by the participant and person obtaining consent
  - Completed prior to participation
- A copy is:
  - Provided to the participant
  - Filed in the participant's medical record or study master file
- The consent process is documented in the participant's medical record as confirmation of the process

9.4 Ongoing Consent and Re-Consent

The Investigator must ensure:

- Participants are informed of:
  - New information that may affect participation
  - Protocol amendments relevant to them
- Re-consent is obtained where required
- Ongoing willingness to participate is confirmed throughout the trial

9.5 Research Involving Participants who are Unable to Give Consent

For participants with impaired decision-making capacity

- Consent must be obtained from a legally authorised representative in accordance with ethical and legal requirements

For emergency or time-critical research

- Consent processes must follow approved ethical pathways

9.6 Teletrial models and Remote Consent

For trials conducted under decentralised or teletrial models:

- Remote consent may be obtained using:
  - Telehealth
  - Electronic consent systems
- The Investigator must ensure:
  - Participant identity is verified
  - Privacy and confidentiality are maintained
  - The process is documented
- The Supervision Plan must define:
  - Where consent is obtained
  - Where consent records are stored

9.7 Withdrawal of Consent

Participants may withdraw consent at any time. The Investigator must ensure:

- Withdrawal is documented
- Participants are informed of what will happen to their data and samples
- Appropriate follow-up care is provided where required

9.8 Examples of Pre-approved Local Adaptations to the Master PICF

A HREC may approve a Master PICF amended with preapproved local adaptations to cover situations where there is a need to:

- Address the Decentralized Clinical Trial (DCT) model
- Obtain records from other health facilities
- Address the use of contraception where a site has a specific requirement
- Cover consent obtained by telehealth/telephone methods
- Examples of preapproved text
    - Obtaining records from other health facilities.
    - Involvement in this study may require the Investigator to access records from other hospitals, health facilities, instances where I have been transported by ambulance. These records may include information relevant to the trial. The Investigator warrants that they will treat the information with the strictest confidence and abide by all relevant privacy policies and legislation.
    - By signing this consent form, I give consent to the Investigator to obtain information, only if required for the purpose of this study and only for the term of the study period from the following:
- ambulance transportation
- any admission to any hospital
- Emergency Department visits
- observation unit stays
- my local doctor
- use of contraception.

    - Refer to the relevant institution's website or HREC for the preapproved contraception text.
    - Consent obtained by telehealth/telephone methods.
    - Consent was obtained using telehealth with "Name of Investigator", whose identification was sighted by the participant who observed the Investigator's signature being written.
    - Consent was obtained using telehealth with "Name of participant", whose identification was sighted by the Investigator who observed the participant's signature being written.
    - Consent was obtained via telephone with "Name of Investigator", on [DD/MMM/YYYY].
    - Consent was obtained via telephone with "Name of participant", on [DD/MMM/YYYY].
    - Participant's signed consent form received by the Investigator on [DDMMMYYYY].
    - Discussed with [participant] via telephone on [insert date] and received signed consent form on [insert date]. Signed by [Investigator].

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 05: Communication
- SOP 06: Site Initiation
- SOP 08: Case Report Forms and Source Records

Appendices

- Participant Information and Consent Form Template
- Consent Process Checklist

SOP 10: Handling and Shipping of Biological Substances (Cat B) and Dangerous Goods

Purpose

To ensure that biological samples and dangerous goods used in clinical trials are handled, processed, stored, and transported safely and in compliance with applicable regulatory, ethical, and governance requirements, while maintaining sample integrity and traceability.

Scope

This SOP applies only to the handling and shipment of Biological Substances, Category B, and dangerous goods (dry ice). Where biological samples, specimens, or substances are referred to in this SOP, Category B is implied.

This SOP applies to all personnel involved in clinical trials, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

All personnel must operate within their scope of practice based on education, training, and experience.

Principles

The following principles underpin a risk-proportionate and quality-by-design approach to the handling and transport of biological substances.

- Participant safety and ethical responsibility

    - Biological samples derived from participants must be handled in a manner that:
        - protects participant safety and confidentiality
        - aligns with consent provided by participants
        - complies with ethical and regulatory requirements.
- Sample integrity and fitness for purpose
    - Samples must be handled and transported under conditions that preserve their integrity and suitability for analysis, in accordance with the protocol/CIP and laboratory requirements.
- Chain of custody and traceability
    - A complete and documented chain of custody must be maintained from:
        - collection
        - processing
        - storage
        - shipment
        - receipt and final disposition.
    - This ensures traceability and supports data reliability and auditability.
- Compliance with regulatory and safety requirements
    - All handling and shipping activities must comply with applicable regulations and standards, including:
        - International Air Transport Association (IATA) requirements
        - Civil Aviation Safety Authority (CASA) regulations
        - National Pathology Accreditation Advisory Council (NPAAC) requirements
- Training, competency and delegation
    - Only appropriately trained and certified personnel may handle and ship biological substances and dangerous goods.
    - Delegation of duties does not remove Investigator accountability.
- Risk-proportionate processes
    - Handling and transport processes must be proportionate to:
        - the type of biological material
        - associated risks (e.g. infectious, temperature-sensitive)
        - trial complexity and logistics.

For trials conducted under decentralised or teletrial models, the following elements are critical:

- Sample handling, storage, and transport processes must be clearly defined across sites.
- Responsibilities must be documented in the Supervision Plan.
- Sample flow between Primary and Satellite Sites (if applicable) must be controlled and traceable.

Procedure

10.1 General Requirements

The Investigator or delegate must ensure:

- Biological samples are collected, handled, and transported in accordance with:
  - Protocol/CIP
  - Laboratory manual
  - Applicable regulatory requirements
- A documented chain of custody is maintained for all samples
- All records (e.g. shipment logs, receipts, tracking documentation) are:
  - Accurate and complete
  - Maintained in the Study Master File (SMF) and/or Satellite Site Study File (SSSF)

10.2 Training and Certification

The Investigator must ensure:

- Personnel handling or shipping biological substances:
  - Hold current certification in IATA-compliant dangerous goods handling (CASA recognised)
  - Complete refresher training at required intervals
- Training is:
  - Documented in Training Logs (refer SOP 03)
  - Supported by retained certification records
- Where personnel are not certified, handling and shipping is undertaken by certified personnel (e.g. pathology services or third-party providers)

CASA Regulations define categories of personnel who are required to attend training and the subject matter in which they must be qualified. These regulations are mandatory and legally binding and must therefore be adhered to in full.

Re-certification is required every two years. Certificates and any training records must be kept for a minimum period of 36 months from the most recent training completion date, and must be made available, upon request to the Sponsor, regulatory authority, and CASA.

10.3 Packaging and Transport

The Investigator or delegate must ensure:

- Biological substances are packaged in accordance with the triple packaging system:
  - Primary receptacle
  - Secondary packaging
  - Outer packaging
- Appropriate labelling and documentation are applied
- Transport conditions (e.g. temperature control using dry ice) are:
  - defined
  - monitored
  - documented.
- Export/import requirements (where applicable) are met

10.4 Equipment and Storage

The Investigator or delegate must ensure:

- Equipment used for sample processing and storage (e.g. centrifuges, refrigerators, freezers) is:
    - maintained, calibrated, and fit-for-purpose
    - monitored in accordance with local policy and manufacturer requirements.
- Sample kits are:
    - stored appropriately
    - within expiry
    - available in sufficient quantity.

10.5 Decentralised trials and Teletrial model - Multi-Site Sample Management

For trials conducted under decentralised or teletrial models, the Investigator must ensure:

- Sample handling and transport processes across Primary and Satellite Sites are:
    - Defined in the Supervision Plan
    - Consistent with protocol and laboratory requirements
- Responsibilities are clearly assigned for:
    - Collection
    - Processing
    - Storage
    - Shipment
- Escalation pathways are defined for:
    - Delays
    - Temperature excursions
    - Lost or compromised samples

10.6 Documentation and Record Keeping

The Investigator or delegate must ensure:

- All sample handling and shipment activities are documented, including collection records, Processing logs, Shipment records and Chain of custody documentation
- Records are complete, accurate, and contemporaneous and retained in accordance with regulatory requirements

10.7 Non-Compliance and Incidents

The Investigator must ensure:

- Any deviations, incidents, or breaches related to sample handling or transport are:
    - Documented
    - Assessed for impact on participant safety and data integrity
- Significant issues are:
    - Reported to the Sponsor
    - Escalated in accordance with SOP 05 and SOP 12
- Corrective and Preventive Actions (CAPA) are implemented where required

Related SOPs

- SOP 02: Investigator Responsibilities

- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 05: Communication
- SOP 07: Study Master File
- SOP 13: Site Close-Out and Archiving

SOP 11: Management of Investigational Product

Purpose

To ensure that investigational products (IP), including medicinal products and devices, are managed in a manner that protects participant safety, maintains product integrity, and ensures compliance with ethical, regulatory, and governance requirements.

Scope

This SOP applies to all personnel involved in clinical trials, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

All personnel must operate within their scope of practice based on education, training, and experience.

This SOP does not cover sourcing or re-labelling of IP.

Sourcing of IP: The Sponsor is responsible for ensuring IP is procured from reputable companies, who ensure IP is manufactured to GMP standards. Where the investigator is acting as the Sponsor, it is recommended they engage the pharmacy for advice on procurement matters.

Relabelling of IP: Is not covered here as it will follow the procedures determined by the Sponsor or follow the Institution's pharmacy procedures for relabelling.

Principles

The following principles underpin a risk-proportionate and quality-by-design approach to investigational product management.

- Participant safety and correct use
    - Investigational product must be prescribed, prepared, dispensed, and administered in accordance with the approved protocol/CIP to ensure that participants receive:

        - the correct product
        - at the correct dose
        - at the correct time.
- Product integrity and storage
    - Safeguards must be in place to ensure that IP is:
        - stored under appropriate conditions
        - protected from contamination, deterioration, or unauthorised access
        - managed in accordance with sponsor requirements and applicable standards.
- Chain of custody and accountability
    - A complete and auditable record of IP must be maintained from:
        - receipt
        - storage
        - dispensing
        - administration
        - return or destruction.
    - This must enable reconstruction of IP use at participant and site level.
- Risk-proportionate management
    - IP management processes must be proportionate to:
        - the type of product (e.g. high-risk, temperature-sensitive)
        - trial complexity
        - distribution model (e.g. central, decentralised, direct-to-participant).
- Documentation and data integrity
    - All IP-related records must comply with ALCOA+ principles and support auditability and traceability.
- Delegation, training and oversight
    - IP management activities may be delegated to appropriately qualified personnel (e.g. pharmacists or trained clinical staff), however the Investigator retains overall responsibility.
- Digital systems and integration
    - Where electronic systems are used (e.g. IRT, pharmacy systems, EMR):
        - Systems must be secure, validated, and fit-for-purpose.
        - Data must be traceable and auditable.
        - Integration between systems must maintain data integrity.

For trials conducted under decentralised or teletrial models, where IP is supplied across multiple sites or directly to participants, the responsibilities of each site team must be clearly defined. Supply of IP, storage and administration processes must be controlled, and oversight must be maintained by the Investigator.

Procedure

11.1 Responsibilities in Management of Investigational Product

The Investigator must ensure:

- IP is managed in accordance with:
    - Protocol/CIP

    - Pharmacy manual (where applicable)
    - Regulatory and institutional requirements
- All personnel involved in IP management are:
    - Trained and competent
    - Appropriately delegated
- Oversight is maintained across:
    - Primary Site
    - Satellite Sites
    - Third-party providers

11.2 Supply Transport and Storage

The Investigator must ensure:

- IP is transported, received, and stored in accordance with:
    - Sponsor instructions
    - Protocol/CIP
    - Dangerous goods requirements (where applicable)
- Storage conditions:
    - Are monitored (e.g. temperature logs)
    - Prevent unauthorised access
    - Ensure segregation from non-trial stock
- Chain of custody is maintained throughout transport and storage
- Any deviations (e.g. temperature excursions, product defects):
    - Are documented
    - Reported to the Sponsor
    - Managed in accordance with instructions
- Equipment used for storage is:
    - Calibrated and maintained
    - Fit-for-purpose

11.3 Dispensing, Administration and Participant Use

Processes must ensure safe and compliant use. The Investigator must ensure:

- IP is dispensed and administered in accordance with the protocol/CIP
- Participants receive clear instructions regarding:
    - Use of IP
    - Storage requirements
    - Return of unused product
- Additional counselling is provided where required (e.g. non-compliance)

For trials conducted under decentralised or teletrial models:

Depending on how the trial is set up, the IP may be:

- Dispensed at Satellite Sites or approved locations
- Supplied directly to participants (if permitted)

Administration may occur by:

- Site staff
- Participants or caregivers (where appropriate)

11.4 Randomisation and Blinding

Randomisation procedures must be followed in accordance with the protocol. The investigator is responsible for ensuring that the systems (e.g. IRT) are used appropriately.

For trials conducted under decentralised or teletrial models, there needs to be clearly defined roles and responsibilities that support oversight of randomisation and delivery of correct IP for satellite sites.

11.5 Accountability and Records

The Investigator must ensure:

- Complete IP accountability records are maintained, including:
  - Receipt and shipment logs
  - Storage and temperature records
  - Dispensing and administration records
  - Return and destruction records
- Records enable traceability at:
  - Participant level
  - Site level
- Unblinding documentation is:
  - Stored securely
  - Kept separate from blinded records
- IP records may be stored in:
  - SMF/SSSF
  - Pharmacy systems
  - Electronic systems
  - Medical Records

Accountability includes documentation of IP in the participants medical record for trials conducted in hospitals.

11.6 Return, Disposal and Archiving

The Investigator must ensure:

- IP is not destroyed without Sponsor authorisation
- Unused or expired IP is:
  - Stored securely
  - Segregated from active stock
- IP is:
  - Returned to Sponsor, or
  - Destroyed in accordance with approved procedures
- Records of return or destruction are maintained
- IP-related documentation is archived in accordance with SOP 07 and SOP 13

11.7 Non-Compliance and Incidents

The Investigator must ensure:

- Deviations or incidents related to IP are:
  - Documented
  - Assessed for impact on safety and data integrity
  - Significant issues are:
    - reported to the Sponsor
    - escalated in accordance with SOP 05 and SOP 12
    - Corrective and Preventive Actions (CAPA) are implemented where required.

11.8 Unblinding

The Investigator must ensure:

- Unblinding occurs only when necessary for participant safety
- Unblinding is only conducted in accordance with the protocol
- Any unblinding is:
  - Documented
  - Reported to the Sponsor

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 05: Communication
- SOP 07: Study Master File
- SOP 10: Handling and Shipping of Biological Substances
- SOP 13: Site Close-Out and Archiving

Appendices

- Investigational Products (IP) Accountability Log Template
- Temperature Monitoring Log Template
- Delegation Log Template

SOP 12: Safety Data Monitoring and Reporting Requirements for Clinical Trials

Purpose

To ensure that safety data in clinical trials is appropriately collected, assessed, monitored, and reported in a timely and risk-proportionate manner to protect participant safety, support ethical oversight, and maintain the integrity of trial conduct.

Scope

This SOP applies to all personnel involved in clinical trials, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- investigational products (medicinal products and devices)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models
- Post-registration/post-marketing studies.

All personnel must operate within their scope of practice and delegated responsibilities.

Principles

The following principles underpin a risk-proportionate, participant-centred approach to safety monitoring and reporting.

- Participant safety and rights
    - The rights, safety, and wellbeing of participants are paramount and take precedence over all other considerations.
- Ongoing safety evaluation
    - Safety monitoring is a continuous process involving identification, assessment, reporting and review.
    - Evaluation must consider participant interests.
- Risk-proportionate safety management
    - Safety monitoring and reporting must be proportionate to:
        - trial design and complexity
        - investigational product risk profile
        - participant population.
- Integrity and reliability of safety data
    - Safety data must be accurate, complete and contemporaneous.
    - Information must be sufficient to support risk-benefit assessment.
- Integration with health service systems
    - Clinical trial safety processes must integrate with institutional:
        - incident reporting systems
        - risk management frameworks
        - clinical governance structures.
    - This requirement is most relevant for clinical trials conducted within health service organisations.
- Timely escalation and communication
    - To enable timely action, safety issues must be communicated promptly to sponsors, HREC, RGO/Institution and Regulatory authorities (TGA, OGTR, NHMRC where applicable).

For trials conducted under decentralised or teletrial models:

- Establish clear reporting pathways across sites including clear identification of roles and responsibilities.
- Ensure timely communication between primary and satellite site.
- Ensure consistent documentation and oversight.

Procedure

12.1 Safety Monitoring

Safety monitoring is conducted in accordance the protocol, the safety monitoring plan (where applicable) and applicable regulatory and institutional requirements.

The investigator must ensure that all study personnel:

- understand safety reporting requirements (NHMRC and trial specific)
- are trained in identification and reporting of safety events
- report within required timelines.

For trials conducted under decentralised or teletrial models, the investigator must ensure that safety oversight is maintained across the primary site, satellite site(s) and any third-party providers.

12.2 Safety Monitoring Committee

Where applicable, the Sponsor may establish:

- Data Safety Monitoring Boards (DSMBs)
- Independent safety reviewers or medical monitors

These bodies may:

- Review accumulating safety and efficacy data
- Assess risk-benefit balance
- Recommend continuation, modification, or termination of the trial

12.3 Sponsor Responsibilities

The Sponsor must:

- Maintain overall responsibility for ongoing safety evaluation
- Establish and maintain:
    - Safety Monitoring Plan (or equivalent)
    - Defined safety reporting processes and timelines
- Evaluate all incoming safety information, including:
    - Site-reported events
    - External safety data
- Maintain safety databases, line listings, and analyses
- Review and update reference safety information (e.g. IB, IFU, Product Information)
- Provide safety communications to relevant stakeholders, including:
    - Significant Safety Issues (SSIs)
    - Urgent Safety Measures (USMs)
    - Updated safety information
    - Annual safety reports (e.g. DSUR)

12.4 Investigator Responsibilities

The Investigator must:

- Identify, assess, and manage all safety events at the site
- Ensure that:
    - All adverse events (AEs) are captured
    - Events are assessed for:
        - seriousness
        - causality
        - expectedness.
- Provide appropriate clinical care to participants
- Maintain oversight of ongoing participant safety
- Ensure safety responsibilities delegated to qualified staff are:
    - Documented
    - Appropriately supervised

12.5 Documentation

The Investigator must ensure:

- Safety events are recorded in:
    - Source documents
    - CRF/eCRF
    - SAE/SUSAR forms (where applicable)
- Participant identifiers are:
    - Coded (no direct identifiers used in reports)
- Follow-up information is:
    - Collected and reported promptly
    - Updated within 24 hours of new information becoming available

For device trials:

- Device identification (e.g. serial number) must be recorded to enable traceability

12.6 Reporting

12.6.1 Reporting to Sponsor

The Investigator must report:

Within 24 hours:

- All Serious Adverse Events (SAEs), unless exempted by protocol
- SUSARs (where applicable)
- Congenital anomalies or birth defects

Within 72 hours:

- Urgent Safety Measures (USMs)
- Safety-critical events or findings

Within 15 calendar days:

- Other significant safety issues

12.4.1 Reporting to HREC/RGO

The Investigator must ensure reporting of:

- Significant Safety Issues (SSIs)
- Urgent Safety Measures (within 72 hours)
- New safety information impacting ethical acceptability

12.4.2 Reporting to Regulatory Authorities (TGA)

Where applicable, safety reporting must comply with TGA requirements, including:

- SUSAR reporting timelines
- Notification of significant safety issues
- Submission of safety reports via approved mechanisms

12.6.4 Significant and Special Safety Considerations

The investigator must ensure that safety reporting is consistent with the definitions and escalation pathways as defined in the trial protocol. Any deviations must be documented, assessed for impact, and escalated as appropriate through the CAPA process or other relevant processes.

12.6.5 Significant Safety Issues and Urgent Safety Measures

A Significant Safety Issue (SSI) is any issue that:

- Adversely affects participant safety, or
- Impacts the ongoing ethical acceptability or conduct of the trial

An Urgent Safety Measure (USM) is a measure taken to eliminate an immediate hazard. The Investigator must:

- Implement USMs where required for participant safety
- Notify the Sponsor within 72 hours
- Ensure appropriate reporting to HREC and RGO

12.6.6 Pregnancy

All pregnancies must be reported to the Sponsor as per protocol and follow-up must occur to determine outcomes (e.g. congenital anomalies).

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 03: Site Staff Qualifications, Training and Capability
- SOP 05: Communication
- SOP 07: Study Master File
- SOP 08: Source Data and CRFs
- SOP 13: Site Close-Out and Archiving

Appendices

- Adverse Event Log Template
- SAE/SUSAR Reporting Template
- Safety Communication Log Template

SOP 13: Site Close-Out and Archiving

Purpose

To ensure that clinical trials are appropriately closed and that all trial-related records are securely retained and archived in a manner that preserves participant safety, data integrity, and regulatory compliance.

Scope

This SOP applies to all personnel involved in clinical trial close-out and archiving activities, including Investigators (CPI/PI/SI), study coordinators, clinical trial staff, contractors, and third-party service providers.

It applies to all:

- clinical trial types (commercial, investigator-initiated, collaborative)
- sites (Primary and Satellite Sites)
- trial models, including decentralised and teletrial models.

All personnel must operate within their scope of practice and delegated responsibilities.

Principles

The following principles underpin a risk-proportionate and lifecycle-based approach to trial close-out and archiving.

- Participant safety and continuity of care
    - Trial close-out must ensure:
        - participants are appropriately informed of trial completion (where applicable)
        - ongoing care arrangements are in place
        - any required follow-up is completed.
- Completeness and integrity of trial records
    - All trial documentation must be:
        - complete, accurate, and contemporaneous
        - reconciled and resolved (e.g. data queries, safety follow-up)
        - sufficient to enable full reconstruction of trial conduct.
- Accountability and traceability
    - The responsible person for archiving must be clearly identified, and:
        - responsibilities for custody and access to records must be maintained

        - any changes in responsibility or storage location must be documented and communicated to the Sponsor.
- Secure record retention
    - Records must be:
        - retained for the required regulatory and institutional timeframes
        - stored securely to prevent loss, damage, or unauthorised access.
- Risk-proportionate and system-aligned archiving
    - Archiving approaches should be:
        - proportionate to trial complexity and risk
        - aligned with institutional systems and digital capabilities.

For trials conducted under decentralised or teletrial models:

- Close-out and archiving processes must be coordinated across Primary and Satellite Sites.
- Responsibilities for record retention must be clearly defined.

Procedure

13.1 Site Close-Out

Site close-out may only occur when:

- All participant-related activities are complete
- All data queries have been resolved
- All safety reporting obligations have been fulfilled
- The Sponsor has confirmed the site is ready for close-out

13.1.1 Premature Termination or Suspension

If a trial is prematurely terminated or suspended, the Investigator must:

- Notify relevant parties promptly, including:
    - Sponsor
    - HREC
    - RGO/Institution
    - TGA (where applicable)
    - Satellite Sites
- Provide a written explanation of the reasons
- Ensure participants (and their primary care provider, where consented):
    - Are informed appropriately
    - Receive ongoing care and follow-up
- Ensure all communication is documented and filed

13.1.2 Site Close-Out Activities

The Investigator must ensure:

- All trial documentation is:
    - Complete
    - Filed in the Study Master File (SMF)/Satellite Site Study File (SSSF)

- All investigational product is:
  - Accounted for
  - Returned or destroyed in accordance with SOP 11
- All outstanding actions are completed, including:
  - Data queries
  - Monitoring findings
  - CAPA actions
- A final report is submitted to:
  - HREC
  - RGO
  - Sponsor (as required)
- Regulatory notifications are completed where applicable

For trials conducted under decentralised or teletrial models, the investigators must ensure:

- Close-out is coordinated across all sites
- Supervision plan requirements are followed
- Satellite sites retain the documentation and provide the agreed set of documents to primary site
- Evidence of the oversight (supervision plan, communication) is retained in the SMF

13.2 Archiving

General requirements for archiving, the investigator must ensure:

- Trial documentation is archived in accordance with:
  - ICH GCP E6(R3)
  - ISO 14155 (where applicable)
  - Institutional policies
- Where retention requirements differ, the longest retention period applies
- Special requirements are considered for:
  - Paediatric trials
  - Device trials (long-term traceability)

13.2.1 Storage and Security

- Archived records must be stored in secure, access-controlled environments and made available for audit, inspection, and regulatory review.
- They must be protected from:
  - Fire
  - Water damage
  - Pest infestation
  - Theft

13.2.2 Archiving Responsibilities

It is the responsibility of the investigator to ensure:

- A designated responsible person is identified from within the trial team
- The Sponsor and Institutional Research Governance Office are informed of:
  - Storage location

    - Person responsible
    - Details of the files for archiving
    - Any changes to storage location and custodianship

Paper Records

The Investigator must ensure:

- Original or certified paper copies are retained
- Participant identifiable documents (e.g. consent forms, identification logs):
    - Are stored securely
    - Are filed separately to other trial documentation
- Sponsor-held files:
    - Do not include identifiable participant information
- Archiving arrangements are:
    - Defined in agreements (e.g. CTRA/CIRA)

Electronic Records

The Investigator must ensure:

- Electronic records are
    - Secure
    - Access-controlled
    - Protected from unauthorised modification
- Systems used for archiving
    - Maintain data integrity
    - Allow retrieval and audit
- Location and responsibility for electronic archives are documented

Conversion to Electronic Format

Where paper records are converted to electronic format

- Processes must be validated to ensure completeness, accuracy and integrity
- Scanned records must be quality checked and follow logical filing architecture (e.g. SMF content)
- Systems must support efficient retrieval and audit and inspection readiness

13.3 Access and Retrieval

The investigator must ensure that archived records are accessible to sponsors, regulatory authorities and ethics committees upon request. All access to documents must be controlled and documented.

In the event of issues affecting archived records, such as loss, damage or breach, these must be managed in the same manner as issues occurring during trial conduct. This includes reporting to the sponsor and relevant stakeholders and management through the CAPA process.

Related SOPs

- SOP 02: Investigator Responsibilities
- SOP 05: Communication

- SOP 07: Study Master File
- SOP 08: Source Data and CRFs
- SOP 11: Investigational Product
- SOP 12: Safety Monitoring and Reporting

Appendices

- Site Close-Out Checklist Template
- Archiving Log Template
- Record Retention Guide

SOP 14: Database Development and Data Management in Clinical Trials

Purpose

To outline the procedures for the development, validation, maintenance, security, and archival of clinical trial databases to ensure data integrity, participant safety, regulatory compliance, and reliable trial results in accordance with ICH E6(R3) and TGA expectations.

This SOP is specifically aimed at CPIs/PIs and Trial teams managing investigator-initiated trials (IIT) and collaborative research group (CRG) trials.

Scope

This SOP applies to:

- all interventional clinical trials conducted under the organisation's governance
- all electronic data capture (EDC) systems, validated databases, and external data systems
- clinical trial management teams, internal staff and external vendors involved in database design, data management and oversight

and includes sponsored and collaborative group studies where database development is performed internally or outsourced.

Principles

These principles build on the foundational concepts in ICH E8: General Considerations for Clinical Trials, which emphasise that quality must be prospectively built into the scientific and operational design of a clinical trial. The reliability of trial conclusions depends not only on the quality of the data generated, but on the quality of the study design, the conduct of the trial, and the systems used to collect, manage, and retain the data.

Database development and data management should be conducted in accordance with the following principles.

- Protection of participants and reliability of results

    - Trial databases must be designed and managed to:
        - protect the rights, safety and wellbeing of participants
        - ensure accurate, complete and reliable data
        - support primary trial objectives.
- Privacy and confidentiality
    - Participant confidentiality must be protected in accordance with Australian Privacy Principles, privacy legislation and regulatory requirements. These include:
        - role based access controls
        - secure data transmission
        - controlled archival access.
- Quality by design
    - Database development should include quality into its design rather than relying on checking and data cleansing at planned analyses.
    - Factors to include are:
        - identifying Critical-to-Quality (CtQ) data and processes
        - prospective risk assessment during protocol and database development
        - system design includes validation checks to support complete and logical data
        - collecting only data critical for protocol aims and objectives
        - include data quality controls, proportionate to trial complexity and risk.
- Data integrity - transparency and traceability
    - All clinical trial data must adhere to ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Enduring, Available)
    - Electronic systems need to support:
        - controlled user access
        - secure audit trails
        - traceability of changes
        - security of data
        - retention capability
        - ongoing internal quality review.
- Technology and system validation
    - The electronic systems used for clinical trials must have the following elements:
        - be validated for use
        - maintain data security and confidentiality
        - data hosting in Australia – ensure data security through local compliance, low latency and robust legal safeguards
        - Secure Daily Backup – ensures data protection, compliance with Australian laws and mitigate cyber risks
        - encryption of data – data is encrypted from acquisition, transfer, and storage. Note: field specific encryption is extra safeguard for highly sensitive data.
        - meet International Security and data privacy requirements (if required).

- Governance and accountability
    - The sponsor has ultimate responsibility for the following aspects
        - oversight of database development and data management
        - ensuring systems are fit for purpose
        - vendor selection includes qualifications, experience and monitoring of their processes (proportionate to risks of the trial operations)
        - compliance to the regulatory requirements.

Roles and responsibilities of each party must be clearly defined, documented and understood, noting that delegation of tasks does not transfer regulatory responsibility.

Procedures

14.1 Database selection

When considering a database, it is prudent to refer to the relevant ICH EFFICACY GUIDELINES, for example:

- E8 General Considerations for Clinical Trials
- E9 Statistical Principles for Clinical Trials
- E19 Safety Data Collection

To ensure relevant data is collected and managed according to best practices. Other guidelines must be referred to with regards to data handling practices at the end of study, access, future use, DBL, exporting, archiving data and the application itself.

As data is the asset, a high degree of control is a priority.

For bespoke database builds, in appointing a vendor, whilst not mandatory as yet, those who are Health Insurance Portability and Accountability Act (HIPAA) and International Organization for Standardization (ISO) certified demonstrate commitment to ensuring the highest level of security of data in their service offering.

14.2 Database access and protection

These are the general requirements to protect the safety and integrity of the database, the data it stores and the user:

- Multifactor authentication with a single sign-on
- Ability to access, anywhere, anytime, on any device (supports as close to real time data collection)
- Data housed in Australian servers and encrypted for maximum security
- Database provider should have ISO accreditations for information security (ISO/IEC 27001 and quality (ISO 9001:2015)

14.3 Building the Database

When approaching the task of building a database where the data generated during the clinical trial will be managed, it is useful to consider the following:

- The nature of the trial, complexity and experience of the team managing the trial
    - How many sites will this trial be conducted across

- Is it only in Australia or NZ and Internationally as well? Therefore does it need to be compliant with other jurisdictions and GDPR
- What is the complexity of the trial
- What are the requirements of database, is it a pure EDC or will it be used for the randomisation, and other trial management functions
- Will you be providing tablets and devices to support real time data capture or for participant questionnaires
- How many people will be requiring access to the database
- How many roles will there be and the need for role-based access controls
- Is your team IT savvy and able to set up the database (if off-the shelf licenced product such as REDCap), and manage the end-to-end process
- Does your team have the capability and resources to develop and execute the database
- Does your team have the capability and resources to support others in the event of issues with the database
- How much training is required for the data team
- How much flexibility is required: moderate or high
- What technical requirements are needed

- Is the database Web based or an installed application
  - What resources are required to install and manage
  - Are compliance regulation documents/licences required
  - Data import processing agreement
  - What levels of encryption are required
  - How are audit logs generated

14.3.1 Developing your database

Type of study	Potential Solution	Key Considerations
Single Centre	• Tailoring an existing off the shelf product • Use a modular approach	• Meets the requirements of the study • Use of appropriate licences software within your organisation's network • Engage architecture, Data Governance and Cybersecurity teams within your organisation to ensure robust risk mitigation
Multicentre, low complexity, simple intervention	Tailoring off the shelf product	• Meets the requirements of the study • Use of appropriate licences software within your organisation's network

		• Engage architecture, Data Governance and Cybersecurity teams within your organisation to ensure robust risk mitigation
Multicentre, Complex, Interventional study, with randomisation, eCRF and full endpoints management functionality including validation and adjudication functionality, drug management, funds management,	Bespoke database development with vendor	• Proven track record for developing CT databases • Data hosting in Australia – ensure data security through local compliance, low latency and robust legal safeguards • Secure Daily Backup – ensures data protection, compliance with Australian laws and mitigate cyber risks • Encryption of data – data is encrypted from acquisition, transfer, and storage. Field specific encryption is extra safeguard for highly sensitive data – helpful to have this functionality ○ Meet International Security and data privacy requirements (if required)

14.4 Data Management Procedures

14.4.1 Data management lifecycle

- Ensure the Trial Manual/Database manual has sections specific to the principles of data collection/acquisition/capture/query
    - Data validation/verification built in systems and crosscheck
    - Data quality systems in place with clearly articulated roles and responsibilities
    - Requirement for site teams to cross check data and not solely rely on central monitoring
    - Centralised data monitoring – with clearly defined thresholds for maintaining data integrity
    - Statistical surveillance – planned interim analyses, reporting to Steering Committee/Data Quality Committee
- Data storage

    - Principles for maintaining integrity of data and database
    - Long term data storage
- Data transfer
    - Encrypted and only shared through approved systems and processes, e.g. no emailing PII, no unauthorised use of personal devices

14.4.2 Establish what data to collect

- Info to ensure data is specific, primary endpoint and secondary endpoints, tertiary endpoints (be clear there is no superfluous data being collected).
    - Data Dictionary is useful to ensure clear definitions, reduces ambiguity and risk of erroneous data
    - Instructions on completing the CRF and database manuals are useful
    - Ensure data collection is simple (if using technology for surveys, questionnaires and e-diaries) and does not place unnecessary burden on participants and investigators.
- How will the PII be managed
    - Screening/randomisation processes
    - Secure storage on site – clear rules for access to data
    - If within database (enhanced security requirements)
    - If outside – ensure that data is also protected and encrypted storage and on transfer
    - Data transfer agreements
- Managing data
    - Source documents
    - Setting expectation of data entry as close to real time as possible
    - Outstanding and missing data
    - Data validation and verification – systemised and through monitoring
    - Data lockout timing

14.4.3 Ownership, stewardship and control of research data

CPI and Trial team should be clear on which institution asserts ownership of the data.

With respect to the ownership of data and information used in or generated by research involving Aboriginal and Torres Strait Islander peoples and communities, institutions or researchers may hold data or information; however, they should not make decisions about the access to or reuse of this data or information without proper consultation with its Indigenous owners, if any.

When researchers move institutions – institution policy to specify details:

- Storage, retention and disposal
    - Refer to the jurisdictional Health Records Acts about retention of docs
    - Encourage institutions to have a documented policy to this effect, e.g. Some institutions have a policy to retain research documents indefinitely.
        - Refer archiving SOP at this point
- Safety, security and confidentiality

    - Institutional policies on the ownership of, and access to, databases and archives that is consistent with confidentiality obligations, legislation, privacy principles and other guidelines
- Access by interested parties
    - Have a clear plan on secondary use of data
- Facilities
    - Types of organisations and facilities
    - Archiving – digital, physical long-term storage, ease of access
- Provision of training for researchers
    - This is critical, cannot assume understanding
    - Instructions for Use of all important trial specific systems (IRT, EDC user manuals)
    - Training provided at Site Initiation, user manual refers to all operational aspects of the trial
    - Updates and re-education as necessary, as triggered by review of data, central monitoring
    - Clearly articulated Roles and Responsibilities,
        - Are to be recorded on delegation log
        - Any training must be recorded on training log.
        - Who will provide oversight
        - Role of data controller - including if breach to privacy/GCP occurs

Appendix – would a flowchart style be helpful here?

Options

Option 1: Keeping the database development inhouse to your organisation: Based on your list of requirements, key stakeholders to engage are:

- IT Architecture team
- IT Architecture generally has that capability to assess whether an off-the-shelf product meet the requirements or do you need a bespoke solution
    - Can also assist on best solution for your needs
- Advise on security controls and architecture principles
    - Security attestation, vulnerability testing
- Third party risk assessment of the vendor to ensure they comply to security controls (for vendors designing a bespoke database).
- Data Governance Team
- Advice on data governance principles which include storage, handling and transfer of data.
    - Encryption requirements
- Cybersecurity teams
    - Assess the technology and systems and devices to ensure they don't introduce cyber security risks
    - Support segmentation of network to mitigate cyber risks and keep your database and data protected

Option 2: Evaluation of vendor for development of a bespoke database and trial management system

- List your requirements and request quote with information on technical details/not sure what is the right word here.
- Engage Digital Health/IT architecture team at your organisation for expert review on quote
- Ensure vendor has a proven track record
- Highly desirable elements are HIPAA certification and ISO certification

Certifications:

- Health Insurance Portability and Accountability Act (HIPAA)
- International Organization for Standardization (ISO) certified = certification to top-tier information security management with robust controls and effective risk management
- Other jurisdiction requirements if the database is to store and analyse international data

Glossary

TERM	DESCRIPTION
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ALCOA+	Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, and Available.
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
ARTG	Australian Register of Therapeutic Goods
CAP	Capability Assessment Process
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIP	Clinical Investigation Plan
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTC	Clinical Trials Coordinator

TERM	DESCRIPTION
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CtQ	Critical to Quality
CV	Curriculum Vitae
DCT	Decentralised Clinical Trial.
DSMB	Data and Safety Monitoring Board
DSUR	Development Safety Update Report.
eConsent	Electronic informed consent process
eCRF	Electronic Case Report Form
EMR	Electronic Medical Record
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association
IB	Investigator's Brochure.
ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IFU	Instructions for Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System

TERM	DESCRIPTION
IWRS	Interactive Web Response System
LAR	Legally Acceptable Representative
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NCTGF	National Clinical Trials Governance Framework
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
QbD	Quality by Design
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
TMF	Trial Master File
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

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All information in this publication is correct as at April 2026