



**Cancer Institute NSW
Standard Operating Procedures
(SOPs)
for Clinical Trial Units**

Background

Good Clinical Practice (GCP) is an ethical and scientific quality standard for the design, conduct, documentation and reporting of clinical research involving human participants. In Australia, all research involving humans must comply with the principles set out in the NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007), along with the principles of ICH-GCP as outlined in the Note for Guidance on Good Clinical Practice (CMP/ICH/135/95). ICH-GCP has been adopted by the Therapeutic Goods Administration (TGA) in principal, while recognising that in some instances the international guidelines are overridden by the National Statement. The Note for Guidance document is annotated with comments, indicating which sections have not been adopted by TGA or require further explanation in terms of local regulatory requirements.

These documents can be found on the websites of the TGA and NHMRC:

- Note for guidance on good clinical practice (CPMP/ICH/135/95 - Annotated with TGA comments - <http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>
- National Statement on Ethical Conduct in Research Involving Humans (2007) - <http://www.nhmrc.gov.au/publications/synopses/e72syn.htm>

Additionally in NSW, the conduct of clinical research must comply with the directives and policy documents set down by NSW Health. These state based policies provide direction with respect to the review and approval of research projects through Ethics and Governance processes.

Further information on the state based policies related to Health Ethics can be found on the NSW Health website:

- <http://www.health.nsw.gov.au/healthethics/>

Standard Operating Procedures

Standard Operating Procedures (SOPs) are detailed written instructions which describe the processes to be followed in the conduct of clinical research, encompassing the guiding principles of all relevant regulatory requirements. SOPs ensure that each specific task and function is conducted in a uniform and standardised manner.

Cancer Institute NSW SOPs

The clinical trials program of the Cancer Institute NSW has the aim of supporting high quality cancer clinical trials and clinical trial units in NSW. A goal of the NSW Cancer Plan 2007-2010 was the development and implementation of a Quality Assurance (QA) program for clinical trial units supported by the NSW Cancer Trials Network. The QA program includes the development of a set of generic Standard Operating Procedures (SOPs) for clinical trial units which can be widely implemented without the need for site specific customisation.

The SOPs document clinical trial processes to ensure that the minimum requirements under national and state (NSW) regulations and guidelines are met. These SOPs detail only Investigator (site) responsibilities from these guidelines. Sponsor responsibilities are outside the scope of these SOPs.

The SOPs have been written in a generic format to ensure they are applicable across all units wishing to implement them without the need for any site specific amendments or customisation. Where additional site specific instruction is required, site specific procedures may be written to supplement the generic SOPs.

The SOPs are broken down into two categories:

GEN-XX - these SOPs cover general study administration and are applicable to all studies where no sponsor SOPs exist.

INV-XX - these SOPs are specific to investigator initiated studies, and cover the development of protocols and participant information and consent documents.

Implementation of the SOPs

This set of Cancer Institute NSW generic site SOPs can be implemented by clinical trial units whether or not additional site specific procedures are in place. Where a unit decides to implement these SOPs in addition to specific SOPs, the site SOPs should be reviewed to ensure that they do not contradict the generic procedures.

In implementing the Cancer Institute NSW site SOPs, the content must not be amended in any way, however the attachments for each SOP have been provided as examples only and may be modified either on a site by site, or a study basis depending on the specific attachment.

1. Site Specific Amendments to Attachments

Eg: SOP GEN-02: Training Record - Documentation, Maintenance and Archiving

In setting up training files for clinical trial staff in accordance with the training SOP, the training file index should be developed to meet the requirements of the individual trial unit. Only content which is applicable at the unit should be included. Eg: if position descriptions are not used at a given unit, this section should not be included on the index. Any additional documentation which the site requires should similarly be added to the index. File notes for “not applicable” sections and “miscellaneous” sections should be avoided.

2. Study Specific Amendments to Attachments

Eg: SOP GEN-05: Handling of Investigational Product (IP)

For trials where the IP handling will be done in accordance with this SOP (where there is no sponsor responsible for the conduct of the study), the inventory logs should be modified prior to the commencement of the study. Modifications made to these logs should ensure that the appropriate information is collected for accountability dependent on the formulation of the IP and how it is dispensed. Eg: the inventory log for a tablet formulation which is sent home with the participant and returned at a future study visit will differ from the inventory log for an IV product which is administered during the study visit.

Training

Implementation of these SOPs is being supported by training which is being conducted by the Cancer Institute NSW and is available to clinical trial units supported by the NSW Cancer Trials Network. Inclusion of SOP training as orientation for new clinical trials staff is encouraged.

Management and Maintenance of SOPs

The ongoing management and maintenance of this set of generic site SOPs remains the responsibility of the Cancer Institute NSW. Review of these SOPs will be done every two years, or as required to reflect any changes to regulatory requirements and/or guidelines.

Current versions of the SOPs will be available and maintained on the Cancer Institute NSW website http://www.cancerinstitute.org.au/cancer_inst/research/trials_sops.html.

Management and maintenance of any site specific SOPs which are developed to complement these procedures is the responsibility of the individual trial units.

Index of SOPs

SOP: GEN-01

Production, Review, Approval and Archiving of SOPs

Attachments:

1. SOP Template

SOP: GEN-02

Training Record - Documentation, Maintenance and Archiving

Attachments:

1. Example: Training File Index
2. Example: Curriculum Vitae Template
3. Example: Employee Training Record
4. Example: Training Attendance Record

SOP: GEN-03

Maintenance of Equipment

Attachments:

1. Example: Equipment Service Log
2. Example: Equipment Calibration Log
3. Example: Temperature Log

SOP: GEN-04

Document Management

Attachments:

1. Example: Investigator Site File Index (ISF Index)
2. Example: Site Visit Log
3. Example: Site Signature and Delegation Log
4. Example: Subject Screening log
5. Example: Subject Identification Register/Log
6. Example: Subject Enrolment Log
7. Example: Protocol Exemption Request Form
8. Example: Protocol Exemption Log
9. Example: Temperature Log

SOP: GEN-05

Handling of Investigational Product

Attachments:

1. Example: IP Receipt Form
2. Example: IP Accountability Form – single subject
3. Example: IP Accountability Form – multiple subjects

4. Example: IP Return Form

SOP: GEN-06

Procedures for Submission of a Clinical Trial to a Human Research Ethics Committee (HREC)

Attachments:

1. Example: Checklist for HREC submissions
2. Example: Serious Adverse Event Notification Form
3. Example: Safety Report Submissions
4. Example: Annual Report Form

SOP: INV-01

Development and Review of Protocols and Protocol Amendments

Attachments:

1. Example: Protocol Template

SOP: INV-02

Participant Information Sheet and Informed Consent Form (PIS/ICF) Development and Review

Attachments:

1. Example: Informed Consent Form Template
2. Example: Informed Consent Form Checklist