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Information and guidance for primary care sites on when and how to archive a study

The purpose of this guide is to provide primary care staff with guidance about when and how to archive a research study when it has finished.

1. What is archiving?

Archiving is the storage of old paper/electronic records or documents so that they can be accessed again in the future. This is particularly important for research documentation to ensure that a study can be reconstructed in its entirety and the study documents can easily be retrieved after the study has closed if they are needed at a later date. Each study will have information detailing how it should be archived.

2. Which documents need to be archived?

Everything that helps re-create the project, including but not limited to the Investigator Site File (ISF), case report forms, pharmacy file and records created by other departments and services who have been involved in the study. These are collectively known as essential documents. The sponsor will often provide a checklist of the documents that need to be archived. In the event that a study is ready for archiving, but the sponsor has not provided a checklist or templates, the ones below may be used.

Please see website to access the steps to follow when archiving.

3. Does PIC documentation need to be archived?

If the practice has acted as a Patient Identification Centre (PIC) only, it is unlikely that there will be a requirement to archive the documentation, as paperwork will likely be a duplicate already in the Trial Master File with the study sponsor. However, the key is to seek advice from the study sponsor on an individual study basis before destroying anything.

4. Do I need to archive electronic data?

Archiving of electronic data is within the same scope as paper records. The study sponsor should provide information on how future access to records and data will be maintained. This information will be in the study protocol.

5. Who is responsible for archiving?

The Principal Investigator at the study site is responsible for archiving but can delegate this task to another member of their local study team.

6. When should a study be archived?

The study sponsor will specify when to archive a study, but it will usually be after the final study report has been written and filed.

7. How long do documents need to be kept for?

On completion of a study, essential documentation must be archived according to the applicable regulatory requirements. This is usually specified in the study documentation, the site agreement and protocol.

As a guide this is normally:

25 years for Clinical Trials of Investigational Medicinal Products (CTIMPs)

5 years or as specified by the sponsor for studies that are not CTIMPs.

8. What about participant clinical records?

Where research involves NHS patients, the medical records should also be retained for the same period as the essential documents. Entries made at study visits are classed as 'source data' and remain in the participants record, they are not archived with the rest of the study documents. It is the responsibility of the Principal Investigator to ensure that the participants' clinical records are suitably flagged to ensure that the records are retained.

9. Where should archived documents be stored?

It is important that research data are stored in a physical location that is weatherproof, pest-proof, secure at all times and environmentally controlled/protected. This can be on or off site including at a third-party. The sponsor may provide additional guidance and payment for archiving.

10. What happens at the end of the storage period?

At the end of the storage period the study documents are usually securely destroyed. Check with the sponsor prior to destroying any study documents. The sponsor should advise how you should do this.

11. What if I need to retrieve an archived study?

If a study is archived on site, the local study team at the site will be able to locate and retrieve the archive boxes. If the study has been archived off-site the sponsor will be able to

advise the study team regarding retrieval. Archived documents should only be accessed with permission from the Principal Investigator.

12. Where can I find out more about archiving?

Further information regarding archiving CTIMPs can be found at

https://www.ct-toolkit.ac.uk/routemap/archiving/ (accessed 06/02/2023)

Bitesize training regarding archiving can be accessed via NIHR learn

https://learn.nihr.ac.uk/course/view.php?id=905 (accessed 06/02/2023)

13. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk