



Standard Operating Procedures

8.0 Essential Documents ©2007

History			
Version	Date	Author	Reason
1.1	10 th Jan 2006	Contributing authors	New procedure
1.2	25 th Feb 2007	S Whicker	Administrative update
1.3	18 th July 2007	B Fazekas	Update prior to MAB review
1.4	16 th October 2007	B Fazekas	Update after David Currow review

Approval				
Version	Author	Signature	Approval Name	Approval Signature
1.4	B Fazekas	<i>B. Fazekas</i>	D Currow (CI)	<i>D. Currow</i>

Scheduled review

Date August 2009

Responsible person PaCCSC Project Officer

8.0 Essential Documents

Purpose

All clinical trials need to demonstrate that documentation meets the ICH GCP guidelines, the documentation shows that the trial was conducted in an ethical and appropriate manner and all legal and auditing requirements have been met.

Other related SOPs

Archiving of Research/Project Materials
Record Destruction
Monitoring
Electronic Data Handling

Attachments

Trial Master Index template

References

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 250207)
<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

NHMRC National Statement on Ethical Conduct in Research Involving Humans 1999 (accessed 250207) http://www.nhmrc.gov.au/publications/_files/e35.pdf

Joint NHMRC/AVCC Statement and Guidelines on research practice 1997 (accessed 250207) <http://www.nhmrc.gov.au/funding/policy/researchprac.htm>

Definitions

Essential documents:

- Those documents which permit evaluation of the conduct of a trial and the quality of the data produced
- those documents usually audited and inspected by the regulatory authorities to demonstrate compliance with GCP and all other regulatory requirements
- assist with trial management
- are those usually audited and monitored
- confirm the validity of the trial conduct and the integrity of the data collected.

The minimum list is usually those documents that are generated:

- before commencement of the clinical phase of the trial
 - ethics, approved documents, approvals
 - protocols, Investigator Brochure
 - Clinical Trial Notification documents
 - funding applications
 - contracts, agreements
 - form development
 - governance documents
 - investigator documents
 - initiation reports.
 - during the conduct of the trial
 - data collection
 - protocol revisions
 - laboratory updates
 - ethics amendments and correspondence
 - monitoring reports
 - consent forms
 - Source documents
 - Investigational product accountability documents
 - safety reports
 - interim analysis and reports.
 - after completion of the trial
 - completed subject identification code list
 - documentation related to the destruction of investigational products
 - final report
 - clinical study report
 - audit certificate (if applicable)
 - treatment allocation and decoding documentation
 - close out monitoring report
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Procedure

Responsibility

Coordinating investigator

To oversee study and ensure that the coordinating site has developed and maintains the system for the files

Project Officer

To develop the Trial Master Index for the study, distribute to all sites, and standardised templates to be used at all sites

Site study coordinator

To ensure that all documents for that site are produced and filed appropriately

Sponsor

To provide necessary information and documents when requested

Recording

All files related to each study will be stored according to the Trial Master Index at all sites. The index will indicate where the original and copies are to be kept and who is responsible.

The filing structure will be established at the initiation of study design and protocol development. The files will then be maintained and expanded as required and according to the Trial Master Index.

Maintenance

The Trial Master Index will be regularly reviewed by the coordinating investigator and Project Officer to ensure its currency and applicability.

The Project Officer will ensure that all sites are made aware of any changes and have been provided with an updated index within 1 week of changes.

Site study coordinators will implement the changes within 1 week of the changes and notify the study coordinator when this has occurred. Confirmation will be in writing (email, letter, fax). These confirmations will be maintained by the site study coordinator for auditing purposes.