UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

8.4.1 Archiving of Research/Project Materials

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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 each study.

This Standard Operating Procedure (SOP) aims to introduce uniformity in the archiving and storage of research and project materials while 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 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

Responsibilities of the Coordinating Principal Investigator/Sponsor (ITCC)

- 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

- The site for archive storage is identified by the site Principal Investigator.
- 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 (e.g. articles etc.)
- Places the files into suitable archive boxes, in accordance with local requirements.
- Checks the labelling requirements of the storage site
- 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 example, 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 meeting records;
- 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; and
- 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
- Final study report
- All source data, including biological specimens.
    - If the source data are patient clinical files, they will be archived as part of the institutional archiving arrangements.
        - The medical record of trial participants are to be tagged as such, to enable specific storage requirements are met
    - Participant data collection worksheets 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 programs and files

Participant files containing the original participant data collection worksheets are stored at the participating site for long-term archiving. The ITCC 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 participant data collection worksheets, including pre-screen worksheets
  - 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 which comprise source data

Related SOPs

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

Related documents

Template 11: Source Document Log

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

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 11/02/2020)

https://www.ich.org/page/efficacy-guidelines

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

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)
2.3	06/12/2018	L Brown	Update to include CST and ©
2.4	11/02/2020	J Lourdesamy	Periodic Review
2.5	30/12/2021	B Fazekas	Periodic Review

Approval		
Version	Approval Name	Approval Signature
2.5	Meera Agar