Standard Operating Procedures (SOPs) for Clinical Trials

A Standard Operating Procedure (SOP) is a formal written document that outlines the step-by-step instructions for carrying out key clinical trial operations. SOPs ensure that trials are conducted, and data are generated, documented and reported in compliance with the protocol, Good Clinical Practice (GCP) principles and other regulatory requirements.

When conducting a clinical trial, you should use both the Sponsor's and Local Site's SOPs where available. You may also need to develop additional SOPs to address the specific needs of the trial. It is considered best practice to review SOPs regularly, ideally every two years, or sooner if there are regulatory changes.

The following SOPs are considered the minimum to comply with the ICH Guideline for Good Clinical Practice E6 (R2) standards when conducting a clinical trial in Australia. For more details, refer to the National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia.

SOP #	Title
SOP 01	Standard Operating Procedure (SOP) Creation, Implementation and Revision
SOP 02	Investigator Responsibilities
SOP 03	Site Staff Qualifications, Training Records and Capability
SOP 04	Protocol and Investigational Brochure (IB) Requirements
SOP 05	Communication with Human Research Ethics Committee (HREC) and Research Governance Office (RGO), Sponsor and Insurer
SOP 06	Site Initiation
SOP 07	The Trial Master File (TMF)
SOP 08	Case Report Forms (CRF) and Source Documents
SOP 09	Participant Informed Consent Process and Documentation
SOP 10	Handling and Shipping of Biological Substances (Cat B) and Dangerous Goods
SOP 11	Management of Investigational Product (IP)
SOP 12	Safety Data Monitoring and Reporting Requirements
SOP 13	Site Close-Out and Archiving

The list of SOPs should also include appendices for templates such as: site SOP template, CV template, training records, delegation logs, supervision plan, protocol deviation log, initiation checklist, trial master file index (with document location), investigational product accountability logs, safety reporting flowcharts, close-out checklist, screening, enrollment and recruitment logs, file note template, and site and sponsor contact details.