



PaCCSC
Palliative Care Clinical Studies Collaborative

Standard Operating Procedures

8.4.2 Record destruction ©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

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

Scheduled review

Date August 2009

Responsible person PaCCSC Project Officer

8.4.2 Record destruction

Purpose

Projects and clinical trials generate numerous files and other material during the course of the project. There are state and national requirements to ensure that the files are destroyed in an appropriate manner after the specified period of time. This SOP is specific for the destruction procedure for research and project materials.

This SOP will ensure that materials are methodically destroyed to:

- Comply with state, national and international regulations and guidelines
- Ensure that materials are not stored once the required storage period has elapsed.

This SOP relates to both temporary and permanent records.

Site Investigators are advised to assume that all record retention and disposal responsibility lies with them. Do not assume that the institutional ethics committee, office of research, publisher etc. has kept a master copy. The site investigator is advised to nominate their own master copy and keep that on file.

Other related SOPs

Electronic Data Handling
Essential Documents
Archiving of Research/Project Materials

Attachments

Other files that apply

Archive Index.xls

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 25/02/07) <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 (RDS)
(South Australia). Guidelines approved under Section 95A of the Privacy Act
1988. NHMRC December 2001, pp47-8.

Definitions

Destruction

A means by which records can be destroyed which renders them unable to be read, accessed or used at any time in the future.

Temporary record

A record that does not have archival value, and can be destroyed once the retention period has elapsed. In most cases this is 15 years.

Permanent record

A record which has archival value and may be required to be permanently retained when the administrative value or 15 years has elapsed (whichever is sooner).

Some research material should be kept as a permanent record, this includes 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.

State records

Individual Australian states and territories have hospital, file archive and destruction procedures and facilities. 'State Records' refers to such a facility.

Person responsible

The named Chief Investigator for PaCCSC is responsible for the long term storage of their research and to negotiate the person and details of destruction (the record holder). This may be the research unit of the Chief Investigator's institution, a 'State Record' facility or some other safe and appropriate storage site.

Destruction responsibility lies with the record holder, the person responsible for the long term storage.

Procedure

When the required storage period has elapsed (15 years)

1. The record holder will notify the Coordinating Investigator nominated on the Archive Index.xls, box label or other identifying label for the material, of the destruction of the material.
2. The box/es containing the study materials should be opened and the following files should be separated:
 - records that have temporary archival status
 - records with permanent archival value (as detailed above)
3. Permanent records:
 - should be removed from the general material, and stored within a separate box.
 - the box should be labelled in line with 'State Records' requirements if the box is to be stored in state facilities.
 - the new box is then sent to State Records for permanent storage.
4. Temporary records
 - complete a 'Notification of the Destruction of Records' form.
 - the form should be completed according to the destruction schedule that applies in the state of storage.
 - paper records can then be shredded, pulped or burnt, within the organisation. If an external means of destruction is used, a confirmation note should be obtained.
 - electronic records should be reformatted, overwritten or shredded, then disposed of through normal channels.
 - complete a destruction register as determined within the State Record Schedule.