Research & Innovation

North Bristol NHS
NHS Trust

Standard Operating Procedure

Archiving

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Document Version History

VERSION NUMBER	EFFECTIVE DATE	REVIEW DATE	REASON FOR CHANGE
1.0	01-04-11	01-04-12	Review
2.0	28-05-12	28-05-14	SOP renamed, updated in line with new template and recoded from ISOP-I03

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

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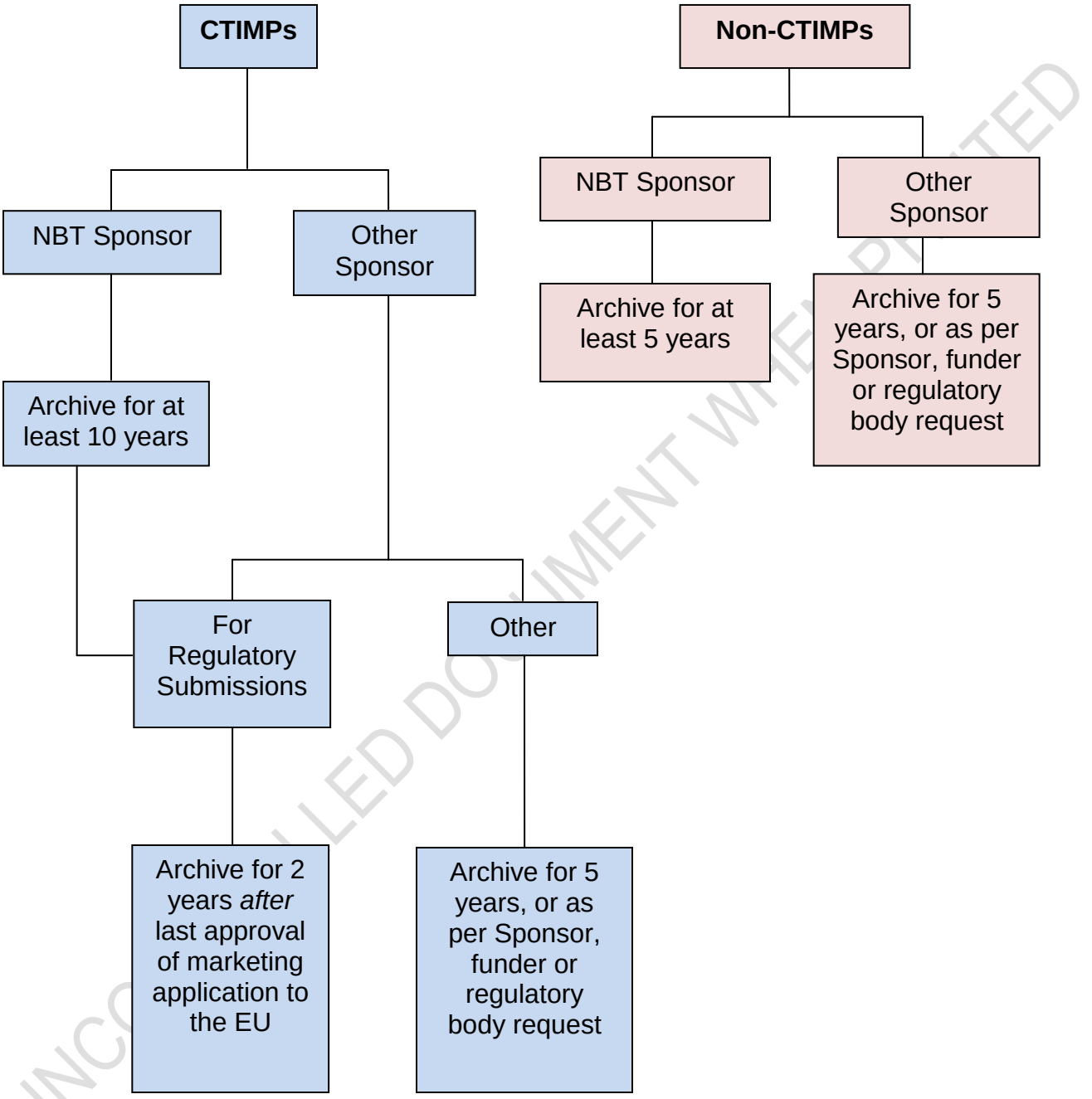
i. SOP Flowchart



Chief Investigator advises Sponsor via R&I if different archiving period is required

1. PURPOSE AND SCOPE

The purpose of this SOP is to describe the procedure for the archiving of all study documents for CTIMPs sponsored by NBT. The focus of this SOP is CTIMPS, however the standards described may be applied to ALL research studies.

The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, provide a legal requirement to archive essential documentation in CTIMPs. Storage of personal data is also subject to the Data Protection Act 1998.

The International Conference on Harmonisation Guidelines for Good Clinical Practice (ICH GCP) define and list all of the documents that are essential for the conduct of a clinical trial (see ICH GCP paragraphs 8.2, 8.3, 8.4).

“Essential documentation” refers to those documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

There is no legal requirement to archive essential documentation for non-CTIMPs. The Medical Devices Regulations 2002 do not include any express legal requirement to archive trial data gathered from clinical investigations of Medical Devices. However, the principles established in ICH GCP “may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.”

The Guidelines state that “the Sponsor or owners of the data should retain all of the sponsor-specific essential documents pertaining to the trial.” In light of this and the possibility of inspection by the Department of Health, it is therefore good practice to archive essential research documentation for non-CTIMPs and thus this SOP also applies to NBT-sponsored non-CTIMP studies.

2. DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical trials of Investigational Medicinal Products
ICH GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
NBT	North Bristol NHS Trust
PI	Principal Investigator
R&I	NBT Research & Innovation Office
NBT	North Bristol NHS Trust
SOP	Standard Operating Procedure
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research

3. WHO SHOULD USE THIS SOP

This SOP should be used by investigators and research team members involved in CTIMPs sponsored by NBT.

4. WHEN SHOULD THIS SOP BE USED

This SOP is applicable for all CTIMPs that are sponsored by NBT.

It is also good practice to archive essential research documentation for non-CTIMPs and thus this SOP also applies to NBT sponsored non-CTIMP studies.

For externally sponsored studies hosted by NBT, the Sponsor's own SOPs will apply with regards to archiving requirements. However, this SOP can be referred to during study set up to ensure that any costs of archiving have been identified and retrieved from the Sponsor if arrangements for archiving have been transferred to NBT by the Sponsor.

5. PROCEDURE

5.1. Responsibilities

The costs of archiving essential documentation **MUST** be included in all research projects. Responsibility for making archiving arrangements lies with the Sponsor. For studies sponsored by NBT, this responsibility is delegated to the CI.

In the case of a multi-centre study sponsored by NBT, essential documentation will be archived by the PI at each study site (NBT should be allowed access to this archived data upon request).

For studies sponsored by NBT or where the arrangements for archiving have been transferred to NBT by the Sponsor, archiving is managed by a reputable third party provider.

5.2. Preparing documents for archiving

At the end of a CTIMP a minimum period of **six months** should be allowed to ensure that all queries are answered and study related paperwork collected. Archiving should take place following this period but within **twelve months** of the end of a CTIMP.

All essential documentation should be checked to ensure the following:

(a) All documentation should be complete and legible

(b) The study file is complete, tidy and documents are stored in a logical order.

(c) All Case Report Forms (CRFs) and other patient-related medical documentation are collated, and ensure all data queries are resolved.

(d) Documents held in lever-arch files are removed in preparation for archiving to reduce the space required for archiving.

(e) Documents may be held together by plastic archiving clips but all paper clips, elastic bands, staples or metallic means of combining sheets should be removed to prevent rusting or other chemical deterioration.

(f) Documents are indexed in a manner that allows all documents to be traceable at all times and readily accessible to the authorities upon request.

(g) An NBT Archiving Record Form should be completed, filling out the list of documents to be archived (or attaching a separate list).

5.3. **Arranging for documents to be archived**

(a) Once documents are prepared and ready for archiving, please contact R&I for the archiving boxes.

(b) Complete a 'Completing the transmittal/using the barcode label' document, if appropriate.

(c) Contact R&I to arrange for collection of the archive boxes for transfer to the off-site storage facility.

(d) A copy of the archiving indices, file location identification (third party barcode/ unique identifier) and archive provider must be provided to R&I when the essential documentation is archived.

(e) R&I will maintain a log of archived projects including their box numbers and locations for retrieval (See section 5.5 of this SOP).

Currently, there are no guidelines relating to the storage of documents in electronic format. It is good practice to print and retain hard copies of this information. Electronic copies should be password-protected or stored in a password-protected folder or drive for backup purposes.

5.4. **Archiving period**

For all research studies, documents must be retained for at least 5 years after the conclusion of a trial and during that period must be:

- Readily available to the licensing authority on request (for CTIMPs).
- Complete and legible.

Retention for 5 years may be considered appropriate under circumstances when trials are not to be used in regulatory submissions. However, longer retention may be required if requested by the Sponsor, funder, or regulatory bodies.

(a) Where NBT is the Sponsor of **non-CTIMPs**, essential documentation must be retained for a period of at least **5 years**.

(b) Where NBT is the Sponsor of **CTIMPs**, essential documentation must be retained for a period of at least **10 years.** If trials are to be included in regulatory submissions then study-specific documents should be retained until at least 2 years after the last approval of a marketing application to the EU (where appropriate). It is the responsibility of the Chief Investigator to determine and to inform the Sponsor via R&I as to when essential documents are to be retained for longer.

5.5. Retrieval of archived documents

R&I will coordinate the retrieval of archived documents.

Retrievals from archive are restricted to a limited number of circumstances and should be kept to an absolute minimum. Retrieval may be permitted where audit of the results is required to comply with a Department of Health, regulatory authority, NBT Trust Board or other quality assurance request.

The retrieval of any documents held under an account with NBT will require the approval of the Deputy Director of Research. Sponsors of externally sponsored studies will be expected to meet the costs of retrieval.

5.6. Destruction of archived documentation

After the retention period has passed, R&I will inform the third party provider as to whether the documentation can be destroyed after this period or arrange for the documentation to be stored for longer. The Sponsor (if not NBT) will need to be contacted and asked if the documentation is to be archived for a longer period of time, or if it can be destroyed.

All essential documentation must be destroyed in accordance with confidentiality guidelines. Where third party organisations destroy the essential documentation on behalf of NBT, evidence of this must be provided to R&I.

R&I will record the destruction documentation in the corresponding R&I study folder.

6. DISSEMINATION AND TRAINING

SOPS will be distributed in accordance with the SOP on Preparation of R&I Research SOPs (RI/QMS/SOP/001). This SOP and any associated templates and forms will be uploaded to the NBT website (www.nbt.nhs.uk/research) shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7. RELATED SOPS AND DOCUMENTS

- Department of Health
  Research Governance Framework for Health & Social Care, 2nd Edition, April 2005
  www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962

- Department of Health (DoH)
  Research involving the NHS: Retention of Records
  https://www.noclor.nhs.uk/sites/default/files/Retention%20of%20Records%20in%20NHS%20Research.pdf

- Department of Health (DoH) & Medical Research Council (MRC)
  Clinical Trials Toolkit: Joint Project Notes on the Archiving, Storage & Destruction of Documents
  www.ct-toolkit.ac.uk/__data/assets/pdf_file/0003/35445/archiving-joint-project-notes.pdf

- ICH Secretariat
  Guidelines for Good Clinical Practice (GCP) (E6 R1 Step 4, 1996)
  www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

- UK Government
  Medicines for Human Use (Clinical Trials) Regulations 2004
  www.legislation.gov.uk/uksi/2004/1031/contents/made

- UK Government
  Data Protection Act 1998
  www.legislation.gov.uk/ukpga/1998/29/contents

- Institute of Clinical Research (ICR Publishing)
  Archiving Clinical Trial Documents (2nd Ed.)

- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/007	Applying for NBT Sponsorship