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HEALTH+MEDICAL RESEARCH

Clinical trial archiving

Standard Operating Procedure



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1. Purpose

To describe the procedure for archiving of clinical trial essential documents (paper and electronic) at the trial site so that all documents are readily available for audit or inspection. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials (except Teletrials)² conducted at NSW Public Health Organisations.

3. Applicable to

The principal investigator (PI) and all site staff involved in a clinical trial.

All support departments where clinical trial documentation may be retained.

The organisation's or department's named archivist(s).

4. Definitions

Refer to SOP-G-01: Glossary of terms.

5. Background

ICH GCP requires that the storage system for essential documents (irrespective of the media used) provides for document identification, search and retrieval. Trial documentation should be readily available on request. The PI has the ultimate responsibility for ensuring that all essential documents are archived appropriately but may delegate the task to suitably qualified individuals. Essential documents are normally archived by the organisation in liaison with the sponsor but they may be archived by the sponsor in an external Investigator archive facility as long as the PI retains control of access of all archived documents.

If supported by local policy, a specialist archive facility may not be required for some trials (e.g. in an investigator-led trial where documents are held in an office/department where the storage area has been assessed as suitable).

Before the investigator site file is archived, it should be checked to ensure that it is complete and that all necessary documents have been filed. Essential documents should be archived in accordance with local policy. Paper records should be stored in boxes that are clearly labelled in accordance with sponsor

requirements and organisation policy. Archived material should be enduring (e.g. fax thermal paper copied to standard paper to prevent fading) and protected from damage or destruction in a secure, environmentally-controlled location (e.g. protection from fire, water damage, pest infestation, and theft). Where electronic documents and data are archived, they must be suitably protected from unauthorised changes.

Transfer of paper records into an electronic format

When original records are transferred to other media for the purpose of archiving, the system of transfer should be validated to ensure that information will not be lost or altered. Filing systems should allow review (e.g. by an auditor) in an efficient manner, analogous to that possible with paper study files. Paper records must be scanned in a logical order (e.g. retaining the study filing/indexing system) to ensure that trial reconstruction is possible.

When paper documents are scanned, the NSW Standard on Digital Record keeping (IB2009_027) should be followed.

Archiving timeframes

Retention periods should be agreed with the sponsor but the organisation must also be compliant with NSW the provisions of the *State Records Act 1998*. GDA17 Research Management 8.0.0 requires retention of clinical trial records for a minimum of 15 years after the date of publication or termination of the study.

Paediatric studies must be archived for 15 years or until the youngest participant turns 25 years of age. Extended timeframes also apply to certain trial types (e.g. gene therapy trials).

Retrieval from archive

Materials that have been archived may, on occasion, need to be retrieved (e.g. for regulatory inspection). The PI/delegate should follow local archive process for retrieval and return to archive, but at a minimum, records should be tracked to and from the archive facility and oversee by a named archivist.

¹ All trials must comply with the principles of GCP (Section 2 of ICH GCP (E6 R2) or Clause 4 of ISO 14155) however sponsors submitting data to regulatory authorities will normally require full compliance with ICH GCP (E6 R2) or ISO 14155 GCP Guidelines.

² NSW Health have published an annotated version of these SOPs for sites utilising a Teletrials model.

6. Procedure

Principal Investigator (PI)

Supervise any individual delegated the task of archiving trial documents.

Ensure that all essential documents (e.g. the investigator site file, case report forms, participant medical records) are archived in appropriate conditions and are retained for the time period agreed with the sponsor.

PI or delegate

Ensure that copies of documents requested by the sponsor before archive do not contain participant identifiable information (unless consent for disclosure of such information to the sponsor has been obtained).

Once the sponsor has confirmed that archiving can occur, contact the named archivist to request the archiving of trial documents and provide all materials to the named archivist as required by the sponsor and local policy.

Named archivist

Initiate the archive process in accordance with local policy.

Oversee the archive process, offering advice and assistance to ensure that the task is carried out in accordance with this SOP.

Keep records that enable the retrieval of all essential documents from the archive (e.g. in the event of an audit or inspection).

Ensure archived documents are only destroyed after the sponsor confirms they are no longer needed. Keep a record of what has been destroyed for a further five (5) years from the date of destruction.

7. References

[ICH GCP \(E6 R2\): Good Clinical Practice Guidelines – Annotated by the TGA](#)

[National Statement on Ethical Conduct in Human Research \(2018\)](#), as amended

[Australian Code for the Responsible Conduct of Research \(2018\)](#)

[State Records Act 1998](#)

[Health Services, Public: Patient/Client records \(GDA17\)](#)

[NSW Standard on Digital Record keeping \(IB2009_027\)](#)

8. Associated documents

Archive record form – available in the Standard Operating Procedures templates [zip file](#)