

# Standard Operating Procedure

## 8.4.2 Record Destruction

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## Introduction / Background

Projects and clinical trials generate numerous files and other material during the course of a study. There are state and national requirements to ensure that the files are destroyed in an appropriate manner after the specified period of time.

The purpose of this SOP is to 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

## Objective

This SOP describes the destruction procedure for research and project materials, both temporary and permanent.

## Scope

This SOP applies to all staff involved in clinical studies conducted by the IMPACCT Trials Coordination Centre (ITCC), including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), irrespective of individual organisational employment, role, or position.

## Ownership and Responsibility

The responsibility for all records retention and disposal rests with the Principal Investigators at each site. Master copies of records retained and destroyed are not the responsibility of the institutional ethics committee, office of research, publisher etc. The Principal Investigator generates their own Trial Master Index or Investigator Site File.

### *Responsibilities of the Coordinating Principal Investigator*

- To maintain and complete the Trial Master Index
- To ensure long term storage of PaCCSC/CST/ITCC central research files
- To select the Record Holder

### *Responsibilities of the Principal Investigator and/or other designee(s) as documented in the Staff Signatures and Delegation Log (refer SOP 4.2.4 Delegation of Duties)*

- To ensure long term storage and destruction of the locally generated files
- To maintain and complete the Investigator Site File

### *Responsibilities of the nominated Record Holder*

- To ensure destruction of all research files

## Procedure

### 1. Persons responsible

The PaCCSC/CST/ITCC Coordinating Principal Investigator is responsible for the long-term storage of PaCCSC/CST/ITCC central research files and to select the Record Holder. This may be the research unit of the Coordinating Principal Investigator's institution, a 'State Record' facility or some other safe and appropriate storage site.

Each Principal Investigator is responsible for the long-term storage and destruction of the locally generated files in accordance with the requirements of the local institution, nominated record holder, and other national and international requirements.

Destruction responsibility rests with the nominated Record Holder.

### 2. Destruction

At the end of the required storage period (usually 15 years):

- The Record Holder notifies the Coordinating Principal Investigator (nominated on the box label or other identifying label for the material) of the end of the retention period.
- The box(es) containing the study materials are opened and the following files are separated:
  - Records that have temporary archival status
  - Records with permanent archival value
- Permanent records:
  - Are removed from the general material, and stored within a separate box
  - The box is labelled in line with the requirements of the state facilities
  - The new box of permanent records is sent to a suitable storage facility for permanent storage
- Temporary records:
  - Complete any required documentation from the Record Holder facility in the Australian State to enable destruction
  - The form is completed according to the destruction schedule that applies in the state of storage
  - Paper records are shredded, pulped, or burnt, within the storage facility. If an external means of destruction is used, a confirmation note is obtained.
  - Electronic records are reformatted, overwritten, or shredded, then disposed of through normal channels
  - Complete a destruction register as determined within the storage facility, or other similar record that logs the documents destroyed in order to comply with state requirements
- The destruction register is filed within the permanent records if required.

## Related SOPs

4.2.4 Delegation of Duties

5.5.1 Electronic Data Handling

8.0 Essential Documents

8.4.1 Archiving of Research/Project Materials

## Related documents

Template 11: Source Document Log

Template 20: Trial Master File Index

## References

Australian Code for the Responsible Conduct of Research 2018 (accessed 11/02/2020)  
<https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>

National Statement on Ethical Conduct in Human Research (2007) Updated 2018 (accessed 11/02/2020) <http://www.nhmrc.gov.au/guidelines-publications/e72>

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 11/02/2020)  
<https://www.tga.gov.au/sites/default/files/ich13595an.pdf>

<b>History</b>			
Version	Date	Author	Reason
1.1	10/01/2006	Contributing authors	New procedure
1.2	25/02/2007	S Whicker	Administrative update
1.3	18/07/2007	B Fazekas	Update prior to MAB review
1.4	7/06/2010	B Fazekas	Periodic review
2.0	3/02/2011	B Fazekas	Changes ratified by MAB
2.1	9/06/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
2.3	06/12/2018	L Brown	Update to include CST and ©
2.4	30/12/2021	B Fazekas	Periodic review

<b>Approval</b>		
Version	Approval Name	Approval Signature
2.4	Meera Agar	