



## Standard Operating Procedures

### PaCCSC SOPs

#### 8.4.1 Archiving of Research/Project Materials ©2008

History			
Version	Date	Author	Reason
1.1	10 <sup>th</sup> Jan 2006	Contributing authors	New procedure
1.2	25 <sup>th</sup> Feb 2007	S Whicker	Administrative update
1.3	18 <sup>th</sup> July 2007	B Fazekas	Update prior to MAB review
1.4	16 <sup>th</sup> October 2007	B Fazekas	Update after David Currow review
1.5	21st January 2008	B Fazekas	Administrative update, new reference

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

#### Scheduled review

**Date** August 2009

**Responsible person** PaCCSC Project Officer

## 8.4.1 Archiving of Research/Project Materials

### Purpose

Projects and clinical trials generate numerous files and other material during the course of the project. There are state and federal laws that require investigators to ensure that the files are archived for a specified period of time. This SOP is aimed at introducing uniformity in the archiving and storage of research and project materials while also ensuring that clinical trial files meet ICH guidelines.

This SOP will ensure that materials are stored to:

- enable access at a later date for follow-up
- comply with NHMRC and jurisdictional regulatory requirements
- allow timely destruction of materials once the required storage period has elapsed.

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### Other related SOPs

Electronic Data Handling  
Essential Documents  
Record Destruction

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### Attachments

Archive labels  
Archive Index.xls

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### Other files that apply

Archive Index.xls

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### 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>

Department of Human Services. Community Health and Special Needs Services Retention and Disposal Schedule. July 2000-June 2010. 2000/0013 Guidelines approved under Section 95A of the Privacy Act 1988. NHMRC December 2001, pp47-8.

International Society of Pharmacoepidemiology (ISPE). Guidelines for good pharmacoepidemiology practices (GPP). 2007; Pharmacoepidemiology and Drug Safety, DOI: 10.1002/pds.1471. Published online in Wiley Interscience ([www.interscience.wiley.com](http://www.interscience.wiley.com)).

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## Definitions

In general, if research involves the use of human subjects, in terms of data collection, interventions, or interviews then the NHMRC requirements of 15 years for safe storage apply.

State and territory schedules for the retention and disposal of records specify retention periods for research material. The longer of any prescribed period should be chosen.

There is some research material that may be specified by state schedules for permanent retention and may include records relating to:

- legitimate and sustained allegations of misconduct that resulted in a formal inquiry and appeals
- the preparation and submission of applications to conduct research
- the establishment of committees/boards/task force, and the records of the meetings
- meeting the requirements of the NHMRC such as annual reports
- evaluation of significant programmes
- obtaining resources to undertake significant projects, which may include project plans, grant proposals, funding applications.
- development of agency wide policies relating to research and ethical research conduct
- master copies of final reports, (published and unpublished) produced by the researcher which document the findings and outcomes.

## Archived documents

The documents to be archived on completion of a study must include the following;

- The study protocol and all approved amendments
- The final study report
- All source data, including biologic specimens. If the source data are patient clinical files, they will be archived as part of the institutional archiving arrangements. CRFs are to be held in the study files, pathology services and laboratories are to archive specimens where possible.
- Printed sample of the master files
- Documentation to identify and locate all computer programs and statistical procedures
- Copies of electronic versions of the analytic data sets and programs. Manually developed calculations should be documented on worksheets and retained.
- All essential documents (See Essential Documents SOP)

- Documentation relating to the collection and processing of data, including notebooks, training and reference documents, coding manuals etc.

**Person responsible**

The coordinating investigator is responsible for the archiving arrangements of their study material.

The coordinating investigator may negotiate the long term storage responsibility with local or intra collaboration research infrastructure.

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## Procedure

### *At the commencement of the study*

At the commencement of the study, the coordinating investigator should clarify what materials need to be stored to meet research archiving requirements. The site for archive storage should then be determined.

### *At the conclusion of the study* the coordinating investigator should:

1. contact the Project Officer or other appropriate person to negotiate the date for delivery of materials and the storage location.
2. all identifiable participant data must be de-identified prior to archiving. This can be done by physically removing the ID from the page or subject file, and then storing this material separately in such a way that identification is no longer directly possible. In other cases, the identifying material should be covered in such a way that the name and other identifiable labels can no longer be read or accessed. This may be through the use of white-out type procedures.
3. all electronic files should be copied onto a storage disc in a transportable format, and labelled. The electronic format should be able to be accessed over time.
4. ensure all files are clearly labelled and ordered (subject data, study administration files, manuscript files etc).
5. remove all reference materials from the study files (articles etc).
6. ensure enough archive boxes are available. Approximately 1 filing cabinet draw will fill 1.5 archive boxes.
7. place the files into the boxes, without the hanging files.
8. check the labelling requirements of the storage site. If appropriate, complete an Archive Label (attached) and attach firmly to the outside of the box. Ensure all parts of the label are completed.
9. the Project Officer should enter the box details onto the Archive Index.xls with:
  - Box name
  - Brief description of the contents of the box
  - Full project/study title
  - All named investigators
  - Any ethics reference numbers
  - Archive and destruction dates
  - Contact person/site
  - Comments
10. arrange for safe and appropriate transport to the storage site.

<b>Investigator:</b>
<b>Study:</b>
<b>Date Archived:</b>
<b>Date for Destruction:</b>
<b>Person for contact:</b>