Standard Operating Procedures

8.4.1 Archiving of Research/Project Materials

Version	V2.2
Author/s	B Fazekas, S Kochovska
Approved	D Currow
Effective date	28/02/2018
Review date	31/12/2019

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION AS AVAILABLE FROM www.uts.edu.au/paccsc

Introduction / Background

Projects and clinical studies generate numerous files and other material during the course of the project. State and federal laws require research files to be archived for a specific period of time following the completion of the study.

This Standard Operating Procedure (SOP) aims to introduce uniformity in the archiving and storage of research and project materials whilst ensuring that clinical study files meet the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines.

Objective

This SOP describes the archiving process to ensure that materials are stored to:

- Enable access at a later date for follow-up
- Comply with National Health and Medical Research Council (NHMRC) and jurisdictional regulatory requirements
- Allow timely destruction of materials once the required storage period has elapsed.

Scope

This SOP applies to all staff involved in clinical studies conducted by PaCCSC irrespective of individual organisational employment, role or position.

Ownership and Responsibility

Responsibilities of the Lead Investigator/Sponsor (PaCCSC)

- To arrange archiving of the central study materials
- To negotiate the long term storage responsibility with local or intra collaboration research infrastructure

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 all identifiable participant data is de-identified prior to archiving
- To ensure that the archiving procedure is followed as per this SOP
- To ensure safe and appropriate transport of study materials to the storage site

Procedure

1. At the commencement of the study

- Clarification and communication are sought regarding what materials are to be stored to meet research archiving requirements.
- The site for archive storage is identified.
- The Principal Investigator (or delegate) prepares a Master File Index (*refer* SOP 8.0 Essential Documents) to ensure that all study materials are filed in an appropriate manner that enables retrieval during the course of the study.

2. At the conclusion of the study

The Principal Investigator (or delegate):

- Ensures that all identifiable participant data is de-identified prior to archiving. This is done by physically storing the identified materials in a different location to the materials identified by PID.
  - Often, the identified materials can be filed along with the Participant Information Sheet and Consent Forms (PICFs)
- Ensures all electronic files are copied onto a storage disc in a transportable format, and labelled. The electronic format must be accessible over time.
- Ensures all files are clearly labelled and ordered (for e.g., subject data, study administration files, manuscript files, etc.).
- Removes all reference materials from the study files (for e.g., articles, etc.).
- Places the files into the boxes, without the hanging files, clips, folders, or other binding materials. File groups can be held together with a band.
- Checks the labelling requirements of the storage site. If appropriate, complete an Archive Label and attach firmly to the outside of the box. Ensure all parts of the label are completed.
- Completes any documentation in accordance with the local requirements
- Arranges for safe and appropriate transport to the storage site. All storage facilities ensure the long term safe storage including fire and theft security and provide a system for retrieval and re-storage if required.

3. Retention of research data and research materials

The Australian Code for the Responsible Conduct of Research (2007) states that for most clinical trials, retaining research data for 15 years or more may be necessary.

State and territory schedules for the retention and disposal of records specify retention periods for research material. The longer period specified is always applied.

There may be individual state requirements that apply to the retention of research materials (for e.g., some states require permanent retention of certain research materials). Each site is responsible for complying with any state requirements for the retention of records relating to:

- The preparation and submission of applications to conduct research
- The establishment of committees/boards/task force, and the records of the meetings

- Legitimate and sustained allegations of misconduct that resulted in a formal inquiry and appeals
- Meeting the requirements of the NHMRC such as annual reports
- Evaluation of significant programs
- Obtaining resources to undertake significant projects, which may include project plans, grant proposals, or 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

4. Archived documents

The documents to be archived on completion of a study include (but are not limited to):

- 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. Case Report Forms (CRFs) are held in the study files. Pathology services and laboratories archive specimens where possible.
- Copies of electronic versions of the analytic data sets and programs. Manually developed calculations are documented on worksheets and retained.
- All essential documents (*refer* SOP 8.0 Essential Documents)
- Documentation relating to the collection and processing of data, including notebooks, training and reference documents, coding manuals, etc.
- Updated Source Document Log (Template 11) to reflect the contents of the archived materials, and the location of other study related materials such as clinical records, pathology samples and/or results, computer programmes and files

Participant files containing the original CRFs are stored at the participating site for long term archiving. The PaCCSC Coordinating Centre maintains copies forwarded to it for the purpose of data checking; these copies are archived centrally. Sites should prepare their participant files in the following manner:

- File for site archive:
  - All CRFs including pre-screen CRFs
  - All file notes
  - Copies of the medication record or concurrent medications
  - Consent forms
  - Medical assessment
  - Original patient measures such as Mini Mental Status Examination, Quality of Life forms, laboratory and test results, NuDesc score sheets, any other score forms given to the participant and then comprise source data

Other related SOPs

4.2.4 Delegation of Duties
5.5.1 Electronic Data Handling
8.0 Essential Documents
8.4.2 Record Destruction

Other related documents

Template 11: Source Document Log

References

Australian Code for the Responsible Conduct of Research 2007 (accessed 20/10/2017) https://www.nhmrc.gov.au/guidelines-publications/r39

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 23/10/2017) https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

National Statement on Ethical Conduct in Human Research (2007) - Updated March 2014 - (accessed 19/10/2017) 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 17/10/2017) https://www.tga.gov.au/sites/default/files/ich13595an.pdf

Praxis Australia

Acknowledgments

Trans-Tasman Radiation Oncology Group (TROG), for generous access to the Policy and Procedure Manual – the Red Book.

History			
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	16/10/2007	B Fazekas	Update after David Currow review
1.5	21/01/2008	B Fazekas	Administrative update, new reference
1.6	7/06/2010	B Fazekas	Periodic review, ratified by MAB
2.0	1/02/2011	B Fazekas	New version with all updates
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)

Approval		
Version	Approval Name	Approval Signature
2.2	David Currow	